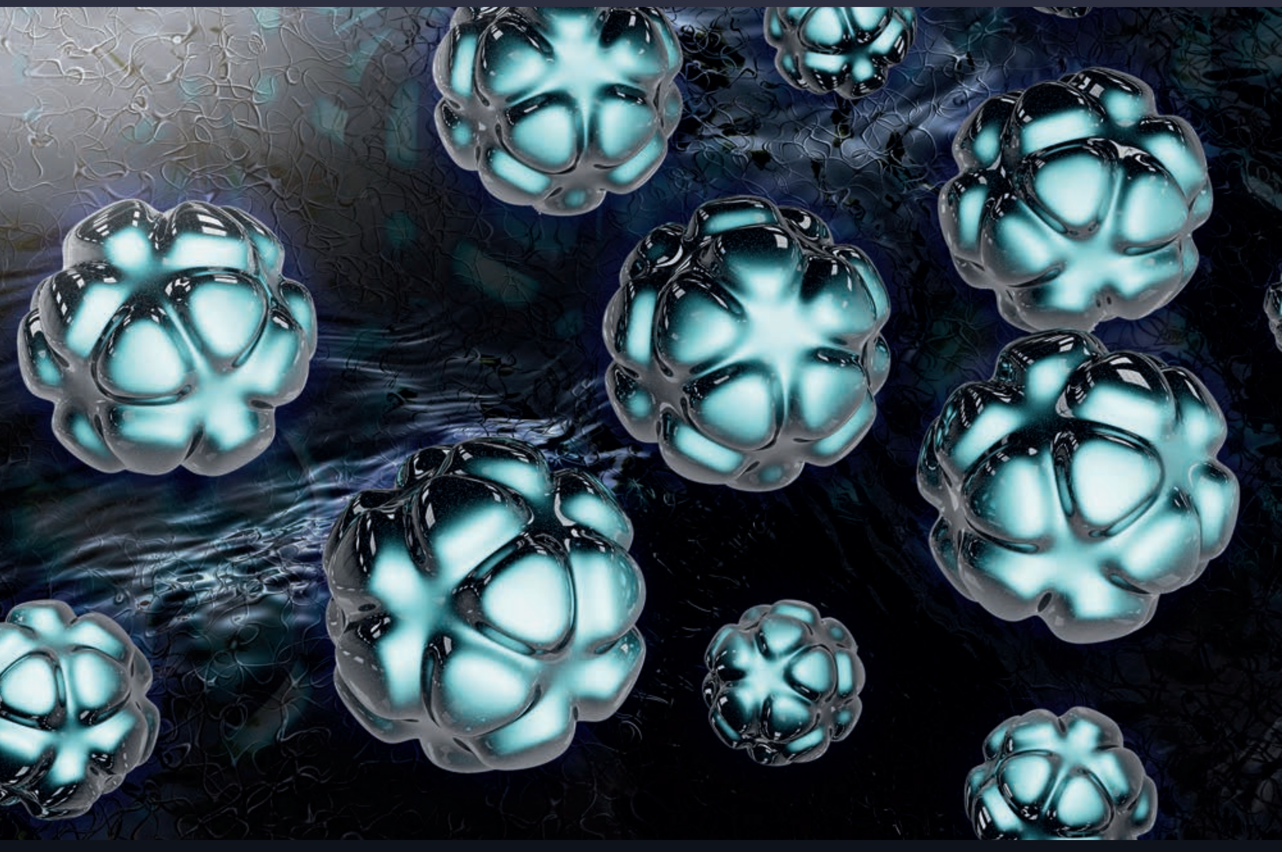
The Legitimacy of Transnational Private Governance Arrangements Related to Nanotechnologies:

The Case of International Organization for Standardization



Evisa Kica Ibraimi

THE LEGITIMACY OF TRANSNATIONAL PRIVATE GOVERNANCE ARRANGEMENTS RELATED TO NANOTECHNOLOGIES:

THE CASE OF INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

Evisa Kica Ibraimi

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ISBN: 978-90-365-3818-3
DOI number: 10.3990/1.9789036538183
Official URL: http://dx.doi.org/10.3990/1.9789036538183
This thesis was printed by CPI - Koninklijke Wöhrmann Print Service, Zutphen.
Cover Design by De Weijer Design, Baarn.
The image was downloaded from the iStockphoto.com and uploaded by xrender (real name hidden).

THE LEGITIMACY OF TRANSNATIONAL PRIVATE GOVERNANCE ARRANGEMENTS RELATED TO NANOTECHNOLOGIES:

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DISSERTATION

to obtain
the degree of doctor at the University of Twente,
on the authority of the rector magnificus,
prof.dr. H. Brinksma,
on account of the decision of the graduation committee,
to be publicly defended
on Friday, 23rd of January 2015 at 16:45 pm

by

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born on 18th of March, 1984
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The dissertation has been approved by:

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Summary

This thesis argues that since the mid-2000 transnational private governance arrangements (TPGAs) have emerged with a great promise to regulate the field of nanotechnologies due to their potential to bring technology to the market, promote innovation and complement existing legislation. These arrangements provide for non-binding norms grounded in practical experience and expertise. TPGAs have not replaced the sovereignty of the nation-state, however, this thesis argues that they have the potential to complement the conventional national and international institutions, and become a precondition for entry into (certain) markets and/or regulatory processes. By providing - amongst others - common vocabularies for nanotechnologies, as well as specific information with regards to risk assessment, occupational safety and different test methods for use at the nano scale, these arrangements have the potential to satisfy particular (technical, scientific or regulatory) needs and/or fill a communication gap. However, as this thesis argues, the potential of these arrangements to satisfy a specific regulatory need and/or serve as tools for regulating technological innovation in such a challenging and emerging field such as nanotechnologies gives rise to important theoretical and political concerns of legitimacy.

Questions of legitimacy in (nano)technology research and regulation have attracted the attention of a wide range of scholars. Current studies have provided various norms of legitimacy, which are crucial to guiding the functioning of governance arrangements to achieve socially desirable outcomes at the transnational level. However, in these studies it is still unclear whether these norms provide sufficient basis for determining the legitimacy of TPGAs related to technology regulation. Furthermore, there have been no serious efforts made to study the legitimacy of TPGAs related to nanotechnology regulation empirically - for example through opinion surveys on how stakeholders perceive legitimacy in practice - on whether they accept technology regulation or why this is not the case.

Theoretically this thesis addresses these issues through a systematic discussion on how legitimacy may be conceptualized at the transnational level and what this concept entails. The core of this thesis consists of developing a comprehensive empirical assessment on the legitimacy of nanotechnology related TPGAs, explored through the case study of the International Organization for Standardization (ISO) Technical Committee on Nanotechnology (ISO/TC 229), which arguable is one of the core TPGAs in the field of nanotechnologies. Data for this thesis come from interviews with 76 stakeholders participating in the setting TC 229 standards. The perceptions of stakeholders are used to understand legitimacy in practice, by conducting empirical analysis through quantitative research methods such as opinion surveys.

The thesis finds that the legitimacy of technology related governance arrangements in practice can be understood when stakeholders come to assess different aspects of a governance arrangement that relate to its decision-making process, expertise and outcomes. It finds that the perceptions of stakeholders on the legitimacy of nanotechnology standards are positively related to their level of participation, representation in the process, but also to the expertise that stakeholders have on nanotechnology standardization issues. The characteristics of the survey respondents suggest that respondents from developed countries (who have been generally more active in the decision-making process) appear to be more concerned with the benefits and problem-solving capacity of standardization outcomes. Respondents from less developed countries (who have been less involved in the setting of TC 229 standards) appear more

concerned with decision-making processes guiding the development of standards for nanotechnologies. At the practical level the responses of stakeholders seem to justify that for a governance arrangement to be perceived legitimate both its processes and outcomes are crucial. It is clear from this research that the participation gap, as well as the challenges to access, control and influence the decision-making process, and benefit from TC 229 deliverables, are likely to have important implications for the perceptions of stakeholders on the legitimacy of TC 229. This thesis argues that the legitimation of a transnational private governance arrangement cannot be viewed as a stable condition, but as something volatile and requires that effective strategies are deployed by relevant arrangements to improve not only the quality of their decision-making processes, but also the quality of standardization outcomes.

Samenvatting

Dit proefschrift betoogt dat *transnational private governance arrangements* (TPGAs) een grote belofte met zich brengen om nanotechnologie te reguleren vanwege hun mogelijkheid om nanotechnologie op de markt de brengen, innovatie te bevorderen en regelgeving te complementeren. Deze *arrangements* brengen niet-bindende normen tot stand die gebaseerd zijn op praktische ervaringen en expertise van stakeholders. Hoewel de overeenkomsten niet in de plaats komen van de soevereiniteit van de nationale overheden, betoogt deze studie dat ze de potentie hebben om de conventionele nationale en internationale instituties te complementeren en dat ze een voorwaarde voor toegang tot (bepaalde) markten en/of regelgevingsprocessen kunnen vormen. Door middel van (onder andere) een gezamenlijke vocabulaire voor nanotechnologie en specifieke informatie ten aanzien van risico analyses, veiligheid op het werk, en verschillende test-methoden voor het gebruik op nanoschaal, bieden deze overeenkomsten de mogelijkheid om aan een bepaalde (technische, wetenschappelijke of regelgevende) vereisten te voldoen en/of om een communicatieve lacune te vullen. Zoals in dit proefschrift wordt geconstateerd, geeft het feit dat deze overeenkomsten aan een bepaalde regulerende behoefte kunnen voldoen en/of om als hulpmiddel te dienen voor de regelgeving van technologische innovatie in een ingewikkeld en opkomend gebied als nanotechnologie, aanleiding tot zowel theoretische als politieke bezorgdheid over de legitimiteit ervan.

Bezorgdheid over de legitimiteit van (nano)technologisch onderzoek en regelgeving heeft de aandacht van een brede groep onderzoekers getrokken. Recente studies hebben geleid tot verschillende normen van legitimiteit die cruciaal zijn om het functioneren van governance overeenkomsten te sturen om zo sociaal wenselijke resultaten op transnationaal niveau te bereiken. Het is echter niet duidelijk of deze normen een voldoende basis vormen voor het bepalen van de legitimiteit van TPGAs in relatie tot technologische regelgeving. Verder zijn er geen serieuze pogingen gedaan om de legitimiteit van TPGAs in verband met nanotechnologische regelgeving empirisch te onderzoeken – bijvoorbeeld middels enquêtes over hoe stakeholders de legitimiteit in de praktijk ervaren, of zij technologisch regelgeving aanvaarden of waarom dit niet zo is.

Vanuit een theoretisch perspectief worden deze punten in deze dissertatie benaderd in een systematische discussie over hoe legitimiteit op transnationaal niveau kan worden geconceptualiseerd en wat dit concept inhoudt. De kern van dit proefschrift wordt gevormd door het ontwikkelen van een uitgebreide empirische beoordeling van de legitimiteit van aan nanotechnologie gerelateerde TPGAs, die worden onderzocht door een casestudie analyse van de International Organization for Standardization (ISO) Technical Committee on Nanotechnology (ISO/TC 229), een van de belangrijkste TPGAs op het gebied van nanotechnologie. De data voor dit onderzoek zijn verzameld via interviews met 76 stakeholders die betrokken waren bij de uitwerking van de TC 229 standaarden. De stakeholder percepties zijn gebruikt om legitimiteit in de praktijk te begrijpen door empirisch analyses uit te voeren met gebruik van kwantitatieve onderzoeksmethoden zoals perceptie-enquêtes.

Deze studie constateert dat de legitimiteit van technologie gerelateerde governance overeenkomsten in de praktijk kan worden begrepen als stakeholders verschillende aspecten

van een governance overeenkomst die in verband staan met haar besluitvormingsproces, expertise, en de resultaten evalueren. Het blijkt dat the percepties van stakeholders over de legitimiteit van nanotechnologie standaarden een positief verband laten zien met het niveau van participatie van stakeholders, hun vertegenwoordiging in het proces, maar ook met hun expertise ten aanzien van nanotechnologie standardisatie. De eigenschappen van de respondenten van de enquête suggereren dat respondenten van meer ontwikkelde landen (die over het algemeen aktiever zijn geweest tijdens het besluitvormingsproces) zich meer bezig lijken te houden met de voordelen en de probleemoplossende capaciteit van standardisatie resultaten. Aan de andere kant, respondenten van minder ontwikkelde landen (die minder betrokken zijn geweest bij de ontwikkeling van TC 229 standaarden) lijken zich meer bezig te houden met de besluitvormingsprocessen die ten grondslag liggen aan de ontwikkeling van nanotechnologie standaarden. Op praktisch niveau lijken de respondenten van mening dat bij de bepaling van wanneer een governance overeenkomst legitiem is, zowel de processen als de resultaten van crucial belang zijn. Het wordt duidelijk uit dit onderzoek dat zowel de participatie-afstand als de uitdagingen met betrekking tot toegang, zeggenschap en invloed op het besluitvormingsproces, en profiteren van TC 229 *deliverables*, waarschijnlijk belangrijke consequenties hebben voor de percepties van stakeholders over de legitimiteit van TC 229. Daarnaast laten de adviezen van stakeholders over hoe legitimiteit zou moeten worden verbeterd zien dat de legitimisering van een transnationale private governance overeenkomst niet kan worden gezien als een vaststaand proces, maar dat het nodig is om over te gaan op effectieve strategieën om niet alleen de kwaliteit van de besluitvormingsprocessen te verbeteren, maar ook de kwaliteit van standardisatie resultaten .

Acknowledgements

WOW!! I cannot believe that I am sitting today, in this lovely New Year season, to write the acknowledgments of my thesis. It feels wonderful and the more I think about it the more confused I get as of where to start with this piece. The PhD journey has been amongst the best experiences I have had in my life. A job I have greatly enjoyed, travelling to places I have never thought of and meeting wonderful people who have always been there for me. At this point, I just want to stop for a while to express my deepest gratitude to those who have made this thesis possible.

To begin with, I want to thank my promoters Bärbel Dörbeck-Jung and Ramses Wessel. Thank you for making the decision to hire me to carry out this project and for believing in my professional capabilities. Bärbel thank you for your patient guidance, encouragement and advise you have provided throughout my PhD studies. I have been extremely lucky to be guided by a supervisor who cared so much about my work, was open to discussions at any time and responded to my inquires so promptly. I want to thank you in particular for your constructive criticism and advise on how should I conceptualize legitimacy and operationalize it in a more detailed way. Your suggestions and guidance has highly influenced my theoretical approach in this thesis, for which I am deeply grateful. I was continuously amazed by yours and Bernard's hospitality and willingness to invite me at your place, which made me feel that I have easily found a second home in the Netherlands. Thanks to you I experienced how beautiful it was to have a team trip in one of the most beautiful Dutch islands, Schiermonnikoog. This trip was amongst the best adventures I have experienced during this period, accompanied by such wonderful discussions, nice food and sightseeing. Ramses thank you for your being extremely supportive and helpful throughout this period. I really appreciate the freedom you have given me to find my own path and for the support you have offered me continuously. Your positive outlook in my research and thoughtful comments have highly influenced the quality of this thesis. I really appreciate your advice on how to structure my approach on transnational governance arrangements related to the governance of nanotechnologies. I have thoroughly enjoyed to work with you during this period and discuss future career paths. I am deeply grateful for the opportunities I have been able to seek thanks to your support and guidance.

My experience as a researcher at the University would not have been half as much fun without the support of Diana Bowman. Diana, I have learned a lot from working with and alongside you. Your straightforward criticism combined with constant support and constructive suggestions have greatly improved my confidence and performance as a new researcher. Your forensic scrutiny on the thesis has been extremely useful. Thank you for taking the time out of your busy schedule to travel to Enschede, have long discussions over my research, and propose excellent suggestions that have significantly helped me to organize my ideas and improve my critical thinking. Your confidence in my research, energy and enthusiasm has greatly inspired me to work with dedication. I greatly enjoyed working with you in several papers and traveling together in many conferences.

For my research I am greatly thankful to all my study participants as well. Without their support and collaboration this thesis would have not been possible. Thank you for your time, critical comments and participation in the survey questionnaire. This study would also have not been possible without the help of the Dutch Standardization Body (NEN) and its staff. I want to thank specially Tanja van Tooren for her endless support, understanding and discussions on nanotechnology standardization issues. Special thanks goes also to the Dutch NanoNext Research Programme and the Dutch Ministry of Economic Affairs for supporting this research financially.

Throughout the entire period of this project I have had the opportunity to share beautiful and exciting moments with many colleagues I have met at the faculty. Nupur, Aline, QingQian,

Clare, Ben and Martin made the PhD experience much nicer for me. Thank you for your valuable friendship and cooperation. I really enjoyed working with you all. A warm thank you goes in particular to Aline, QingQian and Nupur. I am very thankful for your company and for the best coffee breaks and lunch conversations we have had over our academic and personal life. You have given me comfort with your presence whenever I needed to discuss the good news and my troubles with you. I believe that a good friendship with whom you can share so many moments of your research experience is a key to get through a PhD program successfully.

Besides the colleagues from the Law and Regulation Group, I am especially grateful to other colleagues from the Public Administration Department as well as other friends I have made upon my arrival in Enschede. I arrived in Enschede for the first time in 2008 to join my husband, Luan, as he was pursuing his PhD at Twente University. I did not know anybody in this city, but Pieter Hartel (whom I knew through Luan) and his wife, Marijke, did not leave me feel as a foreigner in this new country I have just arrived in. I am deeply grateful to Pieter and Marijke for their hospitality and willingness to help me find my way in Enschede. Your support has greatly impacted my stay in Netherlands, for which I will be forever grateful. My time at Twente University would not have been possible without the support of Nico Groenendijk. Nico thank you for being extremely helpful in providing me constant feedback and support during my first steps as a researcher at the Department. I am grateful to have had the opportunity to work with you in the project of intellectual property rights, which greatly shaped my analytical skills as a researcher, and made me realize that I had still so much more to learn and experience in this exciting profession. I would also want to thank Victor Rodriguez, Michiel Heldeweg, Harry van der Kaap and Martin Rosema for taking out time to discuss with me key issues during the development of my research. Special thanks goes also to the colleagues of the Department of Science, Technology and Policy Studies (StePS), and in particular to Kornelia Konrad, Arie Rip, Stefan Kuhlmann, Bart Walhout, Haico te Kulve and Carla Alvial. Thank you all for your interest to attend the monthly NanoNext Colloquiums I organized, as well as for your fruitful discussions, presentations and suggestions on nanotechnology related issues. I am also indebted to Manon, Annette and Ria for their readiness to help me with administrative issues whenever I needed them.

I also want to thank my friends outside of the University for reminding me constantly that weekends are there to have fun and relax. Blerina, Edmond, Paula, Marina, Trajce and Spase thank you for your friendship. I have truly enjoyed your company, our evening gatherings, cooking experiments and lovely chats about our expat experiences in the Netherlands.

Lastly I would like to thank my parents, my brother and sister, my family-in-law, friends and relatives in Macedonia for their support, encouragement and continuous interest in my work. Special thanks goes to my parents and parents-in-law, who have walked with me in every step I have made. Your enthusiasm about my progress, unconditional support and long Skype conversations made it possible that I never felt really far away. I appreciate the endless encouragement you have provided throughout these years more than you will ever know. Thank you for instilling in me the belief that I can be successful in anything I put my mind to. I owe a lot of my success to you!

Finally I would like to thank Luan. My love, thank you for being such a wonderful partner, for encouraging me to pursue my dreams, for being patient on my moody days and for all the sacrifices you have made to support me in reaching my goals. I am amazed by your willingness to proof read my thesis and for listening to my endless stories about nanotechnology standardization. It feels that you have now become highly knowledgable on standardization issues as well. I am so happy that we have walked through this together and I am looking forward to our next adventures.

Evisa Kica Ibraimi
Utrecht, 19 December 2014

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List of Abbreviations

ANEC	European Consumer Voice in Standardization
AON	Australian Office of Nanotechnology
ASTM	American Society for Testing and Materials International
ASME	American Society of Mechanical Engineers
AIChE	American Institute of Chemical Engineers
BSI	British Standardization Institute
BIAC	Business and Industry Advisory Committee
BIPM	International Bureau of Weights and Measures
BTWG	Technical Management Board Working Group
CAC	Codex Alimentarius Commission
CAG	Chairman's Advisory Group of ISO/TC 229
CBEN	Center for Biological and Environmental Nanotechnology
CD	Committee Draft
CENELEC	European Committee for Electrotechnical Standardization
CEN/STAR	Advisory Committee of the European Committee for Standardization
COPOLCO	Committee on Consumer Policy (EU)
DG	Directorate General
DIS	Draft International Standard
DEFRA	Department for Environment Food & Rural Affairs (UK)
DEVCO	Committee on Developing Country Matters
ECOS	European Environmental Citizens Organization for Standardization
EC	European Commission
ENB	Earth Negotiations Bulletin
ENP	Engineered Nanoparticles
EHS	Environmental, Health and Safety
EPA	Environmental Protection Agency
EP	European Parliament
ERC	Expert Resource Centre (UK)
ETC	Action Group on Erosion, Technology and Concentration
ETSI	European Telecommunications Standards Institute
ETUI	European Trade Union Institute
EU	European Union
FDIS	Final Draft International Standard
FDA	US Food and Drug Administration
FMD	French Ministry Décret
FoE	Friends of the Earth
FSA	Food Standards Agency (UK)
GMO	Genetically Modified Organisms
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICANN	Internet Corporation for Assigned Names and Numbers
ICCM	International Conference on Chemicals Management
ICCR	International Cooperation on Cosmetic Regulations
ICCS	International Conference of Chemicals Safety

ICH	International Conference of Harmonization
ICON	International Council on Nanotechnology
IFCS	Intergovernmental Forum on Chemical Safety
IGS	Innovation and Governance Studies
IEC	International Electrotechnical Commission
IO	Industrial Organization
IR	International Relations
IRGC	International Risk Governance Council
IRMM	Institute for Reference Materials and Measurements (European Commission)
IS	International Standard
ISO	International Standardization Organization
ITU	International Telecommunication Union
IUPAC	International Union of Pure and Applied Chemistry
JWG	Joint Working Group
LDC	Less Developed Countries
MN	Manufactured Nanomaterials
MWCNTs	Multi-Walled Carbon Nanotubes
NCB	Nuffield Council on Bioethics
NGO	Nongovernmental Organization
NIA	Nanotechnology Industries Association
NP	New Item Proposal
NM	Nanometre
NLCG	Nanotechnology Liaison Coordination Group
NRC	National Research Council (US)
NRCA	National Research Council of the Academics (US)
NSF	National Science Foundation (US)
NSI	Netherlands Standardization Institute
NNI	National Nanotechnology Initiative (US)
NSTG	Nanotechnology and Sustainability Task Group
NSB	National Standardization Body
NSTG	Nanotechnology and Sustainability Task Group
NT-001	Australia's Nanotechnology Technology Committee
OB	Observatory
OECD	Organization for Economic Co-operation and Development
PI	Participatory
PCTG	Planning and Coordination Task Group
PG	Project Group
PEN	Woodrow Wilson International Center for Scholar's Project on Emerging Technologies (PEN) (US)
RCEP	Royal Communication on Environmental Pollution (UK)
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation
RI	Research Institute
R&D	Research and Development
RS-RAE	Royal Society and Royal Academy of Engineering (UK)
SAICM	Strategic Approach to International Chemical Management
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks (EU)

SDO	Standard Development Organization
SG	Steering Group
S&TC	Scientific & Technical Council of IRGC
SMEs	Small and Medium Enterprises
SPS	Agreement on Sanitary and Phytosanitary Measures
TA	Trade Association
TG	Task Group
TGA	Transnational Governance Arrangement
TC 229	Technical Committee on Nanotechnology
TGS	Task Group on Sustainability
TGCSDN	Task Group on Consumer and Societal Dimensions of Nanotechnologies
TiO_2	Titanium Dioxide
TPGA	Transnational Private Governance Arrangement
TMB	Technical Management Board
TSCA	Toxic Substances Control Act (US)
TR	Technical Report
TS	Technical Specification
TUAC	Trade Union Advisory Committee
TUO	Trade Union Organization
US	United States of America
UK	United Kingdom
UN	United Nations
UNIDO	United Nations Industrial Development Organization's International Centre for Science and High Technology
UNED	United Nations Conference on Environment and Development
VAMAS	Versailles Project on Advanced Materials and Standards
WSIS	World Summit on the Information Society
WG	Working Group
WHO	World Health Organization
WPMN	Working Party on Manufactured Nanomaterials
WTO	World Trade Organization
ZnO	Zinc Oxide

Chapter 1

1. Introduction

This introductory chapter provides an overview to the thesis. First, it starts with background information on what nanotechnologies are, and reflects on their potential benefits and challenges. Second, it introduces the key regulatory issues accompanying these technologies as well as how these issues are confronted by various actors at the national, European and international level. Third, the chapter provides an introduction to the main research problem and motivation guiding this thesis. Finally, it describes the main research questions and the overall structure of the thesis.

1.1. Background (Nanotechnologies, Characteristics, Potential and Challenges)

The term “nanotechnologies” refers to technologies that are executed on a scale of nanometers (nm)[1] (Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2006). These technologies concern the application and use of materials, structures, devices and systems, which have new properties and functions due to their small size that ranges between 1 to 100 nm (Sayes and Santamaria, 2014), as well as their ability to manipulate materials at this scale (International Risk Governance Council (IRGC), 2007). The term “nanotechnologies” was first mentioned in 1974 by Norio Taniguchi, who used it to refer to “the processing of, separation, consolidation, and deformation of materials by one atom or one molecule (Taniguchi, 1974: 18). Since then different actors and/or organizations have reframed this term (Hansen et al. 2013). For instance the United States (US) National Nanotechnology Initiative (NNI) together with the American Society for Testing and Materials International (ASTM), the American Institute of Chemical Engineers (AIChE) and the American Society of Mechanical Engineers (ASME) have developed a standard (and widely-accepted) definition for nanotechnologies as a term that pertains to “a wide range of technologies (including physics, chemistry, biology, material science, electronics) that measure, manipulate or incorporate materials […] with at least one dimension between approximately 1 and 100 nm” (Sayes and Santamaria, 2014: 78; Hansen et al. 2013: 531; NNI, 2009).

[1] Nanometre is a unit of length in the metric system that is equal to one billionth of a meter.

There are three classes of nanomaterials (or nanoparticles)[2]: natural, incidental and engineered (or manufactured). Natural nanomaterials exist naturally and occur due to seasonal or other environmental influences, such as for example the volcanic ash, dust storms, ocean spray (Buzea et al. 2008; Gray, 2011). Incidental nanomaterials are created incidentally during the industrial processes or material degradation. Incidental nanomaterials include for example particles released by automobiles (e.g. diesel exhaust) or during spraying, blending, and so forth. Engineered (or manufactured) nanomaterials (MNs) are manufactured intentionally and designed to have a specific properties (such as size, shape, chemistry or surface properties). Therefore, as Gray (2011: 22) argues, it is this control and structural uniformity that distinguished MNs from other classes/types of nanomaterials. Hansen et al. (2013: 563) argue that for materials to be considered MNs two criteria must be fulfilled:

> "(1) they must have been purposely engineered to have a structure with at least one dimension in the approximate range 1-100nm, and (2) this nanostructure must give the system properties that differ from those of the bulk (or macro-scale) forms of the same material"

Nanomaterials have been categorized in various ways by many organizations. For instance, in 2007 the US Environmental Protection Agency (EPA) provided different categories of MNs based on the different types of materials, such as: carbon-based materials (include carbon nanotubes - CNTs, fullerenes), metal-based materials (include metal oxides, quantum dots, nanosilver), dendrimers (can be used for catalysis) and composites (include two or more nanomaterials in combination) (EPA, 2007). The US National Academies of Sciences categorized nanomaterials in metal oxides (including zinc and titanium oxides), nanoclays, nanotubes and quantum dots (Goldman and Coussens, 2005).[3]

There are several characteristics that make nanomaterials to behave differently than other bulk materials[4] and have an immense potential. First, at the nanoscale, the properties of a substance (e.g. colour, shape, strength, electrical conductivity, melting and boiling temperatures, weight) can change relative to their macro-scale counterpart . This is physically explained as the

[2] Nanomaterials are defined as "generic term for the structure, devices and systems created through nanoscale engineering, including nanoparticles, nanostructure, and nanoscale substances" (Breggin et al. 2009: 10) […] with at least one external dimension in the size range from approximately 1-100 nm" (NIOSH, 2009). See also: National Institute of Occupational Safety and Health (NIOSH)., 2009. Approaches to Safe Nanotechnology: Managing Health and Safety Concerns Associated with Engineered Nanomaterials, *available at*: http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf

[3] Other classifications of nanomaterials are also provided by the International Council of Nanotechnology (ICON, 2008) and Hansen et al. (2013).

[4] "A bulk material is the material that is ordered, stored, issued and sold by weight (such as for example: bar stock), volume (such as oil) or footage (such as lumber)" see also http://thelawdictionary.org and http://www.businessdictionary.com .

quantum effect (EC, 2013; S&TR, 2003), meaning that a particular material in a nano-sized form can have fundamentally different properties as opposed to the properties that the same material has when it is in a bulk form (or at the macro-scale). For instance, at the nano-scale gold is red, silver is highly antibacterial (killing viruses upon contact), aluminum is highly explosive, and some materials (such as silicon, germanium and diamond) become semiconductors (S&TR, 2003; Sadiq et al. 2011; EC, 2013). The second characteristic of nanomaterials is that they can be fabricated atom by atom by using a bottom-up technique to manufacture nanomaterials (Zhang, 2003; Lue, 2007).[5] This technique seeks to have smaller components (e.g. atoms or molecules) to build up into more complex and functionally richer structures (Hansen, 2013; EC, 2013). For example, some nanoparticles (such as metals) can be combined or integrated to produce coatings that can make surfaces water resistant, dirt-repellent and/or antibacterial; other nanoparticles (such as silicon dioxide and nanosilver) can also be combined and used as a carrier for protein molecules, such as antibodies, for cancer cell treatment (Clariant, 2007; Ulmer, 2011; Sotiriuo et al. 2011).

The third characteristic of nanomaterials, which makes them behave differently than bulk materials, is that in comparison to the volume of material produced in a larger form, nanoparticles have a relatively larger surface area and greater proportion of particles per unit mass (Buzea et al. 2008; EC, 2013; Sayes and Santamaria, 2014). For instance, a cubic volume of a material with sides of one centimeter long has a surface of six square centimeters. If one would divide the same volume into eight pieces the surface area would become 12 square centimeters. Therefore, when the given volume is divided into more pieces its surface area increases. Now, if one would divide the cubic volume into little nanotubes with sides of one nanometre long, the surface area will be ten million times larger than the surface area of the original cube. So as the size of the particles decreases a greater proportion of atoms is found at the surface, which makes materials to become more chemically reactive (Oberdörster et al. 2005; Buzea, 2008; Chaturvedi et al. 2011; Jaspers, 2011).

Due to the aforementioned physico-chemical characteristics, and the ability to manipulate matter at the nanoscale with the purpose to develop materials that have new and advanced properties (e.g. making materials stronger, thinner, more elastic, antibacterial), nanotechnologies are expected to provide the platform and tools for innovative products and applications for consumers by adding value to solutions designed to address a myriad of human and

[5] Another technique is the top-down technique which is a technique for reducing the size of a bulk material to a nanoscale by using different techniques such as high energy ball milling, cryogenic milling or electric wire explosion. See : van Heeren, H.,2007) Fabrication for Nanotechnology, available at: In Nanotechnology Aerospace Applications - Educational Notes RTO-EN-AVT-129bis.

environmental challenges (Bosso, 2010; Sargent, 2008; NNI, 2000). For instance, nanotechnologies hold great promise for improved applications in fields such as:

- *medicine* (e.g. silicon nanoparticles covered with a layer of gold can be used for the destruction of cancer cells; fluorescent quantum dots, carbon nanotubes as well as dendrimers can be used to detect tumors and kill bacteria; gold nanoparticles can also be used as drug delivery vehicles to transport therapeutic agents into specific cells) (Modi et al. 2013; Li and Gu, 2010);
- *energy* (e.g. quantum dots could be combined with polymers to produce highly efficient plastic solar cell substance, which can be sprayed on a surface (e.g. in walls) to convert sunlight to electricity; because of their ability to absorb light efficiently, some nanomaterials such as carbon nanotubes and fullerenes can also be used in photovoltaic devices, which are used to generate electrical power) (Jariwala et al. 2013; Manzetti and Andersen, 2012);
- *food* (e.g. in food packaging silica nanoparticles can be used to improve the mechanical properties (such as strength and durability) and barrier properties (oxygen, moisture) of composites; titanium dioxide can be used to block the ultraviolet radiation (UV) and extend the shelf-life of food) (Silvestre et al. 2011);
- *cosmetics* (e.g. titanium dioxide (TiO_2) can be used in dental/oral hygiene products; TiO_2 and zinc oxide (ZnO) can be used in sunscreens to protect the skin against UV light (Morganti, 2010; Grobe et al. 2008);
- *water purification* (e.g. nanosilver can be used as an anti-microbial agent to disinfect and clean water) (Li et al. 2008).

The high potential of nanotechnologies has triggered agents within government and industry over the last decade to invest heavily in nanotechnology research and development (R&D) programs (Hansen et al. 2008; IRGC, 2007; Sargent, 2013; NRC, 2012). In 2000, the US was the first nation to establish a formal initiative related to nanotechnologies (the National Nanotechnology Initiative (NNI)), along with significant increase in R&D funding for nanotechnology research (Sargent, 2013; Hansen et al. 2013). Since then, other nations have also established their own national initiatives by investing in nanotechnology research. In 2014, Lux Research, an independent research and advisor firm, estimated a total of US$18.5 billion investment in nanotechnologies for 2012, coming from governments, corporations and private investors (Lux Research, 2014). According to Lux Research, since 2010, corporations have increased their investment in nanotechnologies 21%, whereas governmental and private investors have reduced their investments by 5-10%. In July 2011, Cientifica - a privately held nanotechnology consulting firm - estimated that around US$65 billion of global government funding have been invested in nanotechnology research by the end of 2011, with US$35 billion being added by 2014 (Cientifica, 2011). According to Lux Research, the US remains a major investor in nanotechnology R&D with US$2.1 billion of federal and state funding in 2012 alone.

The results of these global investments are steadily coming to fruition, as evidenced by the increasing number of self-reported products incorporating nanomaterials making their way into commerce (PEN, 2013). The Woodrow Wilson International Center for Scholar's Project on Emerging Technologies (PEN) created in 2005 an online inventory of nanotechnology consumer based products.[6] In 2006 PEN inventory contained 212 products for purchase. This number increased to 580 in 2007. In 2011 it was 1317 products, and in 2013 the number was 1628 (PEN, 2013; Hansen et al. 2013; Bergeson, 2013).[7] The majority of these products are health and fitness related products including sporting equipments, cosmetics and sunscreens. Other products fall into the categories of home and garden, food and beverage, children's products, as well as electronics and computers (PEN, 2011; Hansen et al. 2013). The major types of nanomaterials used in the product description of the PEN inventory include: silver (313 products), carbon (91 products), titanium (59 products), silica (43 products), zinc (31 products) and gold (28 products) (Sayes and Santamaria, 2014).

Besides the increase in the global R&D funding, in February 2014 the US National Science Foundation (NSF) identified that the global revenue from nano-enabled products in 2013 was more than US$1 trillion. In a similar vein, Lux Research indicated that the revenue from nano-enabled products has continued to grow during the period of 2010-2012; their estimates suggest an increase from US$339 billion to US$371 billion. By 2018 the value of nano-enabled products is predicted to be US$4.4 trillion, driven by the expected commercialization success in the healthcare and electronics sectors (NSF, 2014; Lux Research, 2014; Ruggie, 2014). Whether this will be the case it remains to be seen. However, earlier studies make important points indicating that estimations about the value of products incorporating nanotechnologies can also be "over-hyped" by news media or ambiguous due to uncertainties related to the size of the "nanotechnology value chain" and the "(sub)areas of nanotechnology that the market evaluation includes" (see for example Seear et al. 2009: 54; Ebeling, 2008).

Concomitant to these debates have been concerns over the unintended consequences of some MNs. These debates have focused on the environmental, health & safety (EHS) risks that

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[6] The inventory is *available at*: http://www.nanotechproject.org/cpi/about/ (last accessed 2 October, 2014).
[7] According to the Nanotechnology Company Database, as of September 2014, there are around 2066 nano focused companies around the world, of which 1063 are based in US and 684 in the EU. See: Nanowerk, 2014, Company&Labs Directory, *available at*: http://www.nanowerk.com/nanotechnology/research/nanotechnology_links.php, accessed 14 September 2014.

some MNs may pose to workers handling nanomaterials, to consumers of nanobased products, and to the public and the environment at large (Maynard et al. 2011a; Medina et al. 2011; Nel et al. 2006; RCEP, 2008). Ironically, the same characteristics that make MNs so useful in technology (such as for example the physico-chemical properties including particle size, shape, large quantum effects, surface area, durability, electrical conductivity) are considered to be the same reasons why these materials may be highly toxic to biological systems (Graves Jr, 2014). The similar properties (such as size and visual similarities) that (some) MNs (e.g. CNTs) have with other ultrafine particles and asbestos fibres, have led to many concerns about the potential risks of nanomaterials (RS-RAE, 2004; Poland et al. 2008; Hansen et al. 2013 & 2014). Ultrafine particles are defined as ambient particles that are smaller than 100 nm (examples of ultrafine particles include particles that are produced incidentally by automobiles such as diesel exhaust) (Sayes and Santamaria, 2014). Research on ambient ultrafine particles has found a correlation between the respiratory ill health (such as pulmonary and cardiovascular diseases) and the number of ambient ultrafine particles (Oberdörster et al. 2005; Rückerl et al. 2011). In addition to size, visual similarities between asbestos fibres and CNTs have also led to concerns that nanomaterials may have similar hazardous properties as asbestos (Donaldson et al. 2006; MacCuspie, 2014).

Toxicological research has also shown that certain nanomaterials (such as CNTs, carbon nanofibers (CNFs) and TiO_2) under specific conditions can cause adverse respiratory effects in rats, indicating therefore that similar adverse effects might occur in humans after exposure to such nanomaterials (Schulte et al. 2014). Recently, studies have also shown, that similar to asbestos fibres, the exposure (of mice) by inhalation to multi-walled carbon nanotubes (MWCNTs) can promote the lung tumor formation (Sargent et al. 2014). It has been shown that similar to asbestos, MWCTs are also carcinogenic to mesothelial cells. In 2010, Wu et al. found a relationship between nanomaterials (e.g. CNTs) in dust inhaled by some respondents during the attack on the World Trade Center in 2001 and the impact of these nanomaterials on their lung disease (Wu et al. 2010). In 2009 Chinese toxicologists reported similar findings, indicating that the exposure of seven workers to certain nanomaterials (for a period of 5-13 months) caused severe damages leading to human deaths and disabilities (Song et al. 2009). Whereas the specific link of these accidents with nanoparticles has been debated by many researchers (e.g. Maynard, 2009; SCENIHR, 2009; Jaspers, 2011; Hansen et al. 2013), they all suggest that caution should be used to limit the exposure of humans to certain nanomaterials (see also Toyokuni, 2013; Sargent et al. 2014).

The antibacterial properties of silver nanoparticles have also received wide attention in recent years (Mikkelsen et al. 2011; Hansen et al. 2013; Faunce et al. 2014). These nanomaterials have been used in a range of consumer products including washing machines, food storage, cleaning products, socks and other textiles. The main concerns with regards to nanosilver focus on that silver from nanoparticles can enter the body vial oral or inhalation routes and distributed to target organs such as liver, lungs, skin and brain (Faunce et al. 2014: 371). Whereas there is a controversy on the specific hazards that nanosilver can pose as an antibacterial or how it is transmitted within the body, some researchers have already indicated that the exposure of rats to silver nanoparticles has produced minimal pulmonary inflammation or toxicity (Stebunova et al. 2011; Mikkelsen et al. 2011). Even though these are only few examples and preliminary studies on specific types of nanomaterials, they serve, as Hansen et al. (2013) argue, as early warnings about the hazardous potential of MNs. These issues have promoted various government funded research programs, commentators, industry and activist groups to engage in many debates about the effectiveness of current regulatory frameworks to regulate nanotechnologies and manage their potential risks (Chaudhry et al. 2006; Marchant et al. 2006; Ludlow et al. 2007; Maynard et al. 2011; Monica et al. 2014).

It is well documented that questions regarding the ability of governments to effectively regulate this ubiquitous technology are not new, as they have emerged within certain corners of academic literature as early as 1994 (Fiedler and Reynolds, 1994; RS-RAE, 2004; Bowman and Hodge, 2007; Bowman, 2014). Though initially quite broad in scope, questions and concerns have since matured and taken on a more tangible form, thus reflecting the maturation of the technology itself. As such, we have seen the debate shift from being about whether nanotechnologies “fall” under the currently regulatory regimes, to one primarily focused on the effectiveness of these inherited regulatory frameworks for dealing with particular classes or categories of nano-based products and processes (Stokes and Bowman, 2012; Bowman, 2014). Many concerns have also been raised about the ability of the industry to adequately protect their workers from nano-specific hazards (RS-RAE, 2004; Mullins and Gatof, 2014).

In Section 1.2, I discuss the regulatory and governance challenges related to nanotechnologies, as well as the activities undertaken by a wide range of actors (such as industry, government and others) to respond to these challenges.

1.2. (Regulatory) Challenges and Uncertainties for Nanotechnologies

Scientific reviews, such as those carried out by the *United Kingdom’s Royal Society and Royal Academy of Engineering* in 2004 (RS-RAE, 2004), the *United Kingdom’s Royal Commission on Environmental Protection* in 2008 (RCEP, 2009) and the *Center for International*

Environmental Law in 2012 (Azoulay, 2012), emphasize that there are scientific and knowledge gaps on the hazardous components, the specific properties of the components, the behavior of nanomaterials in the environment and/or living organisms, as well as the duration of the anticipated levels of exposure (Hodge et al. 2010: 14). Groups such as SCENIHR in the EU have also reported that “the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics” (SCENIHR, 2006: 6). The main uncertainties in this regard relate to determining which physico-chemical properties impact the toxicokinetics and the environmental distribution of nanomaterials (SCHENIHR, 2006). Furthermore, even though it has been reported that some nanoparticles are able to enter the skin or different organs via bloodstream, still there are many uncertainties of how these particles translocate within the body and whether their characteristics (both physico-chemical and size) facilitate this translocation (SCENIHR, 2007; Buzea, 2008; Jaspers, 2011).

Significant uncertainties similarly exist in relation to how human exposure to nanomaterials may occur in different environment (e.g. exposure from inhalation, oral or dermal penetration), as well as how it can be controlled and measured. There are many uncertainties as to how a nanomaterial comes into contact with humans and/or environmental organisms, and whether it penetrates areas of high concern (such as for example brain cells) (Hunt and Riediker, 2011; Linkov et al. 2011). The exposure potential of nanomaterials depends greatly on whether they are bound on a solid or liquid matrix or are free (such as aerosolized nanomaterials, e.g. spray cleaning products). Furthermore, in contrast to some bulk materials, human and environmental exposure to nanomaterials can occur during several phases of the life cycle of the product (such as during the synthesis of the nanomaterials, production, use or disposal) (SCENIHR, 2006; Elsaesser and Howard, 2012). At each of these phases the physico-chemical properties as well as the eco(toxicological) effects of some nanomaterials may change, with each phase adding a further dimension to the potential toxicity to nanomaterials (Maynard, 2009). In this way, challenges for nanoregulation are how to evaluate toxicity, assess and manage accurately the risks associated with nanomaterials, as well as predict the impact of these materials throughout their life cycle (ICON, 2008; Blaunstein et al. 2014; Faunce et al. 2014).

Maynard (2006) and Kandlikar et al. (2007), have added to these debates, arguing that the application of traditional risk assessment methodologies that focus only on mass concentration as an exposure metric may no longer be appropriate to calculate the risks associated with MNs. Given the characteristics of nanomaterials that were mentioned in the earlier section, particle size, particle shape, chemical composition, particle number concentration (or density), as well as the chemical reactivity of particles, are all important metrics for characterizing and assessing the hazards of some nanomaterials (Maynard and Aitken, 2007; Sayes and Santamaria, 2014; Kennedy et al. 2014).

There have been a number of reviews that have also sought to evaluate the adequacy of current regulatory arrangements for the existing suite of nano-related products and processes (e.g. Chaudhry et al. 2006; EC, 2008 & 2012; FSA, 2008; HSE, 2006; Hansen et al. 2013&2014; Ludlow et al. 2007; RS-RAE, 2004; EPA, 2007; FDA, 2007; SCENIHR, 2006). While these reviews have varied in their scope and focus, the analyzes presented in these documents highlight that the existing regulatory regimes capture nanotechnology-based applications in the same manner as their conventional counterparts including, for example, industrial chemicals. However, the main problems, amongst others, relate to the toxicity parameters, threshold minimums, and risk assessment strategies outlined in current regulatory regimes, which were not designed to deal with the unique properties displayed at the nanoscale and the implications that these properties may generate (Ludlow et al.2007; Hansen et al. 2013).

There is a growing consensus within the scientific community that the existing regulatory frameworks may be outdated, inappropriate or may need significant updates to be able to capture the safe production or use of some nanomaterials, and identify the potential hazards that these materials pose to human health and environment (SCENIHR, 2006; Groves et al. 2008; Hansen et al. 2014). The need to rethink the appropriateness of the regulatory frameworks has been identified also in other cases before the development of nanotechnologies,[8] but they serve as a case in point to further highlight the shortcoming of current regulatory frameworks and the need to establish (new) regulatory measures to deal with hitherto unknown materials that have new properties and unknown risks (Hansen et al. 2014; Marchant et al. 2011; Jansen et al. 2011).

One of the key challenges in many regulatory frameworks is that they consider the chemical identity and not the size of the substance as a key criteria for regulatory purposes. In this way they do not differentiate between a material in its nanoscale form and bulk form (RS-RAE, 2004; Karkan et al. 2009; Hansen et al. 2013). For instance, under the current chemical regulatory frameworks in the EU and US nanomaterials are defined as chemical substances. In

[8] For instance in the late 1990s there were many issues and controversies about the regulation of the genetically modified organisms (GMOs) bot in EU and US. The skepticism about regulating GMOs and more specifically labelling products that incorporate GMO components still continues to remain high in some European countries (e.g. France, Spain, Austria). See : Löfstedt, E.R and Vogel, D., 2001. The Changing Character of Regulation: A Comparison of Europe and the United States. Risk Analysis, 21 (3), 399-416; Throne-Holst and Rip., 2011. Regulatory challenges have also been observed at information industries (e.g. internet, telecommunications and information technology industries), See : Weiser, P., 2002. Regulatory Challenges and Models of Regulation. *Journal on Telecommunication and High Tech Law*, 1, 4-15.

particular, under the Toxic Substances Control Act (TSCA) the US EPA defines and regulates nanomaterials as chemical substances (EPA, 2013). Under TSCA, chemical substances are regulated on the basis of their Chemical Abstract Service (CAS number), according to which materials are differentiated on the basis of their chemical composition and not their size (Hansen et al. 2013). A similar approach, as we shall see later, is followed by the EU system as well. This approach ignores the fact that certain physico-chemical properties of nanomaterials, as well as their size and shape may lead them to behave differently from their bulk counterparts (RS-RAE, 2004; Hansen et al. 2013; Blaunstein et al. 2014). Under this approach the nanoscale and the bulk versions of a material have the same CAS number, which means that, for instance, bulk silver and nanosilver, or CNTs and carbon black could be included under the same registration, even though they have different chemical properties (Karkan et al. 2008). This in turn creates difficulties for "triggering regulatory oversight for nanoscale substances" (Hansen et al. 2013: 569), and opens the door for MNs to enter the market quicker (Blaunstein et al. 2014: 259).

However, to gather additional information for the purpose of regulatory review on existing chemicals manufactured at the nanoscale, EPA in accordance with Section 5 (a) (2) of the TSCA, has made use of its "significant new rule" (SNUR). So far this rule has been applied for single-walled CNTs and MWCTs (Matus et al. 2011; Bowman, 2014; Monica et al. 2014). In 2010 EPA submitted a proposal to the Office of Management and Budget (OMB) for establishing a revised general nano-related TSCA SNUR, that would apply to any nanoscale material and require manufacturers to submit SNUR data to EPA before the production of nanomaterials (EPA, 2012). As of October 2014, this proposal is still awaiting the approval of the OMB (Monica et al. 2014).

The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation in Europe is the main regulatory framework used in the EU to ensure the protection of human health and environment in relation to nanomaterials (Breggin et al. 2009). To fulfil this aim, REACH has introduced the precautionary approach and pursuant to Article 5 it prohibits the manufacture or sale of any chemical substance in the EU that is not registered with the European Chemical Agency (ECHA) (Monica et al. 2014). However, REACH does not distinguish between "new" and "existing" chemical substances. Instead, it has created a regime for the registration of all substances based on the volume of the chemical substance that is produced, imported or manufactured (Bowman, 2007; Bowman et al. 2010; Monica et al. 2014). Under REACH manufacturers, producers or importers are required to provide toxicological data and requirements only when the production or imported volumes exceed the threshold of 1 tonne per year of substance. A chemical safety report is provided when the produced or imported volumes exceed 10 tonnes of substance (Bergkamp, 2013). In this way, given that nanomaterials are produced/imported in much lower quantities there has been many controversies about the application of these volumetric criteria to nanomaterials (Breggin et al. 2009; Hansen et al. 2013). Due to concerns about the CNTs in 2008 the European Commission (following the regulatory review of REACH) decided to amend Annex IV in REACH to remove carbon and graphite from being excluded from registration (Breggin et al. 2009). There has been also many discussions on how REACH can be modified to regulate nanomaterials specifically, and the European Parliament has still to vote on whether nanospecific amendments will be included to REACH Regulation (Bowman, 2014).

Another issue relates to the categorization of nano-enabled products. In particular, under the current regulatory frameworks, products such as consumer, pharmaceutical or food, are regulated based on the product type they are (for example food or cosmetics are regulated differently than cleaning products) (Jaspers, 2011). However, given that many nano-enabled products cross boundaries, the categorization of products in this way may be difficult. For example nano-enabled products can be both cosmetics and food (e.g. nanosilver can be used as a cleaning products, personal care product, cosmetics, dietary and/or food supplement) (Breggin et al. 2009; Jaspers, 2011).

Finally, regulators struggle to keep pace with the rapid technological change[9] and uncertainties related to future commercialization paths of nano-related products (Breggin et al. 2009; Sayes and Santamaria, 2014). Whereas current regulatory frameworks focus mainly on "passive" nanomaterials, the complexity of nano-enabled products is likely to increase by involving "active" nanomaterials.[10] These materials have the potential to converge with other technologies (such as information and bio technologies) and create many borderline products (e.g. cosmeceuticals and nutricosmetics),[11] which put into question not only the traditional

[9] Ludlow et al. (2009) argue that the lag of regulatory response to (new) technological developments is not unique to nanotechnologies, with this problem being observed in relation to other technologies as well.

[10] Active nanomaterials are those materials that respond actively to the changes in the environment in order to produce the desired effects. These changes may come as a result of exposure to light, presence of certain biological molecules or mechanical force. For example, nanostructured coatings used in insulate buildings, in a certain temperature can change from heat-absorbing to heat-reflecting. Passive nanomaterials are those materials that do not respond to changes in the external environment. In this case a nanomaterial is added to an ordinary material to improve its performance or functions. This, for example, includes CNTs, silver nanoparticles and so forth, that may add functionality to products due to their physico-chemical characteristics.
See also: Wajert, S., 2009. New Report from Project on Emerging Technologies, *available at*: http://www.masstortdefense.com/2009/05/articles/new-report-from-project-on-emerging-nanotechnologies/; International Dialogue on Responsible Research and Development of Nanotechnology (IRGC)., 2007. Policy Brief: Nanotechnology Risk Governance, Recommendations for a Global, Coordinated Approach to the Governance of Potential Risks.

[11] These products may for instance combine cosmetic products with pharmaceuticals. See also: Falkner, R. and Jaspers , N. 2009. *Anticipating Nanotechnology Risk: Can the US and EU Develop Internationally Harmonized Governance Approach*. Paper presented at the 2009 Annual Convention of the International Studies Association, New York City, 15-18 February.

categorization of products, but also the ability of regulators to develop responses that can respond to this changing technological environment (Breggin et al. 2009; Bowman, 2008a). Furthermore, rapid commercialization of nano-enabled products leads to many uncertainties about the future commercialization paths of these products. According to Breggin et al. (2009), as the scope of complex nano-enabled products expands, new and unknown hazards may emerge which will pose further challenges for regulators to address and assess the risks associated with these materials (see also Faunce et al. 2014).

Authors such as Ludlow et al. (2007) have discussed and summarized a set of uncertainties, which in their view, impact the appropriateness of existing regulatory frameworks to cope with the rapid advancements and the potential risks of nanotechnologies.[12] In particular, Ludlow and her colleagues (2007: 92-94) have identified six horizontal triggers that may "fail to fire" for nanotechnologies:

(1) uncertainty as to whether an existing substance being re-engineered at the nanoscale should be considered an "existing" or "new" substance for regulatory oversight;
(2) inappropriate weight and volume thresholds underpinning regulatory frameworks;
(3) deficiencies in current knowledge regarding the presence (or implications of presence) of nanomaterials in the products that are assessed and approved for entry into the market;
(4) specific gaps relevant to research and development exemptions for those working with nanomaterials;
(5) reliance on existing risk assessment protocols or conventional technique, which may or may not be appropriate for nanomaterials; and/or
(6) reliance on international documents within national regulatory frameworks, that may or may not reflect the current state of the art.

The regulatory uncertainties, EHS concerns related to nanomaterials, but also the rapid commercialization of nano-enabled products, produce also many challenges for industrial actors (as well as their investors, consumers and insurers) (Monica et al. 2014). Industrial actors are increasingly getting involved in making, selling or distributing products incorporating MNs (Monica et al. 2014). Of major concerns are how to ensure worker and environmental safety, develop safer nano-enabled products, ensure valid IP claims on nanomaterials, as well as safe commercialization of nano-related products (Monica et al. 2014; Bell and Marrapese, 2011). According to Monica et al. (2014:270), nanotechnology businesses may face several interrelated

[12] Similar observations have been conducted also by Chaudhry et al.(2006) and Breggin et al. (2009). See: Chaudhry, Q., Blackburn, J., Floyd, P., et al. 2006. Final Report: A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies. Defra, London; Breggin Breggin,L., Falkner,R., Jaspers,N.,Pendergrass, J., and Porter, R., 2009. *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation Report*. Chatham House, London.

legal issues during each stage of the product life cycle, such as for example: IP legal issues associated with difficulties to fulfill the patentability criteria[13], liability for the potential injuries caused to an employer working with nanomaterials (workplace and occupational liability), liability for the risks (reasonable and unreasonable) of injury associated with a consumer product (consumer product safety), liability to instruct a consumer about the danger presented by a product and/or ensure that the product does not depart from its intended design and injures someone (product liability), as well as liability to ensure consistency and/or compliance with (specific) legal provisions that may apply to some nanomaterials (environmental, food and drug regulation including also the environmental contamination of potentially harmful materials) (Monica et al. 2014; Barpujari, 2010). Whereas these issues, as Monica et al. (2014) argue, may not be unique to nanotechnologies, it is unusual that industrial actors face so many legal issues all at once throughout the product life-cycle.

In sum, the complexities and uncertainties accompanying nanotechnologies, have brought many challenges to industry, policy makers and regulators that "dwarf those encountered [for instance] in information [technology] and biotechnology" (Jaspers, 2011: 97).

The debate on how to embrace nanotechnology developments continues among policy makers, while the public and private sectors have voiced fears of the potential for under - and - overregulation. Such concerns are not unique to nanotechnologies (Ludlow et al. 2009), with this "pacing problem" between technological development and regulatory response having been observed in relation to other emergent technologies as well (Marchant et al. 2011). Both US and EU key bodies including, for example, the US Executive Office of the President (Holdren et al. 2011) and the European Commission (EC, 2008) claim that the existing regulations covering chemicals and materials, such as REACH[14] in EU and TSCA in US are adequate to deal with nanotechnologies (see also Hansen et al. 2013). The rider for some policy makers has been the evolving state of the art, with the acknowledgement that such positions may need to be reassessed in light of conclusive scientific evidence that demonstrates harm on a case-by-case basis and justifies new "evidence-based" regulations (Holdren et al. 2011: 5).

[13] The main patentability criteria are: novelty, utility and non-obviousness. The main issues with nanomaterials, it to determine whether they are new or existing materials; whether nanomaterials are new or involve a new composition of a substance or is it only the nanoscale form of the existing matter (see Monica et al. 2014). Furthermore, the lack of uniformity to characterize materials creates many difficulties for the inventors to delineate ownership interests. This in turn, has created many issues for legal practitioners as well, who face many difficulties to identify the scope of the patent and assess the validity of the patent claims (see Bell and Marrapese, 2011).

[14] Although the EU Commission has still not decided about the mandatory registry of nanomaterials at the EU level, there have been several debates on how REACH could be modified to regulate nanomaterials. In addition to this, the EU Parliament and Council has also enacted the EU Novel Food Regulation (*Regulation (EU) No. 1169/2011*), which includes a number of nanospecific provisions including specific labelling requirements (see: European Commission (EC)., 2013. *Regulation of the European Parliament and of the Council: On Novel Food.* COM (2013) 894 Final.

However, some countries have begun to tweak their existing regulatory frameworks. In relation to new industrial nanomaterials, several tentative responses have been observed in jurisdictions such as France (FMD, 2012), Australia (Australian Government, 2010) and California (William et al. 2011), which have moved to set specific requirements for some materials. The European Parliament and Council have adopted more wholesale approaches with the introduction of nano-specific provisions for cosmetics as part of the recast of the Cosmetic Regulation (Bowman et al. 2010; Bowman, 2014).[15] The vast majority of countries, on the other hand, have opted to retain the regulatory status quo (Stokes and Bowman, 2012). For example, countries such as China, the US, the EU, but also the Organization for Economic Co-operation and Development (OECD), have proposed to treat nanomaterials within the existing regulatory frameworks covering their conventional chemical counterparts (OECD, 2013; Hansen et al. 2013). This is not surprising given the evolving state of the scientific art and the uncertainties that surround so many facets of the technology.

Whereas consensus amongst regulators and policy makers on the most appropriate regulatory response remains elusive, at the other spectrum of the regulatory continuum we see the development and implementation of alternative non-sanction-based (or soft) regulatory mechanisms, which refer to "rules of conduct that are laid down in instruments which have not been attributed legally binding force as such, but nevertheless may have certain (indirect) legal [regulatory] effects, and that are aimed at and may produce practical effects" (Senden, 2004: 112).[16] Such mechanisms in the field of nanotechnologies involve various forms of self-regulation, voluntary regulation as well as hybrid regulation, which have emerged to address the regulatory and scientific challenges posed by these technologies (Bowman, 2014; Bowman and Hodge, 2009; Christoph and Widmer, 2010; Hull, 2010; Medley et al. 2007; Malloy, 2012; Weidl et al. 2010).[17]

[15] In July 2013 the EU Cosmetic Regulation (1223/2009) entered in force, which replaced the previous EU legislation on cosmetics (the cosmetic directive 76/68/EEC and the subsequent 67 amendments). It also provides for a higher protection of human health especially on consumer products that use nanomaterials. The new regulation requires from the industry to label all ingredients that are nanomaterials, notify the EC prior to placing the product to the market, and assess the safety of cosmetic products with a specific focus on nanomaterials. See also : http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1223

[16] Soft law may be produced and enforced both by non-state actors and state actors. Public organizations (regulators) may deploy a set of soft law instruments such as action plans, recommendations, communications and guidelines. Private organizations may also use a wide range of soft law instruments, such as guidelines, codes of conduct and standards. As argued by Dorbeck-Jung and Amerom (2008 : 133), soft law can be found in all stages of the regulatory cycle, and may have an important role in preparing the ground for hard law and/or contributing to the interpretation of the hard law.

[17] In the field of nanotechnology, we can observe how the drive towards responsible nanotechnology regulation has led to the emergence of industry-lead codes of conduct (Bowman and Hodge, 2009; Christoph and Widmer, 2010; Malloy, 2012), risk management frameworks or systems (Hull, 2010; Medley et al. 2007; Weidl et al. 2010), and overarching governance frameworks (Renn and Grobe, 2010) developed around and beyond the state level to assist in the responsible development and introduction of nanotechnology into commerce.

Self-regulation "extends regulatory authority beyond the state to include civil society and nonstate actors" (Vogel, 2006: 5). Even though these regulatory mechanisms are mostly dominated by private actors rather than governmental (state) actors, yet they enable state actors to have some level of involvement (Bowman and Hodge, 2008). Self-regulation in most cases is voluntary (Levi-Faur and Comaneshter, 2007). Voluntary regulation includes " a broad category of social and human behaviour in which regulatory compliance is not imposed […] but is based on the choice and the institutional design of the regulatees" (Levi-Faur and Comaneshter, 2007: 156). Hybrid regulatory developments are more complex forms of regulation that build on "the use of a panoply of tools and actors, formal and informal, governmental and nongovernmental" (NRC, 2001: 200). In these way, these developments rest on varied forms of hybridism, that involve combining different actors, strategies and institutions to act on different components of a governance framework (Levi-Faur, 2010). As such, hybrid regulatory developments may include different forms of multi-level regulation, meta regulation, enforced self-regulation and co-regulation[18] (Levi-Faur, 2010; Bowman and Hodge, 2008).

Levi-Faur and Comaneshter (2007) comment on these developments arguing that the absence of a prescriptive state action has provided an opportunity for other actors to engage in a "responsive regulation approach" to the technology. To them, responsive regulation provides "an alternative to command and control and legalistic, prescriptive regulation", and relies on the role of nonstate actors "to nurtur[e] the regulatory regime and encourag[e] sustained compliance" (Levi-Faur and Comaneshter, 2007: 155&162). Scholars often use the term "governance arrangement" to describe these soft regulatory mechanisms that "influence the interaction of various actors in pursuing common goals" (Koenig-Archibugi, 2002:50). In this way, the concept of regulation has broadened to include not only the "rules" made by the government through legislation (Black, 2002), but also the "rules" set by industry and civil society that cover various disciplines and sectors, and include activities that expand beyond the state (Hodge et al. 2009:4). In other words, as Brownsword (2010: 64) argues, regulation refers to "any instrument (legal or non-legal in its character, governmental or non-governmental in its source, direct or indirect in its operation, and so on) that is designed to channel behaviour". In the following I will also use the term "governance arrangements" when discussing about these developments.

A wide range of soft governance arrangements have emerged in the regulatory field of nanotechnologies. For instance, at national level we can observe governmental and non-

[18] For a comprehensive view on these terms see : Faur, D and Comaneshter, H., 2007. The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology, *in* Hodge, G.A., Bowman, D. M., and Ludlow, K.(Eds.), *New Global Frontiers in Regulation: The Age of Nanotechnology,* Edward Elgar Publishing: UK & US (pp.157-159).

governmental (e.g. NGOs) actors such as the Department for Environment, Food and Rural Affairs (DEFRA) in UK, the US EPA, as well as Friends of the Earth (FoE) in Australia. Amongst the main objectives of these arrangements have been to develop "voluntary reporting schemes" or "stewardship programs" to gather scientific data (from the manufacturers and importers of manufactured nanoscale materials) on the characteristics, toxicity and eco(toxity) of MNs, and assist regulators with developing appropriate risk management frameworks for nanoscale materials (Bowman and Hodge, 2009). FoE has also been actively involved in discussions about the capacity of governments to cope with the challenges of nanotechnologies, and have voiced for the prohibition of using nanomaterials in the food sector until nano-technology specific safety laws are established (Miller and Senjen, 2008; Miller and Scrinis, 2010).

Similar non-legally-binding initiatives have also been initiated by private actors, such as for example the *Responsible NanoCode* in UK (developed by four partners - the Royal Society, Insight Investment, the Nanotechnology Industries Association and the Nanotechnology Knowledge Transfer Network); BASF in Germany (which developed the *Code of Conduct for Nanotechnology*); DuPont-Environmental Defense in the US (which developed the *NanoRisk Framework*). The main objectives of these developments have been (amongst others) to develop "in-house" innovative regulatory mechanisms that govern the manufacture of nanoproducts, manage occupational, health and safety risks associated with the development of nanotechnology across all lifecycle phases, and ensure the responsible development, production, use and disposal of nanoscale materials (e.g. BASF *NanoCode*; DuPont *NanoRisk Framework*).

There have been several initiatives taken at the European level as well. For instance, the European Commission (EC) voluntary *Code of Conduct for Responsible Nanoscience and Nanotechnologies Research* - invites Member States to foster their collaboration with industry, research organizations and civil society, and provide a "tangible contribution to the good governance of nanotechnology" (EC, 2007:2). In 2005 the European Committee for Standardization (CEN) set up a Technical Committee on Nanotechnologies (i.e. TC 352) to develop consensus standards related to broader issues of nanotechnologies, such as terminology and nomenclature, metrology and instrumentation, specifications for reference materials, test methodologies, as well as science-based health, safety and environmental practices (British Standards Institution (BSI), 2007).

However, some commentators have been highly critical with the operation of some of these arrangements (e.g. the DEFRA and EPA voluntary reporting schemes), noting that even though they are voluntary in nature they have failed to make a positive impact in practice, resulting in a low number of submission (or the lack of buy-in) from relevant organizations and stakeholders (Bowman and Hodge, 2007; Dorbeck-Jung and Amerom, 2008; EPA, 2007; Hansen et at. 2013). Other arrangements (e.g. the EC Code of Conduct) have also been criticized by some scholars for failing to promote trust-building amongst key stakeholders, disseminate their activities effectively and raise awareness about the potential benefits of implementing these arrangements (Dorbeck- Jung and Shelley-Egan, 2013; Mantovani et al. 2009). Furthermore, the global significance of issues accompanying nanotechnologies (e.g. scientific, regulatory and socio - environmental), the evolvement of the new generations of nanomaterials, the rapid pace of the commercialization of nano-enabled products, as well as the potential of MNs to cross national boundaries are amongst the key factors which pose further challenges for these arrangements to deal with nanotechnologies (Abbott et al. 2010; Falkner and Jaspers, 2012). In this regard, Abbott et al. (2010: 528) indicate that the regulation of nanotechnologies may come to "present a new paradigm for regulation in the twenty-first century - regulation that is proactive, global and capable of adapting to rapidly changing conditions". Therefore, many scholars have been arguing that a transnational approach to addressing scientific uncertainties, knowledge gaps but also the regulatory challenges posed by nanotechnologies, may be more promising (Abbott et al. 2010; Breggin et al. 2009; Falkner and Jaspers, 2012).

In this way, besides governance arrangements established at the national and European level, governance arrangements have been initiated at the transnational level as well (i.e. transnational governance arrangements (TGAs)) to contribute to the regulatory debates of nanotechnologies. By the term "transnational" I refer to "non-territorial policy making or interactions that cross national-borders at levels other than sovereign to sovereign" (Hallström and Boström, 2010:2; Hale and Held, 2011:4). The involvement of multiple actors (e.g. governmental, industrial, civil society actors), knowledgeable experts and epistemic communities in one regulatory setting are considered the key elements that shape the governing authority of TGAs (Abbott and Snidal, 2009; Black, 2008; Börzel and Risse, 2005; Ruggie, 2014; Quack, 2010). As such these arrangements are expected to foster collaboration amongst various actors and also develop transnational harmonized approaches related to safety, social, economic and ethical aspects of nanotechnologies (Abbott et al. 2010 & 2012; Bowman, 2014).

Transnational governance arrangements are also considered to provide voluntary rules or guidelines that are grounded in practical experience and technical expertise (Quack, 2010: 6; Willke, 2007: 33). Due to these components, but also to the flexible character that these rules and guidelines have (i.e. ability to respond to demands for frequent change) they are expected to respond quickly to the evolving scientific, knowledge and market dynamics of nanotechnologies

(Bowman and Hodge, 2009; Dorbeck-Jung, 2011; Christoph and Widmer, 2010; Hallström, 2004), and enable (continuous) regulatory experimentation and adjustments to new insights into nanotechnological developments and risks (Dorbeck-Jung and Amerom, 2008 : 134). Because of these characteristics, TGAs are considered as innovative solutions that are able to respond regulatory challenges of nanotechnologies, as well as to the rapid changes and uncertainties that accompany these technologies (Breggin et al. 2009; Mantovani et al. 2009). However, TGAs bring also many challenges and questions forward. These challenges are discussed in more details in Section 1.3.

1.3. Transnational Governance Arrangements

I use the term TGA to refer to a set of rules/mechanisms within an institutional setting that influence the interaction between various actors (state and non-state actors not bounded by territorial borders) to achieve/pursue common policy goals. TGAs are horizontally structured, relatively institutionalized and bring together actors from around the world to present distinct decisional levels (e.g. national, European or international), share information and/or best practices, and harmonize rules and procedures (Cadman, 2012; Homkes, 2011; Koenig-Archibugi, 2006; Ruggie, 2014). With these arrangements the focus is shifted from pure state-based regulatory approaches that are founded on the governmental institutions of the nation-states, to hybrid public-private regulatory approaches that are not necessarily defined with a particular nation-state, but are approached from a functional, problem solving point of view (Cadman 2009: 17; Benz and Papadopoulos, 2006; Hachez and Wouters, 2011).[19]

Many scholars associate the development of governance arrangements beyond the state level with the concepts of “de-governmentalization” (Benz and Papadopoulos,2006; Bäckstrand, 2007; Risse, 2006), “shifts in governance” (Papadopoulos, 2011) or “contemporary governance” (Cadman, 2012). Others relate these developments with the concept of “informal international law making”, which refers to the informal *actors*, *processes* and *outcomes* characterizing these new governance arrangements as compared to the traditional ones (Pauwelyn, 2012; Wessel, 2011). A wide range of actors (including for example transnational corporations, civil society or other non-state actors) participate in these arrangements not because of their national interests, but mainly because they have an interests to solve a particular issue (e.g. an economic or societal issue) that spans across territorial borders (e.g. international coalitions of consumers,

[19] Scott et al.(2011) argue that transnational governance no longer refers to international treaties or arrangements established solely through the cooperation of nation states. According to Hale and Hel (2011:5) - these arrangements cannot be considered global either, since they do not refer to the transborder interactions that include or claim representation of the entire world.

workers, business associations or other interests) (Pauwelyn et al. 2014: 10). In these arrangements, consensus is most often the key mechanism of decision-making. This implies that they focus primarily on promoting cooperation, and exchanging knowledge and scientific data amongst various experts (Adler and Pouliot, 2011; Risse, 2006; Seabrooke, 2013; Pauwelyn et al. 2014). In this way, TGAs take away the veto or the opting-out power (a mechanism which is highly practiced in traditional international law making) for any given actor and focus on the "thick consensus" of stakeholders (Pauwelyn et al. 2014 : 21). The main outcomes of TGAs are consensus-based protocols, testing and reporting schemes and other voluntary measures in the form of standards. Due to their general flexibility and expert-driven quality these outcomes are considered among many researchers/commentators, to be highly important on filling the current scientific and regulatory gaps, as well as ensuring knowledge diffusion and access of new technologies to global markets (Forsberg, 2010; Quack, 2010; EC, 2008c).

There are various TGAs that have been initiated to contribute to the regulatory debates of nanotechnologies. To begin with, OECD has created the Working Party on Manufactured Nanomaterials (WPMN) where regulatory officials (from both EU and US), industrial actors (i.e. coming from the Business and Industry Advisory Committee (BIAC)), as well as other actors representing trade unions, EU and NGOs (nongovernmental organizations), meet regularly to set find "globally oriented solutions for the challenges posed by [MNs]" (Bowman, 2014: 325). OECD/WPMN does not have regulatory authority (nor does it aim to), rather it serves as a center for international collaboration and policy dialogue, by promoting "international cooperation in human health and environmental safety-related aspects of [MNs], to assist in the development of rigorous safety evaluation of nanomaterials" (OECD, 2008: 3), and building "communities of practice that promote information sharing and harmonization" (Abbott et al. 2012: 291; Falkner and Jaspers, 2012). To achieve these aims OECD/WPMN has created eight projects, amongst which are also projects related to the safety testing and assessment of a set of MNs and the creation of a database on MNs to inform and analyse EHS activities (OECD, 2012a). Recently, OECD/WPMN has also recommended that the existing approaches for the testing and assessment of traditional chemicals are in general adequate for assessing the safety of nanomaterials and only on some cases they may have to be adapted to the specificities of nanomaterials (OECD, 2013). This recommendation, as Bowman (2014) argues, "signifies a substantial progress in the field" (p.326), guiding therefore relevant actors how to proceed with testing nanomaterials. The recommendation has already been endorsed by the Canadian government (Government of Canada, 2014).

The International Standardization Organization (ISO) has also established a Technical Committee working on specific nanotechnology standardization programme (i.e.TC 229). It has created several working groups (WGs) that aim to set international standards to facilitate the exchange of goods and services, and create a smooth transition from the laboratory to the marketplace. This arrangement is dominated mostly by industrial actors, but is also opened to actors coming from the government, consumer associations, trade unions, governmental and regulatory bodies, NGOs, and academia. The WGs of the TC 229 set international voluntary standards to support industrial and governmental needs, and help address the safety aspects of nanotechnologies, by developing :

a) uniform terminology and nomenclature for nanotechnologies;
b) test methods for detecting, identifying and characterizing nanoscale materials and devices;
c) risk assessment tools and occupational protocols relevant to nanotechnologies;
d) protocols for bio and eco (toxity) testing; protocols for evaluating exposure (dermal, nasal, oral, pulmonary) to nanomaterials; and/or
e) nanoscale devices as well as the whole life cycle assessment of nanoscale materials, devices and products, and so forth (ISO, 2012; Hatto, 2010).

The WGs of the TC 229 has set several standards and other deliverables, some of which have been implemented in practice.

Both OECD and ISO have proposed a range of voluntary initiatives, including the development of industry guidelines, risk management frameworks and standards to guide the responsible and commercially successful development of nanotechnologies. These governance arrangements are commonly cited as the most important transnational arrangements, which are working to provide convergent approaches and nano-specific regulatory responses in order to deal with the scientific and the social risks associated with nanotechnologies (Breggin et al. 2009; Jaspers, 2011).

In addition, there are other public-private and private governance arrangements in which nanotechnologies are discussed. These arrangements are mostly focused on a specific sector (e.g. nanomaterial safety) and have led to a range of specific projects, workshops or dialogues. For instance, the International Council on Nanotechnology (ICON), the International Risk Governance Council (IRGC) and the International Cooperation on Cosmetic Regulations (ICCR), provide forums of debate at transnational level on issues related to risk and regulatory governance of nanotechnologies. Other intergovernmental initiatives that seek to contribute to nanotechnology related safety issues and foster the cooperation of scientists, policy-makers and industrial actors are based on the United Nations (UN) and the World Health Organization

(WHO) processes. Such initiatives include UNIDO the United Nations Industrial Development Organization's International Centre for Science and High Technology (UNIDO) and the WHO's Intergovernmental Forum on Chemical Safety (IFCS) (Breggin et al. 2009; Falkner and Jaspers, 2012).

The value and the potential of these arrangements to the regulatory governance of nanotechnologies has been acknowledged in various reports (e.g. Breggin et al. 2009; Davies, 2006; Mantovani et al. 2009& 2010; Hansen et al. 2013; Renn and Rocco, 2006), policy documents (e.g. EC, 2007a; EC, 2008a; EC, 2008c; EC, 2011) and scholarly debates (e.g. Abbott and Snidal, 2009; Abbott et al. 2010; Bowman and Hodge, 2009; Bowman, 2014; Blind and Gauch, 2009; Falkner and Jaspers, 2012; Miles, 2007; Meili and Widmer, 2010; Marchant and Sylvester, 2006).

For instance, the *White Paper on Nanotechnology Risk Governance* emphasizes that the setting of international standards, guidelines and best practices provide a step forward to establish effective and unified frameworks through which regulators, policy makers and private sector stakeholders (such as business actors) can address the uncertainties and the potential risks related to nanomaterials (Renn and Roco, 2006). As mentioned earlier, some of these arrangements (e.g. ISO) provide standards that aim to clarify terminology, measurement and testing methods or provide data reporting programs to share information of the testing of specific MNs (e.g. OECD). These deliverables can be deployed by the government to inform their decision making (Bowman, 2014), but also by industry to inform risk management activities and produce and/or market safe nano-enabled products (Hansen et al. 2014; Bowman, 2014). Furthermore, TGAs are often expected to foster cooperation amongst a wide range of actors across borders, share regulatory and scientific expertise, and coordinate their approaches for addressing technological and regulatory uncertainties and challenges (Abott et al. 2010 & 2012). In other words, as Marchant and Sylvester (2006) frame it: "transnational regulation not only provides an opportunity to cabin potential risks, it also promises to speed research, share regulatory expertise and resources, and avoid potential "nano divide" in which more advanced nations widen their existing technological and regulatory advantage over more impoverished nations" (p.717). Certainly, TGAs do not guarantee these results, as their ability to reach their fullest potential depends on how they overcome and/or manage with the challenges that are mentioned in below.

TGAs are accompanied by many challenges. To begin with, transnationalization has changed four dimensions of regulatory activities, such as: who is regulating, the mode of regulation, the nature of rules and compliance mechanisms (Djelic and Andersson, 2008: 377).

TGAs shift away from the traditional command-and-control regulatory approaches according to which the nation-state is the sole legitimate source of authority, with exclusive powers to make collective binding decisions and provide for public goods (Papadopoulos, 2011). As indicated earlier, decision-making in these arrangements most commonly involves a multitude of actors from, for example, different agencies, private enterprises, NGOs, research institutes, laboratories, environmental and consumer organizations, who contribute to the formulation and implementation of certain policy goals in areas of limited statehood (Abbott and Snidal, 2009; Brühl, 2006; Christiano, 2004; Curtin and Senden, 2011; Delbrück, 2003; Mörth, 2006; Papadopoulos, 2011).

The dispersion of the collective decision-making authority has consequently put pressure on the traditional state-centric conceptions of constitutional, accountable and democratic governance (e.g. Benz and Papadopoulos, 2006; Black, 2008; Scott et al. 2011; Papadopoulos, 2011; Hachez and Wouters, 2011). Furthermore, in the absence of the democratic institutions of the nation state and the global *demos* at the transnational level, many scholars have questioned, amongst others, the ability of TGAs to ensure the effective inclusion and representation of industrial, economic, regulatory and social interests at transnational level (see for example Buchanan and Keohane, 2006; Brühl, 2006; Curtin and Senden, 2011; Scott et al. 2011; Papadopoulos, 2011; Forsberg, 2012; Quack, 2010). As such, TGAs often are considered to provide the "hard case" for legitimacy (Black, 2008: 138). They raise many questions over the clear lines of accountability, stakeholder representation, roots of decision-making and reasons for social acceptability.

1.4. The Issue of Legitimacy and Transnational Governance Arrangements

The traditional concepts of legitimacy have been discussed in the narrow context of the state, according to which citizens refer to government institutions and accept their rules because of the belief that such rules are morally valid, and derive from appropriate and legally constituted governmental authority (Benz and Papadopoulos, 2006; Bernstein, 2004). These institutions are expected to justify their actions while being directly accountable to citizens through democratic means. However, TGAs build on non-hierarchical relationships and shift from the political system of representative democracy (Benz and Papadopoulos, 2006). Such arrangements are not established (or are less likely established) through legal mandates nor involve the components of parliamentary representation. As such, the use of vote or elections as the ultimate instrument of public participation and control to regulator's actions become elusive (Hachez and Wouters, 2011). Decision-making authority in TGAs is generally held by non-elected representatives including those drawn from laboratories, the private sector and academia (Delbrück, 2003; Hahn and Weidtman, 2012; Thatcher and Sweet, 2011). At this point, who selects these experts, and to whom they are accountable, are important questions from the viewpoint of legitimacy that must be asked. Questions must also be asked in relation to the various interests they aim to represent, the technical optimality of their decisions to their stakeholder constituencies and their ability to influence other parties, including governments, to implement their rules (Kica and Bowman, 2013).

Legitimacy in the context of transnational governance is a multidimensional concept with various meanings and interpretations. For many scholars of international law, political science and transnational governance, the concept of legitimacy associates with the ability of the transnational arrangements to exercise power or govern. An important element here is the recognition that a governance arrangement has a moral standing and authority to govern (e.g. Beetham, 1991; Bodansky, 2011; Black, 2008; Buchanan and Keohane, 2006). However, for many others legitimacy is an empirical question (e.g. Weber, 1978; Beishem and Dingwerth, 2008; Cadman, 2011; Take, 2012). A question that relates to how transnational arrangements come to enjoy acceptance by relevant actors or whether they are perceived as legitimate and effective to solve certain regulatory problems.

The focus of this thesis is on answering empirical questions of legitimacy in the context of nanotechnology transnational governance arrangements. The study in this thesis is exploratory and I assess legitimacy through the perceptions of stakeholders (n = 76). The perceptions of stakeholders are used to understand legitimacy in practice, by conducting empirical analysis through quantitative research methods such as opinion surveys (undertaken by using *LimeSurvey* - an open online survey application). There are several reasons that justify the need to explore the legitimacy of TGAs related to nanotechnologies. To begin with, even though these arrangements have not replaced the sovereignty of the nation-state, this thesis argues that they have the potential to complement the conventional national and international institutions, and become a precondition for entry into (certain) markets and/or regulatory processes. The analogy with other regulatory fields teaches us that these non-legally-binding arrangements can highly influence the behaviour of a wide range of actors (including those that are not involved in the setting of transnational rules) (Pauwelyn et al. 2014; Picciotto, 2011; Cadman, 2012; Werle and Iversen,2006; Hallström and Boström,2010). Some examples that can be mentioned here are the International Conference of Harmonization (ICH) standards for setting harmonized certification requirements for pharmaceuticals, the international standards of the Basel Committee for the regulation of financial and monetary matters, as well as the food safety standards developed under the Codex Alimentarius Commission (CAC) (e.g. Abbot and Snidal, 2010; Barr and Miller, 2006; Dorbeck-Jung, 2008; Picciotto, 2011).

The example of the EU Commission *New Approach* Directives illustrates also the importance of soft arrangements in regulation. The Directives lay down a list of "essential requirements" (e.g. protection of health and safety) that certain products[20] must meet before they are placed in the market. However, in order for the industrial actors or other stakeholders to fulfill these requirements they must comply with the European harmonized technical standards developed by the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI). These standards provide a set of technical specifications that guide compliance with the "essential requirements". As such, conformity with these harmonized standards creates a presumption of conformity with the essential obligations provided under the Directives (EC, 2000).

Similar developments we see in the field of nanotechnologies as well, with many commentators supporting, for example, the development of ISO technical standards as key deliverables that can support international trade, regulatory policies and/or legislation by providing common vocabularies for nanotechnologies as well as specific information with regards to risk assessment, occupational safety and different test methods for use at the nano scale (e.g. EC, 2008b; EC, 2011; Breggin et al. 2009; Forsberg, 2010 & 2012; Schepel, 2005; Murashov and Howard, 2011; Miles, 2007).

In 2010 the EU Commission issued a mandate (M461) to the European Standardization Bodies (ESOs) - i.e., CEN, CENELEC and ETSI - to develop European standards related to the characterization and toxicity testing of the nanomaterials, as well as to occupational handling and exposure. An important element of M461 Mandate is that the EC requests the ESOs to develop and adopt European standards in support of the European policies and legislations, by taking into account, and giving priority to, the existing ISO standards (EC, 2008a). In the Mandate nanotechnology standardization is viewed as "a means to accompany the introduction on the market of nanotechnologies and nanomaterials, […] and to facilitate the implementation of regulation" (EC, 2008a: 1).

The role of these voluntary transnational arrangements has become also very important within the law of the World Trade Organization (WTO) (for example the Technical Barriers to

[20] The New Approach Directives cover a wide range of sectors, including : toys; personal protective equipment; low votage electrical equipment; medical devices; chemicals; machinery; equipment and protective systems intended for use in potentially explosive atmospheres and different quality control instruments (EC, 2000: 59).

Trade Agreement (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS)) (Schepel, 2005; Picciotto, 2011). For instance, international standards acquire a prominent role in the WTO through the provisions of the TBT (e.g. Article 2.4) and SPS Agreement (e.g. Article 3.1).[21] The WTO's TBT and SPS Agreements require that member states use international standards[22] or relevant parts thereof (where they exist or are imminent) as a basis for their technical regulation, unless they are ineffective for the fulfillment of legitimate objectives that are pursued (Ababouch et al. 2005; Picciotto, 2011). In this way, these agreements have actually converted voluntary standards, into obligations for the WTO member states (Picciotto, 2011). Both the TBT and SPS Agreements are aware of the differences between countries, and thus they encourage the promotion of international harmonization of trade through standards, as an opportunity to reduce the emergence of non-tariff barriers that may result by following various rules (Bell and Marrapese, 2011). Therefore, even though voluntary in nature, standards may assume a quasi-legal status because of their use as references in legislative instruments (Egan, 2005: 55). They can be used as "benchmarks for judging compliance with the provisions of the [TBT and/or SPS] agreement[s]" (Ababouch et al. 2005: 6). In this way, the soft nature of these arrangements does not mean that they cannot become constraining through other routes.[23]

By looking at the objectives of nanotechnology standards we can also observe that they aim to set non-binding rules that are accepted and followed voluntary by relevant parties. However, if these standards are adopted by national regulators or endorsed by various stakeholders (both at the national and international level), they may become a necessary precondition for entry into certain regulatory and/or market processes. Therefore, such deliverables have a high potential of becoming *de facto* or collectively binding (Egan, 2005).

In addition, as indicated in Section 1.3 some TGAs, such as TC 229, have been working intensively in providing common vocabularies for nanotechnologies, which may assist both

[21]Article 2.4. of the TBT Agreeement requires that: "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them [..] as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued". Article 3.1. of the SPS Agreement indicates that: "[…] members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement" (See: WTO, Uruguay Round Agreement: Agreement on Technical Barriers to Trade).

[22] With regards to the use of international standards, the TBT Agreement indicates that such standards can be set by any organization which is open for membership to all member states of the WTO. The SPS Agreeement is more specific in this regard, indicating that WTO members base their national measures on international standards developed by the Codex Alimentarius Commission (CAC) as well as other bodies which may be recognized by the SPS Committee (see: Picciotto, S., 2011.*Regulating Global Corporate Capitalism*. Cambridge University Press, UK. (pp. 299-342).

[23] Other organizations such as the OECD, Asia-Pacific Economic Cooperation (APEC) and the Southern Common Market (MERCOSUR), also encourage the use of international standards as a mechanism for fostering trade within their member countries (see Bell and Marrapese, 2011).

business actors in their commercial activities and regulators as they try to configure a regulatory response to technical innovations (Bell and Marrapese, 2011: 241). Some TGAs have been highly engaged on setting voluntary mechanisms that aim to contribute to the health, safety and responsible technology developments. By providing (amongst others) specific information with regards to risk assessment, occupational safety and different test methods for use at the nano scale, these TGAs may in fact be used as tools for regulating technological innovation, satisfy a particular (technical, scientific or regulatory) need and/or fill a communication gap (Hatto, 2010; ISO, 2007; Bell and Marrapese, 2011; Hansen et al. 2013).[24]

One of the driving forces in the emergence of the TGAs has been the idea that these arrangements have technical capacity and knowledgeable people with specialized competence (referred by many scholars as *scientific legitimacy*) (Carrier, 2011; Hallström, 2004; Weingart, 2008). However, as these arrangements have chosen to act in such a complex field and cover sensitive issues, such as health, environmental and occupational safety, they cannot exert influence and acceptability without displaying some degree of legitimacy. The potential of these arrangements to satisfy a specific government or policy need and/or serve as tools for regulating innovation in such a challenging field such as nanotechnologies, gives rise to important theoretical and political concerns of legitimacy. They need to justify why compliance with their outcomes is important and why they are suitable arrangements to fulfil the tasks with which current regulatory frameworks are struggling. In other words, the success of transnational and private governance arrangements is highly dependent on " the voluntary cooperation [that they manage to ensure with] rule-addressees and the legitimacy [they generate] from within in order to enforce their rules" (Take, 2012:500).

However, whereas the potential of TGAs and their outcomes has been widely recognized in nanotechnologies (e.g. Abbott and Snidal, 2009; Bowman and Hodge, 2009; Bowman, 2014; Blind and Gauch, 2009; Breggin et al. 2009; Falkner and Jaspers, 2012; Miles, 2007; Meili and Widmer, 2010; Marchant and Sylvester, 2006; Marchant et al. 2012), little attention is paid to the issue of legitimacy (e.g. Abbott et al. 2010 & 2012; Delemarle and Throne-Holst, 2012; Forsberg 2010 & 2012; Thoreau, 2011). In particular, little attention is paid to the actors involved, the processes by which the outcomes of the nanotechnology TGAs are negotiated and developed, as well as the conditions under which these arrangements can gain the support of the relevant stakeholders in the field.

[24] Examples from other sectors serve also as a case in point to emphasize the role of international standards for instance in filling a communication gap or satisfying a particular legal requirement. For example, ISO 14000 on environmental management, have played a crucial role in assisting companies to meet the requirement of an environmental compliance program. The success of this standard has actually led many regulatory authorities in US and EU to view the standard as a useful compliance assistance tool (Bell and Marrapese, 2011).

This thesis aims to provide a better understanding on the legitimacy of technology related TGAs, by providing detailed analysis on how the legitimacy of these developments can be described and evaluated in practice. My focus is mainly on the legitimacy of transnational private governance arrangements (TPGAs), with ISO/TC229 being the central transnational private body in the field of nanotechnologies. TPGAs in this thesis refer to a set of mechanisms within an institutional setting that influence the cross-border cooperation between private non-state actors to achieve non-binding policy goals, with or without the participation of public authorities. In this study I have identified several attributes that explain the potential of TC 229 to contribute to the nanotechnology regulatory governance as compared to other TGAs. These attributes relate to the :

- *degree of institutionalization* (simply put between low, medium and high level of institutionalization);
- the *stages of the regulatory process* that the arrangements address (between agenda-setting, negotiations, implementation, monitoring and enforcement);
- the *functions of the governance arrangement* (information sharing, capacity building, coordination, rule-setting and implementation);
- *the normative scope* (between narrow and broad), and
- *substantive depth* (between significant constraints and excessive flexibility) of transnational outcomes/rules.

TPGAs, and TC 229 in particular, provide an ideal focus for this study since they depart from the state-based approaches and challenge the traditional principles for evaluating legitimacy (e.g. national sovereignty, constitutionality, democracy). Furthermore, TPGAs involve a wide range of non-state actors from around the world, build on highly qualified experts, and set non-binding rules that can highly influence the interests of the public and industry. Judgements about the legitimacy of a TPGA, such as TC 229, have distinctive practical implications. Standards are usually voluntary agreements that focus on the design/ performance of a specific product (e.g. the characteristics that a product should have, including size, shape and their impact to environment) or on the production methods/process (e.g. life-cycle analysis, risk assessment, health and safety principles; work organization methods) or on services (e.g. standards that define the procedure for performing a service) (Egan, 2005; Hallström and Boström, 2010).

In the literature, international standards are considered to lead to many positive effects, such facilitating market transactions, promoting market information and confidence as well as effective commercial decisions by signaling product quality and/or compatibility (Brunsson and Jacobsson, 2005; Hallström and Boström, 2010; Tamm and Hallström, 2004). Moreover, because of the knowledge developed by epistemic communities[25] (Hallström and Boström, 2010), and cooperation with a wide range of actors (e.g. manufacturers, traders, consumers, users) (Tamm and Hallström, 2004), standards are also described as the best solution from a technical point of view (Brunsson and Jacobsson, 2005; Tam and Hallström, 2004: 25; Haas, 1992; Murphy and Yates, 2009). In this way, international standards have often been referenced as the most appropriate solutions for policy and technical issues,[26] supporting therefore regulatory work in different sectors (e.g. in medical devices, road vehicles, railways, food products etc) (ISO, 2007; Bell and Marrapese, 2011).

Given the current regulatory and scientific uncertainties surrounding nanotechnologies, international standardization in this field is of crucial importance. TC 229 has given priority to developing horizontal standards, which "provide foundational support across all sectors that use nanotechnologies or nanomaterials" (ISO, 2012; Hatto and MacLachlan, 2010). Bell and Marrapese (2011) argue that the work of ISO "can be viewed as an 'advanced guard', assembling the collective knowledge of experts from around the world and making it available for immediate application" (p.245). In the business plan it is indicated that a critical task for TC 229 is to :

> "develop standards for terminology, nomenclature, metrology and characterization [that] will support research, commercialization and trade in materials and products at the nanoscale, stimulating growth through the commonality of metrics and terminology. These standards will also support the development of appropriate national and international regulatory regimes, including guidance documents, in the fields of occupational and environmental health and safety" (ISO, 2012: 3).

As such, ISO nanotechnology standards have a high potential in guiding the future market developments, supporting regulation and setting the "conceptual foundation for science and technology development" (Forsberg, 2012: 5).

However, given that nanotechnology international standards are developing at a stage when the technology has not achieved maturity yet and are operating in parallel to many other TGAs, legitimacy takes on an additional importance. Whereas the provisions of different standardization outcomes may justify the existence of TC 229, it does not mean that it will also legitimate its authority. According to Hurd (2007:65), authority refers to "the relationship that exists between a legitimized rule or institution and its audience". Therefore, the ability of TC 229 to perform its functions, may largely depend on whether those to whom the Committee

[25]According to Haas (1992:3) an epistemic community denotes "a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge".

[26] When regulatory authorities decide to reference a standard in the legal text to support their technical regulation they may decide either to reference them "directly by using their identification number or title", or by "registering standards as an information source external to the regulatory text" (ISO, 2007).

addresses its standards agree that this institution and its standards are worthy of support. The perception of legitimacy matters because, in such a controversial, competitive and challenging regulatory and scientific environment in which nanotechnologies are developing, TC 229 can only thrive if it is viewed and accepted as legitimate by relevant stakeholders. In fact, as Forsberg (2012) argues, when speaking about ISO as a governance player in the field of nanotechnologies it is hard to avoid issues of legitimacy. ISO provides an excellent laboratory for "probing a host of issues related to concepts of concerns to political scientists [including those of] legitimacy" (Risse, 2004: 1; Forsberg, 2012).

In addition, the voluntary nature of the TC 229 standards means that they lack the traditional enforcement capacities (or means of coercion) associated with sovereign state actions (Bernstein and Cashore, 2007). Even though TC 229 in some cases has argued that it does not claim a right to primacy in some issues (such as in definition for nano) and that its rules are voluntary in nature, it is important to note that the Committee does represent a "sizeable stakeholder constituency" that are involved extensively on setting standards for this technology (Hatto, 2010a:17). Furthermore, even though nanotechnology standards are voluntary, ISO is the only international standards development body that is recognized by the WTO.[27] These components combined with the recognized position that ISO has globally, may lead one to assume that besides their voluntary nature, TC 229 standards have the potential to impact significantly regulation, industry and commerce (Bell and Marrapese, 2011).

Nanotechnology standards cannot be viewed as purely technical, since they may also involve conflicting interests. Such conflicts, as Forsberg argues, may arise not only for standards for EHS, but also for basic terminological issues (Forsberg, 2012; FoE, 2008). For instance, terminological standards may bring forward many questions such as: " [Whether] we speak about nano objects, substances or nanomaterials? What [could be] the legal, regulatory, labelling and ethical consequences of these terms […]? [How such terminological choices could impact the decisions made on metrology (at the WG2 of the TC 229)] or the EHS recommendations produced at WG3" (Forsberg, 2012: 11-12). There seems to be much more consensus on the lower limits of nanoscale materials (i.e. one nanometre), but many conflicts still remain about the suggested upper limit (of 100 nanometre) (SCENIHR, 2010). In particular, the main debate

[27] The former Director General of the World Trade Organization, Pascal Lamy, considered the relationship of the WTO with ISO vital. In his view international standards are crucial for the international trade, because "if, at the technical level, countries speak a different language, the opportunities for the WTO to maintain an open, equitable and non-discriminatory multilateral trading system [may disappear]". Furthermore, he argued that if "regulatory agencies don't trust the quality or safety of each others products, they may not allow trade to take place" (see ISO., 2011. Pascal Lamy cites "vital relationship" between WTO and ISO. ISO News, 21 September 2011, *available at*: http://www.iso.org/iso/home/news_index/news_archive/news.htm?refid=Ref1463).

is that nanomaterials can form agglomerates composed of nano scale particles which keep their properties, but the size of the agglomerates may be above 100 nm (Throne-Holst and Rip, 2011).

In this regard, FoE Australia (2008) have argued that nanomaterials above 100 nm may have similar toxic and physiological effects as nanomaterials below 100 nm (see also Miller and Senjen 2008; Lövestam et al. 2010). According to FoE Australia (2008: 2) :

> "the size range within which the ISO has defined nanoparticles will have significant implications for health and safety regulation at a national level […] Particles that fall outside the size range deemed to encompass nanoparticles - even if they are not much bigger and also exhibit novel, nano-specific behaviour - will not be assessed as new chemicals. These particles will not trigger new health and safety assessments where substances have previously been approved for use in larger particle form"

Assuming that the international harmonization for the definition of nanomaterials or nanotechnologies will be achieved, ISO definition[28] may have many implications for consumers, workers and the environment, which may not be equally protected from the harm of [other] particles that exhibit nano-characteristics (Forsberg, 2012; FoE, 2008). Furthermore, this could also have policy implications, with regulators making decisions on whether to modify the existing EHS regulatory systems (by incorporating or using international consensus-based standards) to better manage with the novel properties and risks of nanomaterials (Bell and Marrapese, 2011; FoE, 2008; Throne-Holst and Rip, 2011).

What this example tells us is that nanotechnology standardization is not straightforward and it involves a wide range of conflicting interests. The arguments that standardization bodies use technical expert knowledge may be necessary, but not sufficient conditions for ISO (and TC 229 specifically) to justify why others should follow its standards (e.g. Egan, 2005; Hallström and Boström; Forsberg, 2012). The potential of nanotechnology standards to set the "framework in regulation and market" makes the issue of legitimacy very important, but also adds to the responsibility of both the "ISO and the adopters (at least when they are public decision makers)" to ensure that nanotechnology standardization and standards are legitimate (Forsberg, 2012: 7).

1.5. Analyzing the Legitimacy of TPGAs : Research Problem and Argument

Since Max Weber's seminal writing on *"Economy and Society"*, the notion of legitimacy has puzzled social scientists and legal scholars (e.g. Beetham, 1991; Black, 2008; Bovens, 2007; Caffaggi, 2010; Djelic and Sahlin-Andersson, 2006; Habermas, 1979 & 1988; Luhmann, 2004;

[28] Nanoparticles has been defined by the ISO (ISO/TS 27687) as "particles having three external dimensions between 1 and 100 nanometre" (see Hansen et al. 2013: 564).

Jayasuriya, 2005; Scott et al. 2011; Scharpf, 1999; Schmidt, 2010; Schepel, 2005; Steffek, 2003; Suchman, 1995; Teubner, 1997; Trubek et al. 2006). While legal scholars have focused on a right to rule based on formal law ('legality'), social scientists have paid attention mainly to the questions of whether citizens believe that political decision-making is morally authoritative and whether they therefore accept the governmental acts (e.g. Black, 2008; Mayntz, 2010; Schmidt, 2010; Thatcher and Sweet, 2011; Papadopoulos, 2011). With the European integration and the emergence of TPGAs, the focus of the political science debate shifted to the debates on the "democratic deficit" and the appropriateness of the normative standards of legitimacy for transnational arrangements (e.g. ISO; Internet Corporation for Assigned Names and Numbers (ICANN); International Accounting Standards Board (IASB)) (Black, 2008; Bodansky, 2011; Dingwerth, 2007; Mayntz, 2010; Schmidt, 2010; Koppell, 2005; Weinberg, 2000). TPGAs are regarded as deficient mainly because they do not follow the traditional rules on international law making. In these arrangements, private actors and experts are involved who are lacking electoral legitimation and are not democratically accountable (Black, 2008; Mayntz, 2010; Schmidt, 2010; Thatcher and Sweet, 2011).

In technology regulation research,[29] legitimacy issues have been raised by few scholars (e.g. Brownsword, 2009; Chango, 2011; Dorbeck-Jung, 2008; Take, 2012; Forsberg, 2010 & 2012; Hahn and Weidtman, 2012; Vos, 1999; Vos and Everson, 2009; Koppell, 2005; Weinberg, 2000). The limited body of literature includes normative accounts of legitimacy and several empirical studies on the legitimacy of the European and international health and safety regulation (Take, 2012; Vos, 1999; Vos and Everson, 2009), and transnational standardization bodies (Dorbeck-Jung, 2008; Forsberg, 2010; Hahn and Weidtman, 2012; Kica and Bowman, 2012 & 2013; Wood, 2009). Although these accounts offer valuable insights with regard to transnational legitimacy debates, this thesis argues that the conceptualization of legitimacy they propose is often too narrow.

Regarding the normative accounts of legitimacy, in the current debates we can observe two main strands. On the one hand, the European research and innovation policy, associate the concepts of legitimacy with the broader participation of stakeholders in science, technology and responsible innovation (DG Research, 2009; EC, 2008b; EC, 2011; Von Schomberg, 2011). In addition, scholars of deliberative risk management associate legitimacy with the integration of various interests and values in risk regulatory decision-making process (Renn, 1999; Renn and

[29] Technology regulation here refers to the "study of how technologies are or should be regulated". According to Koops the concept of technology regulation has two elements: *technology* - which refers to "the broad range of tools […] that people use to change or adapt to their environment" and *regulation* - which is considered as "an instrument for influencing someone's behaviour" (Koops, 2010: 311). See Koops, B.J., 2010. Ten Dimensions of Technology Regulation - Finding Your Bearings in the Research Space of an Emerging Discipline, *In* M.E.A. Goodwin et al.(Eds), *Dimensions of Technology Regulation* (Nijmegen: WLP), pp. 309-324.

Roco, 2006). On the other hand, many scholars pay attention to legitimacy aspects of regulatory expertise and problem solving capacity of regulators (Esty, 2006; Hodge et al. 2010; Majone, 1999). They focus on the robustness of scientific expertise (Carrier, 2011; Forsberg, 2012; Weingart, 2008), and the trustworthiness of experts (Cutler, 2010; Funtowicz and Strand, 2011; Jasanoff, 2003; Lövbrand et al. 2011; Take, 2012; Quack, 2010). Therefore, these scholars have provided various norms of legitimacy, which are crucial to guiding the functioning of governance arrangements to achieve socially desirable outcomes at the transnational level. However, in these studies it is still unclear whether these norms provide sufficient basis for determining the legitimacy of TPGAs related to technology regulation. What the authors miss in these studies are the attempts to operationalize and specify the content of these norms of legitimacy in a more detailed way. This thesis is an attempt to address this gap on the legitimacy of TPGAs in the context of nanotechnologies.

The study in this thesis is exploratory and aims to provide a basis for examining the legitimacy of technology related TPGAs through a systematic discussion on how legitimacy can be conceptualized at the transnational level and what this concept entails.

The groundwork for the empirical legitimacy research was set by Weber (1978). When Weber speaks of a “chance of obedience” he touches on empirical questions. Empirical issues are about how legitimacy is experienced in practice and to which social action this experience leads. Current empirical studies on transnational technology regulation, and more specifically on nanotechnology transnational regulation, focus mostly on assessing the mechanisms that various institutions use to build legitimacy. For instance, various scholars have tried to assess how TC 229 performs against a set of legitimacy norms (e.g. transparency, accountability, participation, etc) and to determine the possibilities for this TPGA to ensure compliance with its outcomes (Forsberg 2010 & 2012; Kica and Bowman, 2012 & 2013; Thoreau, 2011). Political scientists, as well as scholars of international relations (IR) and transnational governance, have been long arguing that expert and private bodies seem to enjoy higher reputation and acceptance. In their view, higher reputation and acceptance come due to the ability of these bodies to utilize the expertise of a wide range of actors in the decision-making process (Sinclair, 1997; Forsberg, 2012; Quack, 2010), reflect the state-of-the-art of the scientific-technical knowledge (Arts and Kerwer, 2007), or achieve a “thick consensus” amongst stakeholders (Pauwelyn et al. 2014). Others suggest that there is a direct correlation between the legitimacy of the processes by which decisions are made in relevant arrangements and the acceptance of transnational outcomes (Bodansky, 2011; Buchanan and Keohane, 2006; Hurd, 2008; Meyer, 2009). However, these studies do not provide sufficient empirical support for their suggestions.

Until now there have been no serious efforts to study the legitimacy of TPGAs related to nanotechnology regulation empirically - for example through opinion surveys on how stakeholders perceive legitimacy in practice, on whether they accept technology regulation or why this is not the case.[30] This thesis addresses these questions through the development of a legitimacy framework and a matrix suitable for evaluating the legitimacy of nanotechnology related TPGAs in practice, as well as other TPGAs related to technology regulation.

In this thesis I apply the legitimacy framework in the evaluation of the legitimacy of TC 229 - in an attempt to examine, through opinion surveys, whether this arrangement is considered legitimate amongst stakeholders. This thesis provides an empirical investigation and evaluation of the perceptions of stakeholders on how they rate the legitimacy performance of TC 229 in terms of the key legitimacy norms[31] and performance indicators[32] that guide the functioning of this arrangement. To understand the perceptions of stakeholders I use quantitative descriptive statistical analysis. The key legitimacy norms identified in this study are: *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes.*

For each legitimacy norm I have identified certain performance indicators, such as:

- *inclusiveness*, *representation*, *resources* - (indicators for *meaningful participation*);
- *participatory decision-making*, *comprehensive agreements*, *communicative agreements*, *effective dispute settlement* - (indicators for *deliberative decision-making*);
- *transparency*, *internal accountability*, *external accountability*, *domestic accountability* - (indicators for *effective process control*);
- *competent expertise*, *robustness*, *scientific validity*, *objective judgments* - (indicators for *trustworthy expertise*); and

[30] Some of the empirical studies worth mentioning with regards to the legitimacy of technology related TPGAs are: Egyedi, M.T., 1996. Shaping Standardization: A Study Of Standards Processes and Standards Policies in the Field of Telematic Services, PhD Thesis; The study of Ingo Take (2012) - on the legitimacy of governance arrangements related to internet regulation (i.e., ICANN, ITU and the WSIS) - is also one of the few studies that provides empirical analysis on stakeholder perceptions on the legitimacy of TPGAs related to technology regulation. However, this is a qualitative interview study with the representatives of these institutions and lacks detailed quantitative analysis on the extent to which stakeholder believe that legitimacy norms are followed in practice and accept a governance arrangement as legitimate.

[31] Legitimacy norms are an acceptable standard of behaviour shared by the members of the group. Norms act as a means of influencing the behaviour of the group members. According to Weber (1964), norms are "social actions that result from a commitment to social rules". See : Weber, M., 1964. *The Theory of Social and Economic Organization*. Edited by Talcott Parsons. New York: Free Press.

[32] Performance Indicators specify in details the content of the legitimacy norms and verify to what extent actions have been taken by relevant actors/institutions to comply with the norms of legitimacy. Indicators measure the performance of relevant actors/institutions in relation to legitimacy norms. See for similar observations: Gilley, B., 2006. The Determinants of State Legitimacy: Results for 72 Countries, *International Political Science Review* 27 (1), pp.47-71, and Cadman, T., 2012. *Quality and Legitimacy of Global Governance*. Palgrave Macmillan, US.

- *problem solving capacity*, *rule benefits*, *rule clarity* and *compliance* - (indicators for *implementable outcomes*).

These indicators serve as parameters for measuring compliance with legitimacy norms. In this thesis, I develop an evaluative matrix to assess the legitimacy performance of technology related TPGAs by using the norms and indicators identified above. Building on the perceptions of stakeholders on legitimacy, the thesis provides also recommendations on how the legitimacy of TC 229 can be enhanced in practice. Such recommendations are of crucial importance as they guide this TPGA, the policy makers and other governance arrangements with similar institutional structure on how to establish themselves as legitimate actors at transnational level.

1.6. Research Focus and Central Question

The primary research question addressed in this thesis is as follows:

❖ ***How can the legitimacy of transnational private governance arrangements related to nanotechnologies be described, evaluated and enhanced in practice?***

I answer the primary research question by breaking it down to four sub-research questions. The first step is to analyze the landscape of various TGAs and explain why certain arrangements have gained a leading role at the transnational level, what are their characteristics, sources of power and capacity to contribute to the regulatory governance of nanotechnology. Therefore, the first sub-research question is as follows:

➢ *What are the current transnational governance arrangements for nanotechnologies and how can we assess their role in regulating this field?*

As indicated in Section 1.5 it is of crucial importance to develop the concept of legitimacy and provide an operationalization of the key legitimacy norms. Both of these elements are essential to establish the analytical framework in this thesis, which will serve as a basis for evaluating the legitimacy of technology related TPGAs in practice. Therefore, the second sub-research question is as follows:

➢ *How can the legitimacy of transnational private governance arrangements be conceptualized and operationalized?*

Following this sub-research question, the next step is to apply the framework to our case study, and in particular, to assess the legitimacy of TC 229. I focus on the perceptions of stakeholders to understand how they perceive legitimacy in practice. I approach legitimacy as a concept that relates to the extent to which stakeholders accept TPGAs and their rules on the grounds that they:

- believe that the legitimacy norms, which guide TPGAs and promote the setting of transnational rules are effectively taken up in practice,
- perceive the outcomes of TPGAs to present effective regulatory solutions, and
- voluntary comply with these outcomes.

This brings up the third sub-research question:

➢ *To what extent is international nanotechnology standardization perceived as legitimate by stakeholders*?

As indicated earlier, the aim of this thesis is not only to provide a framework for evaluating legitimacy in practice and for understanding the perceptions of stakeholders, but also to provide recommendations for enhancing the legitimacy of international standards created for nanotechnologies. Therefore, the fourth sub-research question is as follows:

➢ *How can international nanotechnology standardization enhance its legitimacy?*

Taken together these four sub research-questions provide the basis for answering the main research question. These questions are addressed individually in the chapters of this thesis. The progress of this thesis consists of several steps. First, I provide an overview of the TGAs in the field of nanotechnologies. Second, I provide a framework for conceptualizing and evaluating the legitimacy of technology related TPGAs. Third, I develop the methodology for the case study and explain the research process. Fourth, I conduct the case study (i.e. TC 229) through document analysis and surveys with key stakeholders in the field. Finally, I reflect on the main findings and conclusions.

1.7. Structure of the Thesis

This thesis consists of six chapters. Whereas Chapter 1 provided the introduction to the problem, as well as research questions and objectives of the study, Chapter 2 addresses the first sub-research question. In that chapter, I start by reflecting on the key factors that have led to the emergence of TGAs in the field of nanotechnologies. Afterwards, I introduce a typology that categorizes governance arrangements on the basis of different attributes, such as the *actors involved*, the *degree of institutionalization*, the *regulatory process*, *functions*, as well as the *normative scope* and the *substantive depth* of transnational outcomes. I apply these attributes to describe the characteristics of various TGAs and determine the actions taken by these arrangements to contribute to the transnational debate of nanotechnology regulation. In this chapter I also explain why TPGAs (and more specifically why TC 229) seem to be better positioned to take a lead on the transnational regulatory governance of nanotechnology.

Chapter 3 addresses the second sub-research question. The chapter begins with a reflection on the main legitimacy challenges characterizing technology related TPGAs. Afterwards, the normative and empirical perspectives of legitimacy are discussed. Building upon the current stream of research on transnational legitimacy, I provide a framework for analyzing the legitimacy of technology related TPGAs in practice. To develop the analytical framework two major steps are followed :

a) first, I bring together the procedural and substantive norms of legitimacy, which guide TPGAs and provide the basis for their legitimacy, and

b) second, I define how the legitimacy of governance arrangements related to transnational technology regulation can be measured in practice by reconceptualizing the influential distinction between *input*, *throughput* and *output* legitimacy.

Furthermore, in this chapter I develop an evaluative matrix against which the legitimacy of TPGAs can be evaluated in practice.

Chapter 4 presents the research design and methods used in this study. In particular, I explain the key aspects that guided the constructing of this study, i.e., the research methods, data collection, as well as the recruitment and analytical strategy.

Chapter 5 presents the results of the case study (i.e. TC 229). It aims to respond to the third and the fourth sub-research questions. The chapter begins with an evaluation of the institution's performance and background, which is based merely on document analysis. Afterwards, I reflect on the perceptions of the stakeholders on the legitimacy of TC 229 following the analytical framework and the evaluative matrix developed in Chapter 3. The chapter provides a detailed investigation of stakeholders' perceptions on each performance indicator and provides some concluding observations on each legitimacy norm. The perceptions of stakeholders are measure by using a Likert scale ranked from 1 (very low) to 5 (very high) against each performance indicator identified in Chapter 3. This chapter reflects also on the main recommendations provided by stakeholders for enhancing the legitimacy of TC 229. The recommendations provided in this chapter are essential for this study, since they come from highly qualified experts in the field and can be taken up by TC 229 and by other governance arrangements, policy makers and other actors involved in transnational regulatory developments.

Chapter 6, the conclusion, highlights the main findings and contributions of this thesis, reflects on its limitations and discusses avenues for future research.

Chapter 2

2. Transnational Arrangements and the Governance of Nanotechnologies [33]

2.1. Introduction

In this chapter I address the first sub-research question: *What are the current transnational governance arrangements for nanotechnologies and how can we assess their role in regulating this field?* In Section 2.2, I discuss the factors that have contributed to the emergence of TGAs and emphasizes why these arrangements are considered appropriate to respond to the nanotechnology regulatory challenges. In Section 2.3, I introduce a typology according to which governance arrangements are categorized on the basis of *actors involved*, as well as the *functions* and *regulatory stages* in which TGAs contribute. The main argument in this section is that TGAs can be characterized not only by these attributes, but also by their *degree of institutionalization*, as well as the *normative* and *substantive depth* of transnational outcomes.

In Section 2.4, I discuss the role[34] of several transnational nanotechnology governance arrangements, which provide key forums of debate at transnational level and contribute to establishing informal coordination mechanisms. In particular, my focus is on five key TGAs, such as TC 229, OECD/WPMN, IFCS, IRGC and ICON. These arrangements have displayed well-defined strategies to develop voluntary mechanisms that are relevant to the governance of nanotechnologies. There has been no formal delegation for these arrangements to contribute to the field of nanotechnologies or set norms which can serve as reference points. However, all of them have managed to establish internal mandates by securing resources and collaboration with influential stakeholders and experts in the field. As a result, the contribute of these arrangements to the governance of nanotechnologies has been acknowledged in various reports (e.g. Breggin

[33] A previous version of this chapter was presented at the 5th Biennial ECPR Standing Group for Regulatory Governance Conference on "Regulatory Governance: between Global and Local", June 2014, Institut Barcelona d'Estudis Internacionals (IBEI) in Barcelona. Parts of this chapter are also published at: Bowman, D., Stokes, E and Rip, A., 2014, *Embedding and Governing New Technologies: A Regulatory, Ethical & Societal Perspective*, Pan Stanford Publishing, Singapore.

[34] The role of TGAs to the regulatory governance of nanotechnologies is approached by taking a more comprehensive approach. In particular, the role of these arrangements is determined by looking at more than one attribute and includes the *actors involved* in governance arrangements, their *functions*, the *regulatory stages* in which governance arrangements contribute, their *degree of institutionalization*, as well as the *normative scope* and the *substantive depth* of transnational outcomes.

et al. 2009; Davies, 2006; Mantovani et al. 2009& 2010; Hansen et al. 2013; Renn and Rocco, 2006), policy documents (e.g. EC, 2007a; EC, 2008a; EC, 2008c; EC, 2011) and scholarly debates (e.g. Abbott and Snidal, 2009; Abbott et al. 2010; Bowman and Hodge, 2009; Bowman, 2014; Blind and Gauch, 2009; Falkner and Jaspers, 2012; Miles, 2007; Meili and Widmer, 2010; Marchant and Sylvester, 2006). In the last sections of this chapter I compare the actions taken by these TGAs to contribute to the transnational debate of nanotechnology governance (i.e. Section 2.5), and provide some concluding remarks (Section 2.6).

2.2. The Transnationalization of Nanotechnology Governance

There appears to be a general consensus amongst scholars that the internationalization of markets, as well as the emergence of transnational communication networks and new technologies have challenged the ability of national governments to define and provide public goods (Knill and Lehmkuhl, 2002). Hence, the creation of new forms of governance arrangements has been steadily increasing in part as a result of the limitations of the command and control regulation (Handl, 2012). The proliferation of TGAs in the field of nanotechnologies can be related to several political, regulatory and technological factors.

First, as indicated in Chapter 1 (see Section 1.1) over the last few decades nanotechnologies have emerged as a new transformative force in industrial society, covering a broad range of applications in chemicals, pharmaceuticals, electronics, energy, goods and cosmetics (Breggin et al. 2009). Therefore, these emerging technologies have attracted the attention of a wide range of actors coming from regulatory, civil society and business organizations whose activities span beyond national borders (Abbott et al. 2010; Mantovani et al. 2010). Nanotechnologies have also attracted a diverse range of skilled scientists,[35] who contribute to the creation of new products/services and advice for any innovation in this field.. As a result, nanotechnology governance has become highly exposed to the direct influence of non-state actors (Abbot et al. 2012; Breggin et al. 2009).

Second, the research, manufacturing, use and commerce of nanotechnologies are all global in nature (Abbot et al. 2010; Abbot et al. 2010; Marchant et al. 2012). The experience with other technology developments on genetically modified organisms (GMOs) and regulatory issues associated with asbestos, have led to many debates on how to develop appropriate and congruent governance frameworks for nanotechnologies (Bonny, 2003; Forsberg, 2012; Vogel, 2006). Furthermore, the case of GMOs emphasize clearly the challenges and issues that may arise when products that may be traded internationally face a patchwork set of national rules and

[35] Most of these scientists have expertise in physics, chemistry, biology, information technology, toxicology, engineering and materials science.

regulations (Marchant et al. 2012).[36] Given that nanotechnologies are so new and still have not achieved their maturity, Abbot et al. (2010 : 528) argue that it is not necessary to "superimpose [transnational regulatory developments such as] international standards [for example] onto a lattice of diverse, pre-existing national rules". There are many considerations that support a transnational approach to the regulation of nanotechnologies. Abbott and other colleagues (2010:539-541) argue that a transnational approach to nanotechnology regulation can contribute to providing better opportunities for dialogue and learning by which harmonized regulatory requirements could be established for product testing, risk assessment, reporting and labeling. Harmonized requirements would in turn assist producers, manufacturers and distributors to benefit throughout the product life-cycle, and regulators to avoid regulation that is "ill-informed or too stringent" (Abbott et al. 2010: 541). In addition, it will assist multinational companies at the supply, manufacturing, consumer and disposal stage to deal with environmental, occupational health and safety issues. A transnational approach to these issues can lead to uniform compliance requirements, product stewardship, worker training, occupational safety and reporting programs (Abbott et al. 2010; Bonny, 2003; Breggin et al. 2009; Falkner and Jaspers, 2012). Furthermore, the global reach of nanotechnology research and trade provide additional incentives for developing regulatory frameworks at transnational level, which are expected to facilitate commerce, underpin good industrial practice and avoid regional divide (Abbott and Snidal, 2009; Abbott et al.2010; Falkner and Jaspers, 2012).

Third, as mentioned thoroughly in Chapter 1 (see Section 1.1), whereas nanotechnologies are surrounded by great expectations, scientific evidence indicates that the ongoing expansion of nanotechnologies may lead to the production of novel nanostructures that cause unknown forms of hazard (Breggin et al. 2009:12). As emphasized in Section 1.2 regulators are facing many challenges and uncertainties about the adequacy of the existing risk assessment and management frameworks to define, characterize and assess the (potential) risks associated with nanotechnologies. The rapid pace of commercialization followed by the evolvement of new generations of nanomaterials pose additional challenges to the current regulatory frameworks to deal with emerging technologies (EPA, 2007). Regulatory systems are expected to face several challenges, which relate mainly to their ability to:

- deal with novel materials and uncertain risks;

[36] The various regulatory frameworks and standards used at the EU and US has created a wide range of problems, including restrictions on trade in products that were approved in some countries and not in others, as well as many conflicts with regards to the technical issues on the labelling of products containing GMO components (see: Marchant, E.G., Abbot, W.K., Sylvester, J.D and Gulley, M.L., 2012. Transnational New Governance and International Coordination of Nanotechnology Oversight, in Dana, A.D. (Eds), *The Nanotechnology Challenge: Creating Legal Institutions for Uncertain Risks*, Cambridge University Press : NY (pp.179-203)).

- anticipate and respond rapidly to the new and changing technological systems;
- develop frameworks that offer sufficient flexibility and adaptability;
- expand the scientific capacity to include a diversity of mixed experts from public and private sectors; and
- develop globally oriented information-gathering systems to cope with the globalization of nanotechnology (Davies, 2006).

Given the fundamental nature of these challenges and the inability of the individual states to tackle these issues effectively, many scholars urge for transnational coordination and cooperation (Abbott et al. 2010; Breggin et al. 2009; Cadman, 2011; Falkner and Jaspers, 2012; Forsberg, 2010).

Finally, over the last two decades, nanotechnologies have exploded from a purely technical field, into an arena that has to cope with constitutionally recognized interests also. The development of nanotechnologies involves issues related to health, environment, occupational safety, employment, scientific research, technological development, national security and so on (Dorbeck-Jung and Amerom, 2008:131). The potential of nanotechnologies to manipulate properties at the nano scale (i.e. making materials stronger, thinner, more elastic and so forth) has made these technologies to impact almost every industrial sector (Forsberg, 2012). However, the growing production and use of nanomaterials (in particular manufactured nanomaterials) may increase the potential of exposure for workers, consumers and environment (NRC, 2012). This has triggered representatives of various civil society and labor coalitions to become highly interested on the benefits and risks of nanomaterials, as well as on the regulatory responses addressing these issues (ETC, 2007; Mantovani et al. 2010). As a result, nanotechnologies have experienced an evolving political landscape, with many countries, national regulators, socio-environmental actors and international organizations, participating in voluntary (and often privately led) initiatives to promote the regulatory coordination of nanotechnologies (Abbott and Snidal, 2009; Abbot and Snidal, 2009a; Abbott et al. 2010; Kica and Bowman, 2012). These developments, I would argue, provide additional incentives for the emergence of TGAs. In the following section I provide a typology for understanding the characteristics and the potential of various governance arrangements at the transnational level.

2.3. Transnational Governance Arrangements Generally and Their Attributes

As indicated in the introductory chapter, TGAs are identified mostly as voluntary, informal and flexible arrangements beyond the nation state in which private actors are systematically engaged (Hallström and Boström, 2010; Homkes, 2011; Risse, 2006). These arrangements are largely horizontally structured and bring together actors from various sectors to share information, best practices and harmonize rules and procedures in order to pursue certain policy goals (Cadman, 2011; Homkes, 2011; Koenig-Archibugi, 2006; Ruggie, 2014). TGAs come in different forms at transnational level. Whereas there is no single characteristic that would distinguish TGAs from the traditional modes of governance, Pauwelyn (2012) indicates that new governance arrangements are characterized by:

1) *process informality* - (these arrangements build on the cross-border cooperation between public and private actors in a forum other than a traditional international organization);
2) *actor informality* - (these arrangements build upon the cooperation of actors other than traditional diplomatic actors (e.g. regulators or agencies))[37]; and
3) *output informality* - (these arrangements do not result in a formal treaty or legally enforceable commitment).

These characteristics come close to the characteristics of the transnational new forms of governance that Abbott and Snidal have discussed (2009:521). In their framing new forms of governance are fundamentally distinguished from old governance models by:

1) *differing roles of the state in regulation* - (in new governance the state is a significant player, it acts as a facilitator for supporting voluntary and cooperative programs, rather than as a top-down commander);
2) *decentralization of the regulatory authority* - (in new governance regulatory responsibilities are shared among different actors coming from the state agencies and private sectors);
3) *dispersed expertise* - (new governance seeks to harness the expertise of a wide range of actors, it looks beyond professional regulators and also seeks to incorporate those who may have ‘local’ expertise on relevant issues); and
4) *non-mandatory rules* - (new governance relies on flexible norms and voluntary rules).

In a similar vein, Börzel and Risse (2005:196) argue that the more we enter the realm of new modes of governance, the more we decentralize the regulatory authority, include non-hierarchical forms of steering and share the regulatory responsibilities between public and

[37] In is interesting to note that in these arrangements the governance contributions are not explicitly restricted to those actors whose organizational objective lies in the provision of certain public goals (e.g. regulators, humanitarian or environmental organizations). Rather, the authority of transnational governance arrangements might also emerge from various private actors, such as business associations, industry or multinational companies. See: Knill, Ch. and Lehmkuhl, D., 2002. Private Actors and the State: Internationalization and changing patterns of governance, *Governance* 5, p. 42.

private actors.[38] As a result, various forms of governance arrangements have emerged at transnational level encompassing different actors, modes of steering, processes and outcomes (Handl, 2012:6). Therefore, a typology of TGAs is important to understand their key features and their role to respond to regulatory issues (Andonova et al. 2009; Börzel and Risse, 2005).

Scholars have proposed various typologies painting the key features of TGAs. To begin with, Andonova and colleagues (2009) propose a typology according to which governance arrangements can be characterized on the basis of actors involved (*types of actors*) and *functions*. With regards to the *types of actors*, they argue that TGAs involve a variety of state and non-state actors that contribute different capacities and sources of authority. They distinguish between:

1) *private arrangements* - (established and managed by non-state actors);
2) *public arrangements* - (established by public actors acting independently from the state); and
3) *hybrid arrangements* - (established by public and private actors jointly).

However, the *types of actors* are considered as a necessary, but not a sufficient condition for distinguishing amongst transnational arrangements. The authors argue that these arrangements should be clustered also in terms of the *functions* that they can or do perform. In their framing, *functions* determine the resources and the power used within a particular arrangement to steer members to achieve certain goals (Andonova et al. 2009). In principle, the *functions* of the TGAs are divided into five categories:

1) *information sharing* - (arrangements that influence political and civil discourse through learning forums or collaborative events);
2) *capacity building* - (arrangements that provide resources or institutional support through fundraising campaigns or sponsorship);
3) *coordination* - (arrangements that coordinate state and non-state activities in a particular sector);
4) *rule-setting* - (arrangements that contribute to adopting international norms, regulations or standards that respond to respective regulatory problems); and
5) *implementation* - (arrangements that provide monitoring and service provision to enable action or implementation of national or international policy goals).

[38] Building upon the constellations of state and non-state actors to induce regulation at transnational level, Börzel and Risse (2005) distinguish four types of arrangements: *cooptation* (regular consultation and cooptation of private actors in international negotiation systems); *delegation* (delegation of state functions to private actors); *co-regulation* (co-regulation of public and private actors); *self-regulation* (private self-regulation in the shadow of hierarchy).

A different approach is taken by Abbott and Snidal (2009a), who propose the concept of a governance triangle to depict the involvement of various actors (i.e. states, firms and NGOs) in respective governance arrangements. Similar to the framework employed by Andonova et al. (2009), the typology of Abbott and Snidal focuses on rule-setting. These authors take a wider perspective and divide rule-setting (in the authors' words - the regulatory process of standard setting) into five distinct phases:

1) *agenda-setting* - (ability of the arrangement to place an issue on the regulatory agenda);
2) *negotiations* - (ability of the arrangement to draft and promulgate standards);
3) *implementation* - (ability of the arrangement to contribute to the implementation of the standards);
4) *monitoring* - (ability of the arrangement to monitor compliance)*;* and
5) *enforcement* - (ability of the arrangement to ensure effective compliance).

Their basic premise is that in order for the TGAs to succeed in the regulatory process they need a suite of competences, such as: independence from the targets of regulation, representativeness, expertise of several kinds and concrete operational capacity (including resources) (Abbot and Snidal, 2009a:66). However, since in the most cases single-actor schemes do not have all the necessary competences, the authors argue that collaboration with different types of actors is essential for these governance schemes to assemble the needed competences and act effectively in the regulatory process. According to their line of argumentation, the potential of TGAs can be understood by looking at the design choice of these arrangements - in particular at the relative input that states, NGOs and firms exercise in a respective arrangement and the actions taken by the TGAs to fulfill any competency deficit. Focusing on the regulatory standard setting schemes of pre – and – post –1985, the authors observe a shift from old to newly emerging multi-actor schemes, characterized by high level of decentralization and dispersed expertise (Abbott and Snidal, 2009a: 52-57). Whereas these characteristics make these arrangements better suited to address regulatory gaps at transnational level, the authors suggest that some form of "facilitative state orchestration" is important to reduce the bargaining problems between firms and NGOs to achieve socially desirable outcomes (Abbott and Snidal, 2009a: 88).

In addition to the *types of actors* and *functions*, Abbott and his colleagues (2012), Liese and Beishem (2011), Homkes (2011) and Martens (2007) suggest a typology for mapping TGAs based on the *level of institutionalization* and the *design choice*. In the view of Martens (2007) and Homkes (2011) these are the key factors driving the decision-making power of the governance arrangements. Martens (2007) notes that governance arrangements can be classified in *low*, *medium* and *high levels of institutionalization*. Whereas *high levels of institutionalization* refer to permanent multistakeholder institutions that have formal membership, firmly established governing bodies, institutionalized rules of decision-making, a secretariat and budget authority; *medium levels of institutionalization* refer to institutions that have a clearly defined membership, but not a separate legal status or formalized decision-making structures; and *low levels of institutionalization* refer to ad-hoc initiatives with narrowly defined objectives, no formalized membership or governing body. Scholars of transnational governance have also given increasing credence to the *regulatory design* - referring in particular to the stages of the regulatory process that the arrangement addresses, the relative precision of the rules (they frame this as *normative scope*), as well as the obligatory status of the transantional outcomes (they frame this as *substantive depth*) (Abbott et al. 2012; Liese and Beishem, 2011).

In this way, the typology of TGAs has become a complex and multidimensional phenomenon, which cannot be analyzed through one prism only (Djelic and Andersson, 2006). To assess the role of these arrangements in a regulatory governance one should understand how various attributes characterizing TGAs interact with each other and contribute to the efficiency of the arrangement (Abbott et al. 2012). Table 2.1 emphasizes the key attributes of the TGAs, which can be used to categorize them into various groups and assess their role in a structured way. In Section 2.4, I apply these attributes to understand the landscape and the role of current transnational governance arrangements in the regulatory governance of nanotechnology.

Table 2.1: The Key Attributes of Transnational Governance Arrangements

Actors Involved	***Functions***	***Regulatory Process***	***Degree of institutionalization***	***Normative Scope***	***Substantive Depth***
Public Actors (Single Actor Scheme)	Information sharing	Agenda-Setting	Low Level	Narrow	Significant constraints
Private Actors (Single Actor Scheme)	Capacity building	Negotiations	Medium Level	Broad	Excessive Flexibility
Public and Private Actors (Multi-Actor Scheme)	Coordination	Implementation	High Level		
	Rule-Setting	Monitoring			
	Implementation	Enforcement			

2.4 .The Governance of Nanotechnologies : A Typology of Transnational Governance Arrangements

Since the mid-2000, various TGAs have emerged to contribute to the regulatory debates of nanotechnologies. In the following I focus on five key arrangements and discuss their activities in the field of nanotechnologies.

2.4.1. ISO Technical Committee on Nanotechnology (ISO/TC229)

ISO commenced its work in 1947. It develops international standards with a view to "facilitating trade, spreading knowledge, disseminating innovative advances in technology, as well as sharing good management and conformity assessment practices" (ISO, 2011: 2). As of the beginning of 2014, ISO has a membership of 164 NSBs from several regions of the world and has developed over 19,000 standards.[39] These standards are expected to provide benefits for almost all sectors, such as "agriculture, engineering, construction, manufacturing, transport, medical devices, information and communication technologies, the environment, conformity assessment and services" (ISO, 2011: 2).

ISO moved in the arena of nanotechnologies relatively recently. With the increasing publication of divergent national documents by jurisdictions such as the US and EU member states, the need to establish standards for nanotechnologies at the international level became strikingly obvious at the turn of the century. However, this call was formalized in 2002 at a joint Versailles Project on Advanced Materials and Standards (VAMAS) and Advisory Committee of the European Committee for Standardization (CEN/STAR) Workshop on the Measurement Needs for Nano-Scale Materials and Devices. In articulating the need for international action, it was noted that there was "an overarching need for methods, standards, reference materials and guidelines in mechanical property determinations for the characterization of nano-scale materials and devices" to support science and research developments, as well as the commercialization of new devices and components (Rides, 2002: 2).

Despite this call to arms, the first formal proposals towards such international activities did not manifest until 2004 when experts from 25 countries and the EU met in Virginia for the "International Dialogue for Responsible Development of Nanotechnology" (IRGC, 2004). The event culminated in 12 recommendations, some of which related directly to standardization, including:

[39] See: *ISO Standards in Action, available at*: http://www.iso.org/iso/home/news_index/iso-in-action.htm.

> developing a nomenclature for engineered nanomaterials; developing measurement instruments; developing standardized risk assessment methods; promoting good practices with respect to risk assessment, human and environmental health and safety; developing guidelines and standards for risk assessment, production and handling, and commercialization of manufactured nanomaterials (EC, 2004).

The high level group clearly articulated the pressing need for the development of standards within the international community, which would be ideally implemented before the upscaling of commercial developments.[40] It can be argued that a key driver in the push for standardization was the recognition that for commercial success, standardization, and in particular, nanoscale measurement and instrumentation, was needed.

However, momentum for standardization was not evident until late 2004 when CEN established the Technical Management Board Working Group (BTWG166). The body was specifically charged with developing a strategy for nanotechnology standardization for the EU. BSI submitted a proposal for a new field of technical activity to the Secretariat of ISO TMB in January 2005. The proposal was approved by the Secretariat, with TC 229 being established in June 2005 to:

> "provide industry, research and regulators with a coherent set of robust and well-founded standards in the area of nanotechnologies […] whilst at the same time providing regulators, and society in general, with suitable and appropriate instruments for the evaluation of risk and the protection of health and the environment" (ISO, 2005: 2).

The official functioning of TC 229 however started in November 2005, with the first plenary meeting in London. The first plenary meeting focused on articulating the scope of TC 229, which was defined in relation to the standardization process as including either or both of the following:

1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications; and
2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties (ISO, 2005a).

[40] The main reason for this was basically to take early steps towards the development and international harmonization of nanotechnology standards and regulations, and to avoid what was seen to happen with asbestos and GMOs. See: European Commission., 2004. Nanotechnologies : A preliminary risk analysis on the basis of a workshop organized in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission 24-27, *available at* http://ec.europa.eu/health/ph_risk/documents/ev_20040301_en.pdf.*; See also:* Hatto, P., 2007. Nanotechnologies, ISO Focus*: Management of the International Organization, no.4.*

Functionality and the need to develop an institutional structure for TC 229 and Working Groups (WGs), as well as a strategic policy statement and the business plan, drove much of this first meeting. In the first plenary meeting of TC 229 consensus was reached on the establishment of three WGs working on:

1. *Terminology and Nomenclature* - WG1- develops uniform terminology and nomenclature for nanotechnologies to facilitate communication and promote common understanding ;
2. *Measurement and Characterization* - WG2 - develops measurement and characterization standards for use by industry in nanotechnology-based products; and
3. *Health, Safety and Environment* - WG3 - develops science-based standards that aim to promote occupational safety, consumer protection and environmental protection (ISO, 2012).

In December 2006, proposals for joining forces between TC 229 and the IEC/TC113 were made, resulting in the establishment of the Joint Working Group (JWG) 1 on *Terminology and Nomenclature* and JWG2 on *Measurement and Characterization*. Individual roadmaps for each WG were set, each of which was designed to contribute to the overall ISO/TC229 roadmap. On early 2008 a fourth WG on *Material Specifications* (WG4) was established to develop standards that specify relevant characteristics of engineered nanoscale materials for use in specific applications.

Other internal structures were also formed. These included a Chairman's Advisory Group (CAG), and the Planning and Coordination Task Group (PCTG) to coordinate leadership roles, titles and the scope of the WGs. CAG provides advice to the chair of the Committee and is composed by the permanent members comprising the Chairman and the Secretary, the WG convenors and secretaries, and the rotating members based on regions of the world. PCTG monitors the work program of TC 229 to ensure that it supports the roadmaps as approved by the TC. Other bodies involve the Nanotechnology *Liaison* Coordination Group (NLCG), which aims to harmonize the work of the relevant TCs and other organizations in the field of nanotechnologies. Nanotechnology and Sustainability Task Group (NSTG) reviews the opportunities for nanotechnologies to address issues in the sustainability arena (see Figure 2.1).

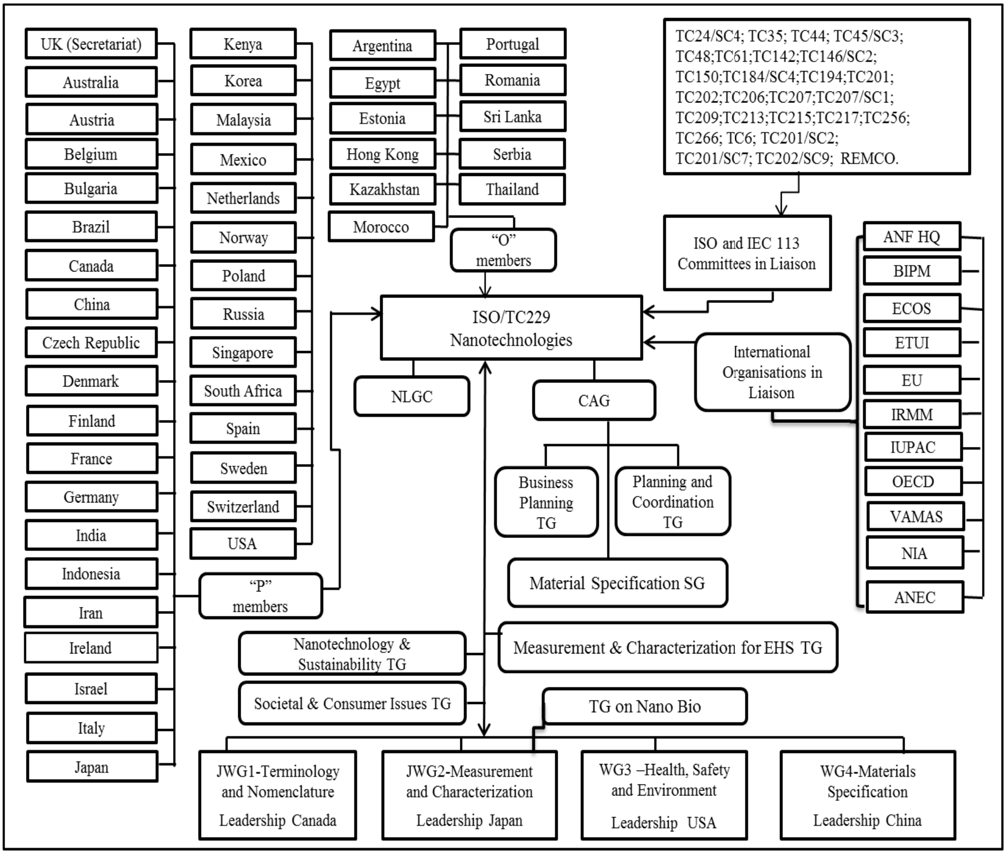
Working groups conduct the main work at TC 229 (ISO/IEC, 2012). Experts, who are individually appointed by a participating ISO member body, a *liaison* organization or both, carry out the main tasks within the WGs. Besides the central Secretariat leading the work of TC 229, each of the WGs has its secretaries and convenors who arrange the meetings and communicate important information to the participants. The inclusion of various WG with different aims and objectives, emphasizes that TC 229 has shifted the focus from working only on technical issues related to defining the size and concept of nanomaterials, to addressing broader aspects of the technology, such as risk management, health, environment and safety issues (Kica and Bowman, 2013). Furthermore, in 2011 TC 229 took a leading role to developing a guidance document related to the labeling of nanomaterials, which complements the current regulatory initiatives on the labeling of food and cosmetic products containing manufactured nano-objects. An increasing focus on health, safety, and environmental issues appear to have provided ISO/TC229 with the impetus to publish ISO/TR12885 on *Nanotechnologies-Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, which is considered one of the largest published documents on nanotechnology standardization (Maynard, 2008).

Following this evolution in the development of nanotechnology standards, in 2009 the former chair of TC 229 stated that ISO standards now serve three key objectives:

1) supporting commercialization and market development;
2) providing a basis for procurement through technical, quality and environmental management; and
3) supporting appropriate regulation and voluntary governance structures (Hatto, 2009).

In this way, TC 229 and its standards seem to have multiple functions. Furthermore, the Committee provides a forum for debate for various stakeholders. Its plenary meetings organized every tenth month of the year, as well as WG meetings provide opportunities for experts to meet with other delegates, exchange information on standardization issues and set uniform standards. As of October 2014, TC 229 has had 16 plenary meetings, followed by many other conferences and expert meetings. ISO applies the principle of national delegation and its administrative work takes place through a Secretariat located in one of the National Standardization Bodies (NSBs) (ISO/IEC, 2012). Delegates participate in ISO/TC meetings in negotiations and consultations. There are 35 participatory and 13 observatory members involved in the work of TC 229. Figure 2.1. provides an illustration of the internal structure of TC 229 in 2014.

Figure: 2.1: International Organization for Standardization - ISO/TC229- Nanotechnologies[41]



ISO has established procedures for including industrial actors as well as other actors in the standardization process (Forsberg, 2010). Within ISO the participating actors are divided into: industry and trade associations; consumer associations; governments and regulators; as well as societal and other interests. TC 229 has a number of collaborations and relationships with other organizations and standardization bodies as well (David, 2007). These stakeholders are known as *liaison* members, and include, amongst others, groups concerned with the rights of consumers, workers and environment (e.g. the European Consumer Voice in Standardization (ANEC); the European Environmental Citizens Organization for Standardization (ECOS); the European Trade Union Institute (ETUI)). TC 229 has also established two Task Groups (TGs) working on Sustainability (TGS) and on Consumer and Societal Dimensions (TGCSDN) (ISO,

[41] Figure 2. 1 is adapted from ISO, *ISO TC 229 Business Plan* 8 (2012), *available at* http://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/customview.html?func=ll&objId=687806&*objAction*=browse&sort=name [hereinafter ISO, *Business Plan*].

2012). These TGs advise TC 229 on the priorities for standards development in the area of consumer and societal dimensions, and the mechanisms that the Committee may develop to receive input from consumer, societal or other relevant organizations (ISO, 2012). In 2013 another TG was created to work on NanoBio issues (Friedrichs et al. 2013) (See Figure. 2.1).

Regarding the outcomes of TC 229, as of October 2014, there were 40 deliverables published under the direct responsibility of TC 229.[42] In particular, TC 229 has published three standards (i.e. ISO 10801: 2010; ISO 10808: 2010; ISO 29701: 2010), as well as 26 documents developed in the form of technical reports (TR)[43] and 11 documents in the form of technical specifications (TS).[44] As articulated in TC 229 business plan, the Committee has given priority to developing horizontal standards that "provide foundational support across all sectors that use nanotechnologies or nanomaterials" (ISO, 2012; Hatto and MacLachlan, 2010). These deliverables are voluntary and there are no legal obligations to comply with them (Hatto, 2010). However, as we shall see in the next Chapters (and more specifically in Chapter 5), in practice many stakeholders (coming from industry, governmental agencies as well as civil society organizations) find these deliverables beneficial for their organizations, and argue that TC 229 standards may have a positive impact to facilitate global trade, reduce scientific uncertainties and ensure risk and regulatory analysis in the field of nanotechnologies. Furthermore, a limited number of stakeholders (coming mainly from industry) have also started to comply with TC 229 standards (e.g. ISO 10801: 2010; ISO 10808: 2010; ISO 29701: 2010; ISO 27687).

2.4.2. OECD Working Party on Manufactured Nanomaterials (OECD/WPMN)

The OECD is an intergovernmental organization and 34 member governments are responsible for determining the substantive agenda and the outputs of the organization.[45] In the OECD, the Council is considered as the highest decision-making body, and is comprised of representatives

[42] The main deliverables in ISO are : international standards, technical recommendations (TR) and technical specifications (TS). TRs and TSs are usually approved when there is no immediate agreement to publish an international standard. However, after a certain period of time, these documents are reviewed with the options of "withdrawal", "extension for three years" and also "conversion into international standard". See: ISO/IEC Directives., 2012. Procedures for the Technical Work, p. 33-34.

[43] Such as : ISO/TS 10797:2012; ISO/TS 10798:2011; ISO/TS 10867:2010; ISO/TS 10868:2011; ISO/TS 11251:2010; ISO/TS 11308:2011; ISO/TS 11888:2011; ISO/TS 11931:2012; ISO/TS 11937:2012; ISO/TS 12025:2012; ISO/TS 12901-1:2012; ISO/TS 12901-2:2014; ISO/TS 13278:2011; ISO/TS 13830:2013; ISO/TR 14786:2014; ISO/TS 16195:2013; ISO/TS 17200:2013; ISO/TS 27687:2008; IEC/TS 62622:2012; ISO/TS 80004-1:2010; ISO/TS 80004-3:2010; ISO/TS 80004-4:2011; ISO/TS 80004-5:2011; ISO/TS 80004-6:2013; ISO/TS 80004-7:2011; ISO/TS 80004-8:2013

[44] Such as: ISO/TR 10929:2012; ISO/TR 11360:2010; ISO/TR 11811:2012; ISO/TR 12802:2010; ISO/TS 12805:2011; ISO/TR 12885:2008; ISO/TR 13014:2012; ISO/TR 13014:2012/Cor 1:2012; ISO/TR 13121:2011; ISO/TR 13329:2012; ISO/TS 14101:2012

[45] *List of OECD Member Countries—Ratification of the Convention on the OECD*, OECD, http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm

from all member states and the European Commission. The Council meets regularly at the permanent representative level and once a year at the ministerial level. Permanent representatives of the member states are represented by ambassadors in Paris, where their goal is to make sure that the OECD work reflects the interest of their governments. On the other hand, the Council's ministerial annual meetings involve government officials, policy makers, and experts. A limited number of non-member states and other organizations representing the industry, trade, and social interests, may also participate as observers at the sessions of the OECD ministerial Council meetings. The Council maintains strategic control over the OECD, and authorizes the Secretary-General to carry policy and management responsibilities related to the Organization's program of work and budget, and to execute Council decisions (OECD, 2011).

The Secretariat is considered the heart of the OECD, responsible for the efficient administration of the Organization (Woodward, 2009). The Secretariat subdivides into Directorates and Departments that relate to key issues in certain policy fields. Most Directorates have established one or more substantive Committees, whose members review the broader developments of certain policy areas. The composition that the Committees follow is flexible, as they decide their work structure and the desired level of collaboration with other organizations or stakeholder groups. The Committees meet in ministerial sessions and bring together officials from the member countries, non-member economies, international organizations and representatives from the EU Commission and industry to address issues of common concern.

To facilitate work through experts in the field, Committees establish subsidiary Working Groups or Expert Groups. For example, the main Committees of the Environment Directorate include the Environmental Policy Committee (EPOC) and the Chemicals Committee. The Chemicals Committee has set up several task forces and WGs, part of which is also the Working Party on Manufactured Nanomaterials (WPMN). These bodies are considered of crucial importance for the Organization as they produce the "outputs of the OECD, the policy advice, guidelines, principles ('soft law'), and best practices" (OECD, 2011: 10-11).

The safety of MNs was first addressed at the OECD Chemicals Committee in November 2004. This Committee functions under the OECD Environment, Health, and Safety Division and consists of member country delegates (that is, governmental officials from the OECD countries) responsible for chemicals management who meet every year to plan and decide on the current and future work of the OECD Chemicals Programme. Representatives from non-member countries and other stakeholder groups also participate in the work discussions of the Committee (Visser, 2007). In 2005, health and safety questions relating to nanomaterials were viewed as areas of increasing priority, with the OECD Chemicals Committee organizing a Special Session on the "*Potential Implications of Manufactured Nanomaterials for Human Health and Environmental Safety*" and a Workshop on the "*Safety of Manufactured Nanomaterials*." The aim of the Special Session was "to inform delegations on nanotechnology and consider possible issues where the OECD may be usefully engaged" (Willis, 2007). The Session provided the first opportunity for a number of government officials to collaboratively begin the process of identifying environmental, human health, and safety (EHS) aspects related to MNs. As the report of the Special Session clearly indicates, there was a strong convergence of views and preoccupations amongst participants with regards to "the need for international coordination, information sharing and exchange for harmonizing the baseline information when addressing regulatory frameworks, assessment methodologies and testing schemes" (OECD, 2006: 12).

Building on this momentum, the Chemicals Committee hosted a Workshop in Washington, D.C. shortly thereafter. The Workshop provided the platform for governmental officials, non-member economies, and other stakeholder groups such as the Business and Industry Advisory Committee (BIAC) and other NGOs to discuss issues related to the safety of nanomaterials on the international stage (OECD, 2009). Amongst the main recommendations coming out from this Workshop was the creation of a subsidiary body within the Chemicals Committee that would further develop international cooperation in the field of nanotechnologies. The proposal was discussed and approved by the Executive Committee of the OECD Council.

In September 2006, the OECD/WPMN was established with the aim "to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials, in order to assist in the development of rigorous safety evaluation of nanomaterials" (Locascio et al. 2011:186). As indicated by the NRC, the OECD/WPMN committed itself to the responsible development of nanotechnology, which also implied a commitment to "develop and to use nanomaterials to meet human and societal needs while making every reasonable effort to anticipate and mitigate adverse effects and unintended consequences" (NRCA, 2009: 3).

The first meeting of the OECD/WPMN was held in London towards the end of 2006 (OECD, 2006). Participation of stakeholders in the WPMN was discussed at the WPMN's first meeting, at which time it was decided that the Working Party should encourage the participation of observers and invited experts that participate in the work of the Chemicals Committee (OECD, 2009a). Member countries are represented at the WPMN meetings by the delegation heads, each of whom is drawn from their national agencies responsible for chemicals regulation and the safety of human health and the environment. These delegates serve as the main contacting point to the Working Party. Within the decision-making process, member countries drive the agenda and the output of the OECD and WGs, while financing a major part of the work of the Committees and voting on proposals and policy recommendations (see Figure 2.2). Observers, in contrast, may only contribute in two ways: through policy dialogue and consultations or through commenting on country policy reports. They do not have voting rights. These parties include Russia, China, Thailand, South Africa, India, the EU Commission, UN agencies (e.g Food and Agriculture Organization, International Monetary Fund, World Bank, International Atomic Energy Agency), and other stakeholder groups such as those represented through the Trade Union Advisory Committee (TUAC) and BIAC (see Figure 2.2).

On the first meeting of the OECD/WPMN the draft program of work for 2006-2008 was also developed, and the organization of work and the modalities of cooperation with other international organizations were set (OECD, 2009). The OECD/WPMN work programme was adopted by the Chemicals Committee in November 2006 and focused primarily at:

> "Promot[ing] international co-operation … develop[ing] methods to efficiently assess the safety of manufactured nanomaterials so as to avoid adverse effects in the short, medium and longer term … ensur[ing] that the approach to hazard, exposure and risk assessment is science-based and of a high internationally harmonized standard" (OECD, 2009a:10).

At the same time the Committee decided that OECD/WPMN works on three areas:

1) Work Area 1: *identification, characterization, definitions, terminology and standards* - with the main objective to develop working definitions of MNs for regulatory purposes within the context of human health and environmental safety;
2) Work Area 2: *test methods and risk assessment* - with the main objective to encourage cooperation and coordination on risk assessment frameworks, and to harmonize health and environmental safety testing methods for MNs; and
3) Work Area 3: *information sharing, co-operation and dissemination* - with the main objective to foster co-operation and share information on current and planned initiatives on risk assessment and risk management programmes, and regulatory frameworks (Visser, 2007).

To fulfill these overarching aims, OECD/WPMN developed six individual projects, which focus on:

1. the development of an OECD Database on EHS research for approval (Project 1);
2. the EHS research strategies on MNs (Project 2);
3. the safety testing of a representative set of MNs and test guidelines (Project 3);
4. MNs and test guidelines (Project 4);

5. co-operation on voluntary schemes and regulatory programmes (Project 5); and
6. co-operation on risk assessments (Project 6).

Each project is carried out by a steering group (SG) comprised of experts nominated by the delegation heads participating in the work of the OECD/WPMN (OECD, 2013a). Some of these delegates also chair the work of the SGs. The operational plans of the SGs that emphasize the objectives and future work of the groups were agreed to in the WPMN's second meeting. At this time - in 2007 - the WPMN began to extend its operations to include issues related to toxicity testing and exposure to nanomaterials. These initiatives resulted in the establishment of two additional projects, the remit of which is:

- the role of alternative methods in nanotoxicology - (Project 7); and
- exposure measurement and mitigation with an initial focus on occupational settings - (Project 8).

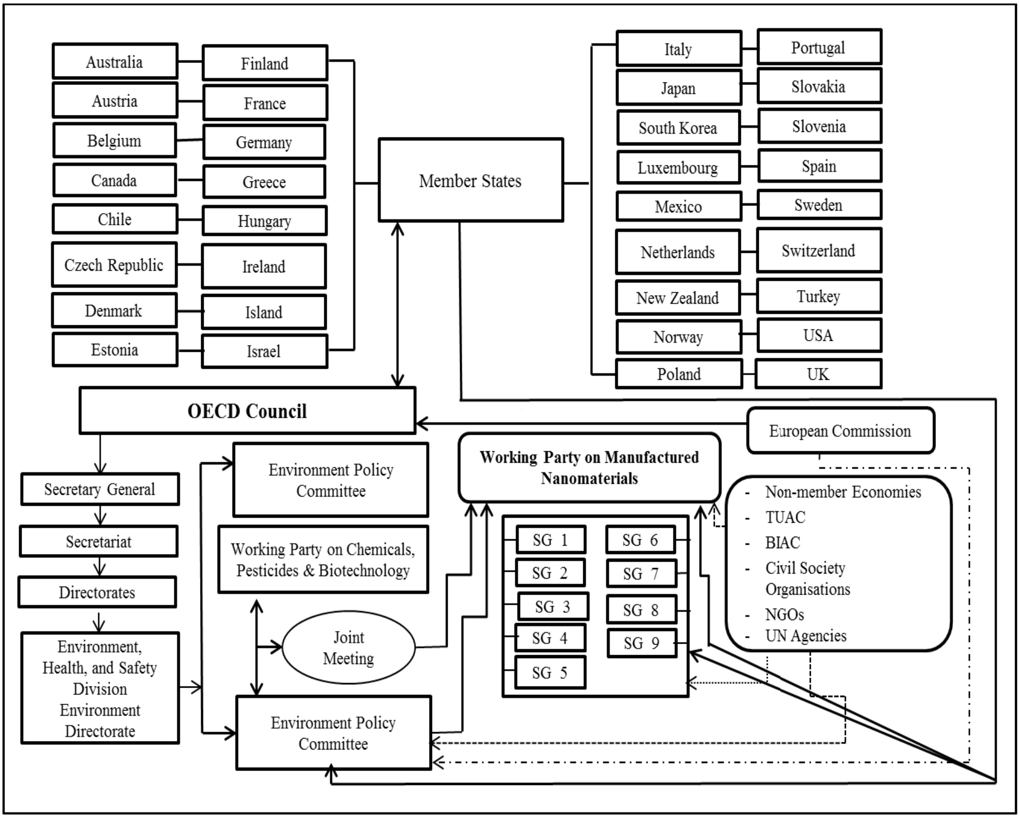
Since 2009, the WPMN has continued to broaden the focus of its work. Today, it is not only considering certain toxicological endpoints, but also the positive and negative implications that nano-enabled applications could have on the environment and health, at different stages of development (OECD, 2011a). This led to the creation of another project within the WPMN, which focuses on cooperation on the environmentally sustainable use of MNs (*Project 9*).

In the OECD, the decision-making process for relevant working areas and projects of work consists of several stages. The first stage - *the data collection stage* - comes right after the Council decides that a particular policy problem will be dealt at the OECD. Following this, the next step is for the OECD to collect data; and as required by Article 3 (a–b) of the OECD Convention, members have to supply the Organization "with the information necessary for the accomplishment of its tasks; … carry out studies and participate on agreed projects … and where appropriate take coordinated actions" (Woodward, 2009; OECD, 1960). These data are collected and analyzed by the OECD Secretariat - *the data analysis stage,* and are forwarded to the OECD Committees to discuss policy based on information - *the discussion stage*. At the *discussion stage,* the Committees and the WGs build upon the Secretariat's commentary and analysis, and participants exchange ideas on their experiences and the impact that certain proposals may have for their economy and society. Following these discussions, national delegates define their position and proceed to *the decision-making stage,* in which they propose solutions or best practices for the policy issue in question (Woodward, 2009).[46] Decisions and recommendations within the Organization are made through consensus; however, in cases when

[46] See also: *What We Do and How*, OECD, *available at*: http://www.oecd.org/about/whatwedoandhow

consensus cannot be achieved, qualified majority voting procedures are applied (OECD, 2013a). Figure 2.2., provides a detailed illustration of the OECD's organizational structure.

Figure 2.2: The OECD's Organizational Structure and the WPMN[47]



Since its establishment in 2006, there have been ten meetings - so-called *Tour de Table* - of the OECD/WPMN, which have been supplemented with workshops (i.e. related to the safety of manufactured nanomaterials, exposure assessment and mitigation, risk assessment of the MNs in a regulatory context), expert meetings and conferences. *Tour de Tables* are held every eight months (OECD, 2009). Neither the OECD Council nor the OECD Secretariat have a role in deciding which delegates the member countries and the stakeholder groups should send to these meetings; this is done, instead, by those parties themselves. Nominated delegates are selected by consensus on the basis of merit, and their roles and duties are set up by the Committee and the OECD/WPMN (OECD, 2013a).

[47] Figure 2.2., is adapted from OECD. *See* OECD.,2013a., Rules of Procedure of the Organisation.

However, as indicated earlier, OECD has also taken several steps to establish close relationships with non-member countries, as well as industry and civil society. These parties have been invited to participate as observers in the work of OECD/WPMN (see Figure. 2.2). The wide range of actors emphasizes clearly the drive within the OECD to opt for a multistakeholder representation and secure support for its policy recommendations through a broader range of experts. This also allows us to assess OECD/WPMN as a transnational arrangement.

With regards to the outcomes, the SGs of OECD/WPMN have worked intensively on gathering and exchanging information with respect to risk management and assessment of MNs. The key achievements/outcomes of this Working Party are the *Sponsorship Programme* (launched in 2007 in Project 3), the *OECD Database on MNs to Inform and Analyze EHS Research Activities* (launched in 2009 in Project 1), and the *Guidance on Sample Preparation and Dosimetry for the Safety Testing of MNs* (published in 2012 in Project 4).

A fundamental role has been given to the *Sponsorship Programme* to improve existing data and provide knowledge about the human health and safety implications on MNs (Locascio et al. 2011: 186). The intention of the Sponsorship *Programme* is to test a particular set of MNs[48] for their physico-chemical properties, potential for environmental degradation, and environmental and mammalian toxicology, and to determine if there are any "intrinsic properties" that characterize these MNs (OECD, 2009 & 2012). The list of the representative MNs was selected by the WPMN based on their commercial relevance. In conjunction with BIAC, several member countries volunteered to sponsor and cosponsor the safety testing of one or more MNs or contribute by providing test data, reference or testing materials to the lead sponsors.[49] By pooling expertise across traditional jurisdictional borders, the *Sponsorship*

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[48] There are 14 identified manufactured nanomaterials tested within OECD, such as fullerenes (C60), single-wall carbon nanotubes, multi-wall carbon nanotubes, silver nanoparticles, iron nanoparticles, carbon black, titanium dioxide, aluminum oxide, cerium oxide, zinc oxide, silicon dioxide, dendrimers and nanoclays.

[49] In the following the sponsors, co-sponsors and contributors for the testing of the 14 identified MNs are provided. For Fullerenes (C60) (key sponsors have been Japan and US, contributors Denmark and China); for single-wall carbon nanotubes (key sponsors have been Japan and US, contributors Canada, France, Germany, EC, China and BIAC); for multi- wall carbon nanotubes (key sponsors have been Japan and US, co-sponsors Korea and BIAC, contributors Canada, Germany, France, EC, China, BIAC); for silver nanoparticles (key sponsors have been Korea and US, co-sponsors Australia, Canada, Germany and Nordic Council of Ministers, contributors France, EC, China and Netherlands); for iron nanoparticles (key sponsors have been BIAC and China, contributors Canada, US and Nordic Council of Ministers); for carbon black (key contributors have been Denmark, Germany and US); for titanium dioxide (key sponsors have been France and Germany, co-sponsors Austria, Canada, Korea, Spain, US, EC and BIAC, contributors China, Denmark, Japan and UK); for aluminum oxide (key contributors have been Germany, US and Japan); for cerium oxide (key sponsors have been US, UK and BIAC, co-sponsors Australia, Netherlands and Spain, contributors Denmark, Germany, Switzerland, EC, Japan and Netherlands), for zinc oxide (key sponsors have been UK and BIAC, co-sponsors Australia, Spain, US and BIAC, contributors Canada, Denmark, Japan, Germany and Netherlands); for silicon dioxide (key sponsors have France and EC, co-sponsors Belgium, Korea and BIAC, contributors Denmark and Japan); and for polystyrene (key contributors have been Austria and Korea).

Programme served as an incentive for countries to collaborate, share best practices, and follow a consistent approach with regards to the testing of specific endpoints of representative MNs. To assist sponsors and others involved in the *Sponsorship Programme,* the SG for Project 4 has developed a *Guidance Note on Sample Preparation and Dosimetry for the Safety of MNs*. The *Guidance Notes* provide detailed information on data and characteristics of nanomaterials that should be considered and reported during the testing process and the sample preparation techniques needed for undertaking such testing (OECD, 2010 & 2012a). These notes are expected to have an important role on estimating the endpoints of the MNs agreed under the *Sponsorship Programme*, since the effective application of the testing methods will largely depend not only on the appropriate consideration of the characteristics of nanomaterials, but also on the samples that are prepared for testing (OECD, 2009; OECD, 2013a; OECD, 2011; OECD, 2012; OECD, 2012a).

In 2011-2012 the results of the Sponsorship testing programme were analyzed by the OECD to determine whether its member countries needed to modify the existing test methods or guidelines used for testing traditional chemicals (OECD, 2012). In September 2013, the Council of the OECD issued a recommendation on the *Safety Testing and Assessment of MNs*. The recommendation indicates that member countries apply the "existing international and national chemical regulatory frameworks to manage the risks associated with manufactured nanomaterials" and that only in few cases these "systems may need to be adapted to take into account the specific properties of manufactured nanomaterials" (OECD, 2013).

In 2014, in the summer issue of the *Canada's Chemicals Management Plan Report*, it was indicated that the Canadian government has endorsed the recommendation from the OECD/WPMN - according to which "countries apply the existing international and national chemical regulatory frameworks or other management systems, adapted to take into account the specific properties of manufactured nanomaterials" (Government of Canada, 2014: 2). Even though limited in numbers, the case of Canada emphasizes that the outcomes of OECD have started to be taken up in practice. According to NIA (NIA, 2013), in 2016 OECD will also conduct a review to assess how the recommendation has been followed by member and partner countries.

2.4.3. International Risk Governance Council (IRGC)

The IRGC is an independent foundation that was initially funded by the Swiss government to help the understanding and governance of systemic risks[50], which span in more than one country and/or sector) and impact human health and safety, environment, as well as the economy and society at large (Renn and Roco, 2006). Since the beginning of 2005 the Council has also been working actively on nanotechnology issues. In this regard, the key objectives of IRGC are:

> "to develop and make available specific advice for improving risk governance; provide a neutral and constructive platform on the most appropriate approaches to handling the risks and opportunities of nanotechnology, and enable all actors to reach a global consensus" (Renn and Roco, 2006: 6).

The key bodies within the IRGC are the Board Members, Advisory Committee, the Executive Committee and the Scientific & Technical Council (S&TC). Members of the Board (7 members) are drawn from governments, industry, science and nongovernmental organizations. These members come from US, Germany, France, Belgium, Korea, Switzerland, China and Canada.[51] The Executive committee (which is composed of the Chairman Board, a board member and the chairman of the S& TC) prepares and implements the decisions of the Board. The Advisory Committee is the key body, which comprises of individual members (17 members)[52] appointed by the Board to act as advisors and make proposals to the S&TC on the possible issues that need to be addressed by the IRGC. The S&TC is the leading scientific authority of the foundation. It

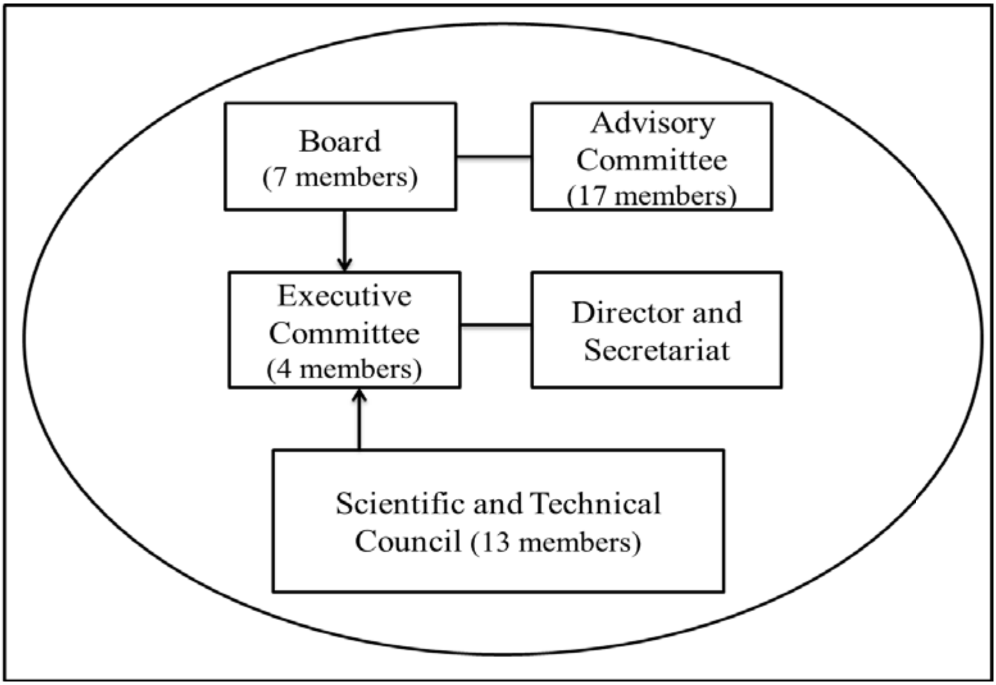
[50] According to IRGC systematic risks are risks that "affect the system on which the society depends […] and denote the embeddedness of any risk to human health and the environment in a larger context of social, financial and economic consequences" (IRGC, 2010: 53).

[51] Members of the Board are from: Switzerland (4 members coming from State Secretary for Education and Research; Swiss Reinsurance Company ; Secretary-General for Disaster Risk Reduction and Ecole polytechnique fédérale de Lausanne); Portugal (1 member from the Laboratory for Particle Physics), China (1 member from the Ministry of Science and Technology) and UK (1 member from the Marsh & McLennan Companies Global Risk Center).

[52] Members of the Advisory Board come from: US (4 members coming from the Institute of Science for Global Policy, the Carnegie Institution for Science , the National Center for Atmospheric Research and the Institute of Medicine); France (2 member coming from the International Futures Programme, OECD); Switzerland (5 members coming from the World Wildlife Fund International, Swiss Agency for Development and Cooperation and Risk Center at the Federal Institute of Technology and Laboratory for Physical Chemistry, Swiss Federal Institute of Technology); Canada (1 member coming from Global Risk Institute), China (1 member coming from Councelor's Office of the State Council); Germany (1 members coming from the Technical University of Munich); Korea (1 member coming from the Korea Society of Risk Governance) and Belgium (2 members coming from the European Parliament and Von Karman Institute for Fluid Dynamics).

comprises experts (13 experts)[53] form a range of scientific and organizational background, who review the scientific quality of the IRGC work and its deliverables. These experts are mainly associated with universities and come from US, UK, Portugal, India, China, Switzerland and Germany. The participation of these actors at the IRGC is voluntary, but there is less available information on how they are selected and how the decision-making process is structured in this arrangement (see Figure. 2.3).

Figure 2.3: The Organizational Structure of the IRGC[54]



The IRGC's nanotechnology programme is a key forum for dialogue and is financially supported by the Swiss Reinsurance Company, EPA and the US Department of State (IRGC, 2007). To tackle issues of nanotechnology the IRGC, and the S&TC in particular, proposed the establishment of the working group on nanotechnology. The main aim of this working group was to provide an independent and cross-disciplinary approach to nanotechnology risks and

[53] The members of the ST&C are from : US (4 members coming from Carnegie Mellon University, Indiana University, Massachusetts Institute of Technology, Duke University); Portugal (1 member coming from Técnico Lisboa); Switzerland (1 member coming from Institute for Water Resources and Water Pollution Control and Ecole polytechnique fédérale de Lausanne), Germany (1 member coming from the University of Stuttgart); UK (2 members coming from University College London and Leeds University Business School); China (1 member coming from Tsinghua University) and India (1 member coming from Center for Study of Science, Technology & Policy, Bangalore).

[54] Figure 2.3. is adapted from IRGC , Organization and Funding, *available at*: http://www.irgc.org/about/organisation-structure

hazards (Renn and Grobe, 2010). The working group has focused on two projects: *on the risk governance of nanotechnology* (in 2005) and *on nanotechnology applications in food and cosmetics* (in 2007). These projects were led by expert bodies consisting of recognized subject experts in the field of nanotechnology and risk governance, who prepared and reviewed the project reports (IRGC, 2007). For instance, the first project was led by Dr. Mihail Roco of the National Science Foundation (NSF) and a team of scientific experts coming from universities, research centers, governmental bodies and laboratories.

Over a period of two-years, the IRGC held two expert workshops (May 2005 and January 2006) (IRGC, 2006 & 2007). During the second workshop, the IRGC working group also organized four surveys on the implications of nanotechnologies with stakeholders coming from research organizations, standardization organizations, nanotechnology start-ups and NGOs. The aim of the surveys was to identify the organization interest in nanotechnology research, the governance gaps as well as measures that were needed to address potential risks. These activities resulted in the publication of the "*White Paper on Nanotechnology Risk Governance*" in 2006 and the "*Policy Brief: Recommendations for a Global, Coordinated Approach to the Governance of Potential Risks*" in 2007 (Breggin et al. 2009; IRGC, 2007). The *White Paper* and the *Policy Brief* suggest a regulatory framework, which anticipates two frames for four generations of nanotechnologies:

1) frame one includes the first generation of nanostructures (the steady function nanostructures) that have stable behaviour and do not constitute excessive risks; and
2) frame two involves the second generation (active function nanostructures), the third generation (systems of nanosystems) and the fourth generation of nanostructures (heterogeneous molecular nanosystems).

Since frame two involves nanostructures that change their design, it is more difficult to predict their behaviour (IRGC, 2007). It is important to note that the *White Paper* and the *Policy Brief* have been amongst the first publications to provide detailed recommendations for the risk governance of nanotechnologies (IRGC, 2007). They recommend national and international decision makers, who are involved in nanotechnology risk issues, "to improve knowledge base, strengthen risk management structures and processes, promote stakeholder communication and collaboration, and ensure social benefits and acceptance" (IRGC, 2007:15). As such, the *White Paper* and the *Policy Brief* have been cited in various reports and documents (e.g. Breggin et al. 2009; Mantovani et al. 2010; Pelley and Saner, 2009), but there is no concrete evidence about the actual impact that these recommendations have had in practice.

2.4.4. International Council on Nanotechnology (ICON)

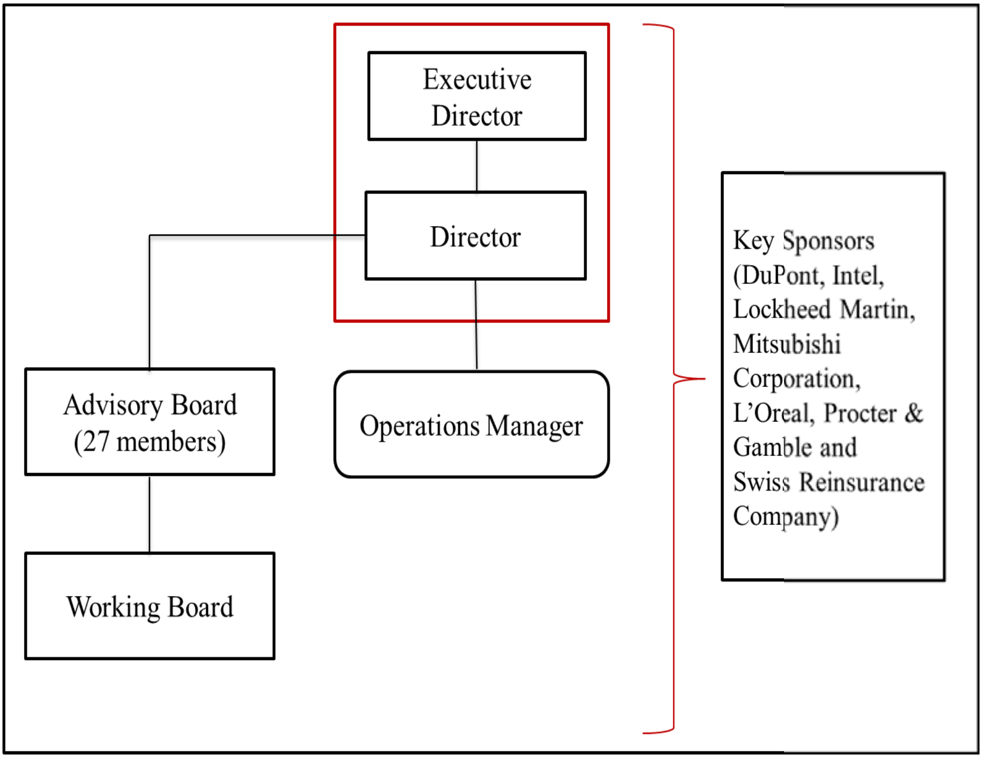
ICON was created in late 2004 within the program of the federally funded Center for Biological and Environmental Nanotechnology (CBEN) at Rice University. Shortly after its creation, ICON extended its activities beyond CBEN to include other national and international centers. ICON has been actively involved on tackling nanotechnology related issues (Pelley and Saner, 2009). The stated mission of ICON is to:

> "assess, reduce and communicate information regarding the potential environmental and health risks of nanotechnology, while maximizing its societal values" (ICON, 2009:3).

The key bodies of ICON are the Director and the Executive Director, who are responsible for managing the internal coordination of the Council and ensuring an effective external presence. The Council is largely funded by industry. The key sponsors of ICON's work are: DuPont, Intel, Lockheed Martin, L'Oreal, Mitsubishi Corporation, Procter & Gamble and Swiss Reinsurance Company (ICON, 2009). The Council has established an Advisory Board, which is composed of prominent nanomaterial international safety experts coming from industry, government agencies, academic institutions and nongovernmental groups. Participation in ICON is voluntary and non-compensated. There are around 27 members participating in the Advisory Board coming from France, Japan, the Netherlands, Switzerland, Taiwan, the UK and the US.[55] The Executive Committee, consisting of the Director and Executive Director, has the ultimate authority over ICON's finances, the membership of the Advisory Board and the setting of new committees (ICON, 2009). Figure 2.4. emphasizes the organizational structure of ICON.

[55] In the Advisory Board there is one member coming from each of these organizations: from the U.S. Environmental Agency, the Japanese National Institute of Advanced Industrial Science (AIST), North Carolina State University, U.S. Consumers Union, Swiss Reinsurance Company, Intel, Bracewell & Giuliani, Lockheed Martin, Mitsubishi Corporation, Procter & Gamble, University of Michigan, DuPont, Unidym, Nanobusiness Alliance, University of Rochester, Foresight Institute, National Nanotechnology Coordination Office, Sandia National Laboratories, L'Oréal, Japanese Industrial Standards Committee, UK Napier University, National Institute for Materials Science -Japan, U.S. Consumer Product Safety Commission, Academia Sinica-Taiwan, Federal Institute for Access to Information and Data Protection-Mexico.

Figure 2.4: The Organizational Structure of ICON[56]



ICON has been working on several projects related to nanotechnologies, such as the *International Assessment of Research Needs for Nanotechnology Environment, Health and Safety*; the *Current Practices for Occupational Handling of Nanomaterials;* and the *Good NanoGuide.* The main objectives of the first two projects have been to:

a) facilitate the documentation of current best practices for identifying and managing risks that come during the production, handling, use and disposal of nanomaterials; and
b) prioritize research needs related to the classification nanomaterials (ICON, 2009).

As such, these projects have given rise to several workshops. In particular, during the period of 2007-2009 ICON hosted three workshops to assess research needs on EHS aspects of nanotechnologies (ICON, 2010). The workshops were financially supported by ICON, the U.S. National Science Foundation, the U.S. National Institutes of Health and the Swiss Reinsurance Company. These workshops brought together many experts (around 50 experts in each

[56] Figure 2.4. is adapted from International Council on Nanotechnology (ICON)., 2009. *Governance Structure and Operational Plan*, available at: http://cohesion.rice.edu/centersandinst/icon/emplibrary/ICONmanagementv2009_1_Full_Text.pdf

workshop) representing various countries (13 countries),[57] and stakeholder groups (industry, academia, governments and NGOs) (NRCA, 2012).[58]

The main goals of these workshops were to bring experts together to identify critical research needs in three areas:

1) "prioritize research needed to establish a science-based assessment of potential risk of different classes of nanomaterials"
2) "identify the research needs and milestones to inform predictions of an engineered nanoparticle's biological effects"; and,
3) "identify strategies to advance the eco-responsible design and disposal of engineered nanomaterials" (ICON, 2010: 2).

Altogether these workshops identified 46 specific needs for research to ensure the safe development of MNs (NRCA, 2012). The three workshop mark the first efforts to integrate various stakeholders and experts to discuss and share information on the impacts of nanomaterials. Many experts that were involved in these workshops commented about their impressions and expectations on these workshops. For instance, a representative from Inter argued that the work of ICON is an important step "toward developing a prioritized NanoEHS Research Roadmap. The results of this international multi-stakeholder group should enable prioritization of environmental health and safety research […] and enable industry to better understand potential EHS issues with nanomaterials and improve both risk assessment and risk management" (ICON Blog, 2008).[59]

However, even though the reports provided by these workshops mark the first efforts to integrate various stakeholders and experts to discuss and share information on the impacts of nanomaterials, there is no evidence about the concrete impact that these reports have had to the regulatory governance of nanotechnologies. The progress that ICON has made with regards to its third project - i.e. the *GoodNanoGuide*, seems to suggest similar issues about the practical relevance of ICON's outcomes. *The GoodNanoGuide* - is an internet based collaboration platform designed to help experts to exchange ideas on how to handle nanomaterials safely (ICON, 2009a; Kulinowski and Matthew, 2009). The key Objective of the *GoodNanoGuide* is to establish an open forum that complements other nanotechnology information projects by

[57] In particular: US, Switzerland, Japan, Canada, UK, Belgium, Italy, Germany, Netherlands, Ireland, South Africa, China and France.
[58] A detailed list of participants in the workshops is provided at: ICON., 2008. Towards Predicting Nano-Biointeractions: An International Assessment of Nanotechnology Environment, Health and Safety Research Needs, available at: http://cohesion.rice.edu/CentersAndInst/ICON/emplibrary/ICON_RNA_Report_Full2.pdf
[59] ICON Blog., *Towards Predicting Nano-Biointeractions*, published on May, 2008, *available at*: http://iconnanoblog.blogspot.nl/2008/05/towards-predicting-nano-biointeractions.html

providing up-to-date information on good practices for the handling of nanomaterials in an occupational setting. The *GoodNanoGuide* is freely accessible for everyone, but only experts who are members of the *GoodNanoGuide* are able to post information. The forum has attracted a wide range of stakeholders to collaborate and contribute at both intellectual and financial levels (Kulinowski and Matthew, 2009).[60] However, according to its Director, the main weakness of the *GoodNanoGuide* is its reliance on industry funds only, which "reduces the credibility [of this platform to] stakeholders and challenges [its] sustainability in a down economy" (Abbott et al. 2012: 296). The platform has been used by various experts to put information related to the good practices of handling nanomaterials,[61] but it is difficult to see the actual impact that the *GoodNanoGuide* has had in practice. The platform was set in 2008 and since 2009 there are no updates about the progress of the platform . Furthermore, in the website it is indicated that the *GoodNanoGuide* is still in a beta version, which means that this web-based application is running, but it is still not fully ready and is being continuously revised.[62]

2.4.5. Intergovernmental Forum on Chemical Safety (IFCS)

IFCS was established in 1994 in the International Conference of Chemicals Safety (ICCS). The main objective in establishing IFCS was to:

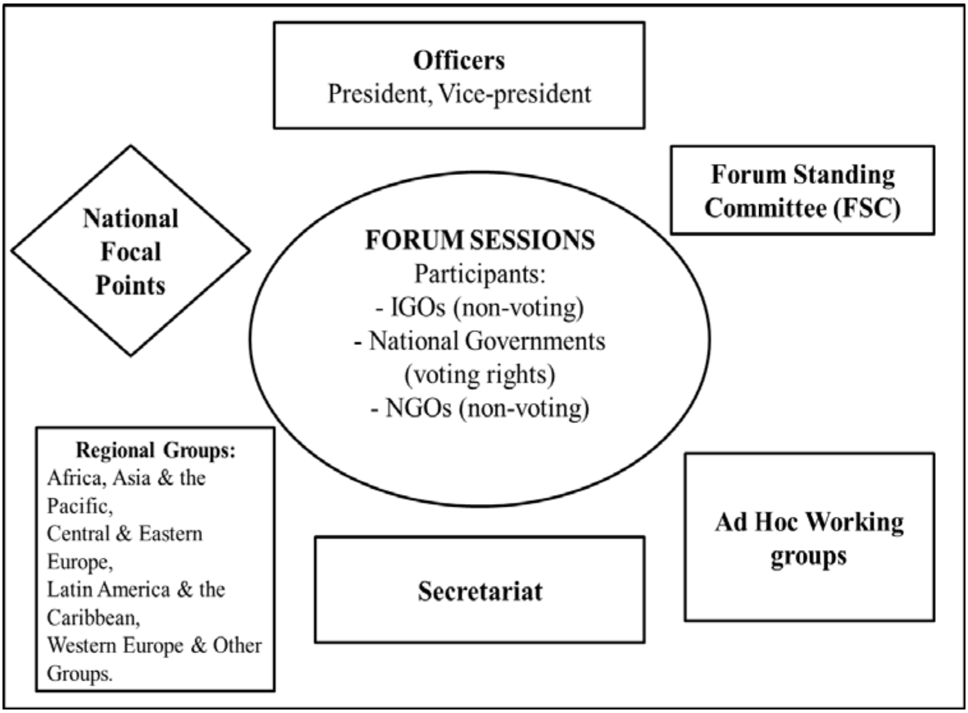
> "create an overarching framework through which national governments, NGOs and intergovernmental organizations could work together and build consensus to promote chemical safety, and address the environmentally sound management of chemicals" (IFCS, 1997:2).

The idea to establish IFCS was created in 1991, during the preparations for the United Nations Conference on Environment and Development (UNED). The Forum is under the administration of WHO, which also provides the secretariat for IFCS. Participation in the IFCS is open to governmental participants (including all member states of the UN and its specialized agencies); intergovernmental participants (including participants representing political, regional and economic groups involved in chemical safety); and nongovernmental participants (including NGOs concerned with the environmental, health, science, consumer and workers' interest) (IFCS,1997a; IFCS, 2009). Participation is voluntary and financially supported by the members. The work of IFCS is organized in sessions at intervals of two to three years. To achieve its

[60] The following Canadian organizations have been the key financial supporters of the *GoodNanoGuide*: NanoTech BC, NanoAlberta, Industry Canada, Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) and Nano Quebec.
[61] See: GoodNanoGuide., Progress Report, *available at*: http://icon.rice.edu/projects.cfm?doc_id=12207#ProgressReport
[62] Ibid.

objectives, IFCS has established the Forum Standing Committee (FCS) to provide advice and assistance during the preparations of Forum meetings, monitor progress on the work of the IFCS and assist with regional efforts. FCS is composed of 25 participants, who serve as representatives of the views of participant countries in respective IFCS regions, NGOs or intergovernmental organizations.[63] Figure 2.5 emphasizes the organizational structure of IFCS.

Figure 2.5: The Organizational Structure of IFCS[64]



Since its creation IFCS has held six meetings/sessions. In its sixth session in 2008, IFCS considered, for the first time, the opportunities and challenges of nanotechnologies and MNs. The final outcome of this meeting was the *Dakar Statement on Manufactured Nanomaterials* - calling for more international cooperation in information sharing and risk assessment (Breggin

[63] FCS has divided its members in this way: President, 5 members are Vice-Presidents ,1 member from IOMC (Inter-Organization Programme for the Sound Management of Chemicals) (Chairperson of Inter-Organization Coordinating Committee IOCC), 4 members from NGOs - industry, science, public interest, workers
2 members from Africa; 2 members from Central and Eastern Europe; 2 members from Latin America & Caribbean; 3 members from Asia and the Pacific and 3 members Western Europe and Other Groups; 1 member from the Host Country for next Forum meeting. For more information see: Forum Standing. IFCS Officers, Regional Representatives, NGO Representatives and IOMC/IOPCC Chair, available at : http://webcache.googleusercontent.com/search?q=cache:U-4THQ5soFkJ:www.who.int/ifcs/documents/forums/forum5/fsc_19sep08.doc+&cd=1&hl=en&ct=clnkIFCS

[64] The organizations structure of IFCS is adapted from http://www.who.int/ifcs/documents/IFCS_structure.pdf?ua=1

et al. 2009). The meeting had around 200 delegates, representing 70 national governments, 12 intergovernmental organizations and 39 NGOs[65] (including for example representatives from Sciencecorps, the Center for International Environmental Law, the International Trade Union Confederation (ITUC), the International Society of Doctors for the Environment) (IFCS, 2008).

Two main items were discussed in this session. The primary issue was whether the mandate of the IFCS, which was mainly limited to chemical safety, could also include the social and ethical implications of nanotechnologies (Chowdhury, 2011). In this regard, several NGOs and developing countries argued for the inclusion of these issues in the IFCS agenda. A number of European countries (e.g. Netherlands, UK, France, Switzerland) commented on the importance of this issue, by highlighting the distinction between nanotechnologies and MNs, and supporting the inclusion of MNs into the IFCS agenda.

The issue of whether to include the social and ethical implications of nanotechnologies in the IFCS was resolved in the *Dakar Statement*. In this *Statement* a preambular paragraph was added, which acknowledged "the need to address the safety aspect of nanotechnologies", while limiting the focus "on the safety aspects of nanomaterials only" (IFCS, 2008:5). Amongst other recommendations, the *Dakar Statement* called the governments and the industry to apply the precautionary principle throughout the lifecycle of the MNs (IFCS, 2008:12). The *Statement* recommended the evaluation of the possibilities to develop proper global codes of conduct, and provide information on MNs through websites, databases, cooperative actions between stakeholders […] and product labeling (IFCS, 2008: 6). These recommendations provided an important contribution for advancing the sound management of chemicals globally and were sent to the International Conference on Chemicals Management (ICCM) for consideration and further actions (ENB, 2012; IFCS, 2008). However, as discussed in Section 2.5.1 these recommendations were not taken into account by the ICCM.

Another key agenda item during the sixth meeting of the IFCS was the future of this Forum. In light of the agreement on the Strategic Approach to International Chemical Management (SAICM) in 2006, the delegates of the IFCS agreed to invite the ICCM (during its second session, ICCM2) to integrate the Forum as an advisory body into the ICCM (ENB, 2012). This invitation was crucial for IFCS, since the decision of the ICCM2 to reject the request of the IFCS put into question the existence and the potential of this Forum to contribute to the field of nanotechnologies. This is further elaborated in the next Section.

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[65] In IFCS NGOs are divided into: NGOs industry (e.g. BIAC/OECD), NGO science (e.g. International Society of Doctors for the Environment), NGO public interest (e.g. Sciencecorps) and NGO labour (e.g. The International Trade Union Confederation). For more information see: http://webcache.googleusercontent.com/search?q=cache:ORwnul-tVOoJ:www.who.int/ifcs/documents/forums/forum6/substitution.doc+&cd=1&hl=en&ct=clnk

2.5. A Comparative Look at the TGAs Related to Nanotechnologies

In the following I compare the role of the aforementioned TGAs in the regulatory governance of nanotechnologies by looking at :

1) *the types of actors,*
2) *the degree of institutionalization,*
3) *the functions and regulatory processes,* and
4) *the substantive depth and the normative scope.*

2.5.1 Types of Actors

With regards to the *types of actors*, it is clear that that nanotechnology TGAs have all taken various initiatives to assemble the needed competencies by combining the expertise and experiences of multiple actors. Yet, the relative input that states, NGOs and firms have in these arrangements differs considerably. To begin with, ISO is amongst the most recognized international organizations, which has strongest linkages with experts and dominant private industry actors coming from more than 40 countries around the world. However, to ensure the representation of other stakeholders TC 229 has established *liaisons* with other actors representing government, trade unions, consumer associations, NGOs and the EU. The Directives of ISO specify in details that its TCs shall seek the “full and, if possible formal backing” of *liaison* organizations on each document in which these organizations are interested (ISO/IEC, 2012: 20). In addition to this, the establishment of the Task Groups (i.e. TGS and TGCSDN) appears to have been one approach to opening up the membership of TC 229, and thus making its actions formally accountable to a broader range of actors. Since 2005, TC 229 has been able to broaden its activities, membership and the diversity of actors involved in the standardization process (Forsberg, 2010 & 2012; Kica and Bowman, 2013). TC 229 plenary meetings involve a wide range of practitioners, industrial hygienists, pharmacologists, toxicologists and ecotoxicologists, chemists and physicists who exchange knowledge and contribute substantially to establishing international standards (Kica and Bowman, 2012).

The activities of the OECD clearly emphasize that in this organization member countries drive the agenda and the output of the OECD WGs, while financing a major part of the work of the Committees and voting on proposals and policy recommendations. However, member countries have sought extensive consultation with other non-governmental organizations (especially with BIAC) (Woodward, 2009). This is exemplified in relation to the OECD/WPMN through the opening up of the discussions to observers of non-member countries, industry and civil society groups (Kica and Bowman, 2012).

Both TC 229 and OECD/WPMN have managed to ensure collaboration and the (political) support with key actors in Europe also (EP, 2006; EC, 2008a). Of greatest importance is the support of the EU members and the EC. In 2007, the EC Communication on *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009*, stated that OECD/WPMN and TC 229 are "principal forums for the coordination of activities at the international level" and that "the Commission, the European Bodies and Member States are expected to continue contributing to these international efforts" (EC, 2007a:10). The Council's conclusions on *Nanoscience and Nanotechnologies* also stated that "the Commission needs to take into account in its policy making all activities within the OECD" (EC, 2006: 428). Regarding the role of the international standards in nanotechnologies, in 2010 the EC addressed a mandate to the ESOs (i.e. M461). As indicated in Section 1.4 an important element of this Mandate is that it considers nanotechnology standards important mechanisms that may facilitate the implementation of regulation (EC, 2008a). Furthermore, the Mandate asks ESOs to develop nanotechnology related standards, by considering and giving precedence to the existing ISO standards. The Mandate also asks the ESOs to work in close collaboration with ISO and OECD. These statements indicate clearly that the EU not only is aware of the work undertaken by ISO and OECD, but it also suggests that these arrangements and their deliverables are relevant and can contribute to the nanotechnology regulatory debate in the EU.

The other governance arrangements analyzed in this chapter have also been able to ensure collaboration with influential stakeholders. IFCS, for instance, managed to provide equal representation to state actors, NGOs and intergovernmental actors. However, even though being one of the key actors to consider the issues of nanotechnologies within the international chemicals agenda, the rejection of the ICMM2 to include IFCS as an advisory body put into question the ability of this forum to contribute effectively to nanotechnology governance (ENB, 2012). In the final resolution the ICMM2 recognized the potential health and environmental issues related to nanotechnologies and MNs, but no reference was made to the *Dakar Statement*. In light of these events, in the last session of the Forum (Forum IV) the FCS agreed to suspend its work (ENB, 2012).

IRGC and ICON have also established a network of growing stakeholders. As mentioned in Section 2.4.3 the main work of the IRGC is done through its Advisory Committee. This Committee is representative of a less number of European countries as compared to TC 229 and OECD/WPMN, but it has the support of important regulatory agencies, such as the EPA. In 2006, IRGC organized a Conference to promote stakeholder dialogue and feedback on the IRGC *White Paper* (IRGC, 2006 & 2006a). In this event, actors from regulatory agencies (e.g.

DEFRA), as well as industrial actors (e.g. DuPont), were involved. In a similar way, ICON (even though largely funded by industry), has also ensured collaboration with stakeholders coming from government agencies, academic institutions and NGOs. The Council of ICON has also been working with EPA to review the best practices for nanomaterial safety (IRGC, 2006a).

At this point, it may be important to note that, whereas the relevance of IRGC and ICON has been mentioned in some documents (EC, 2006; EC, 2007b; Mantovani et al. 2010), none of them has been involved formally by the EU institutions. Furthermore, in comparison to TC 229 and OECD/WPMN, these arrangements have not established any formal collaboration with the key actors in Europe, such as the EU Commission for example.

2.5.2 Degree of Institutionalization

With regards to the *degree of institutionalization*, nanotechnology TGAs differ considerably in terms of their structure, membership and organizational goals. TC 229 and OECD/WPMN are the most organized working groups with secretariats, clear rules of membership, governance structure and decision-making procedures (Forsberg, 2010; Kica and Bowman, 2013). They have organized regular meetings for their members to share knowledge and information, and developed roadmaps that guide future actions and strategies. Such a well-defined structure has helped these arrangements to contribute substantially to shaping nanotechnology policy and communication agendas at transnational level, promote collaboration and harmonization, and establish regulatory governance mechanisms (e.g. standards, guidelines or other regulatory options) (Abbott et al. 2012; EC, 2008 & 2008a; Kica and Bowman, 2013).

ICON and IRGC have a moderate level of institutionalization. IRGC in the initial phases of its work on nanotechnologies developed an ad-hoc working group to provide an independent and cross-disciplinary approach to nanotechnology risks and hazards. However, this group does not have the same structure with clear rules for membership, formalized decision-making structures as well as strategies for future work, like TC 229 for instance. ICON, on the other hand, has also a moderate level of institutionalization. Compared to ISO and OECD, the working groups of ICON are less structured with few members and less formalized decision-making strategies. Of all TGAs, IFCS seems to have the most informal structure. IFCS operates under the intergovernmental regime of the WHO, but it considers itself as a "non-institutional arrangement", a forum that builds on the loose grouping of interested parties and experts, who come together to integrate national and international efforts to promote chemical safety (Mercier, 1995:886).

2.5.3 Functions and Regulatory Processes

With regards to *functions* and *regulatory processes*, it is clear that the nanotechnology TGAs reviewed in this chapter have all engaged in *agenda setting* and related preliminary steps. For instance, ICON and IRGC have focused mainly to push forward the international collaboration and coordination on nanotechnology safety and regulatory debate. They have served as leading fora for gathering information on the risks of nanoscale materials to inform future regulation and support coordination amongst decision makers on handling these issues (Breggin et al. 2009). However, none of these arrangements aims to go beyond information exchange and international coordination (Falkner and Jaspers, 2012: 23). In addition, the actual impact of the outcomes provided by these arrangements (such as reports of the workshops, *White Paper*, *Policy Brief*) seem to be marginal. There is no evidence yet that these outcomes are accepted or followed in practice. IFCS was a pioneer in identifying nanotechnology as an important part of the international chemical safety agenda. It aimed at sharing information and promoting coordination on nanotechnologies and MNs to increase awareness on the potential benefits, challenges and risks posed by nanotechnologies. However, given that FCS suspended its work, the recommendations provided in the *Dakar Statement* have not played a significant role in practice.

Other TGAs, such as OECD/WPMN and TC 229 have managed not only to place relevant issues on the policy and regulatory agenda, but also to draft and promulgate several standards and projects. As such they have moved towards the *negotiation stage*. For instance, OECD/WPMN has served as the main forum for gathering and exchanging information on the risk assessment of MNs. It has managed to establish projects that focus on providing a consistent approach to the testing of specific endpoints of representative MNs (as part of the *Sponsorship Programme*) (OECD, 2012a; Rauscher et al. 2014). These projects have led to specific recommendations provided by the OECD/WPMN. In particular, OECD/WPMN has recently published a recommendation on the *Safety Testing and Assessment of MNs* (OECD, 2013). This recommendation as Bowman (2014: 325) argues “signifies a substantial progress in addressing the human and environmental health and safety considerations associated with nanomaterials”. As such, it has already started to be implemented at the national level (i.e. by the Canadian government). In a similar way, TC 229 has also published several deliverables that call relevant actors to act in accordance to certain standards. TC 229 has been able to negotiate three international standards, as well as several TSs and TRs (see Section 2.5.4). The potential of these deliverables in the regulatory governance of nanotechnology is acknowledged in various documents (e.g. EC, 2008a; Abbott et al. 2012; NIA, 2013), but also by many stakeholders coming from industry, government and civil society organizations (see also Chapter 5).

2.5.4 Substantive Depth and Normative Scope

Regarding the *substantive depth* and the *normative scope*, a comparative look at these arrangements suggests that whereas all nanotechnology TGAs provide for voluntary non-binding rules that do not pose significant constraints on the behaviour of relevant actors, the *normative scope* of these rules differ. The *normative scope* of the outcomes of some TGAs seem to be narrower, focusing almost entirely on certain products (e.g. IFCS on safety aspect of MNs; OECD/WPMN on human health & environmental safety implications of MNs limited mainly to the chemical sector), settings (ICON - and *GoodNanoGuide* in particular - on workplace) or activities (IRGC on risk governance) (Abbott et al. 2012; OECD, 2011a). In contrast to these arrangements, TC 229 and its deliverables go beyond health, environmental and safety issues.

In the business plan of TC 229 it is clearly indicated that the Committee aims to set standards that would promote “good practice in the production, use and disposal of nano-materials, nanotechnology products and nanotechnology enabled systems and products” (ISO, 2012: 5).With its standards, TC 229 provides terminology and nomenclature, measurement techniques, calibration procedures, reference materials, test methods to detect and identify nanoparticles, occupational health protocols relevant to nanotechnologies, as well as risk assessment tools (Forsberg, 2010; Mantovani et al. 2009; Miles, 2007).

There are a number of deliverables produced by TC 229, which focus on the characterization of carbon nanotubes (e.g. ISO/TS 13278: 2011), single-wall carbon nanotubes (e.g. ISO/TS 10797: 2012; ISO/TS 10798: 2011; ISO/TS 10867: 2010), multiwall-carbon nanotubes (e.g. ISO/TR 10929: 2012; ISO/TS 11888: 2011) or titanium dioxide (e.g. ISO/TS 11937: 2012) (Rauscher et al. 2014). Other deliverables of ISO/TC229 are more general and address nanoparticles, nanomaterials or nano-objects (e.g. ISO/TS 10808: 2010; ISO/TR 11360: 2010; ISO/TS 12805: 2011; ISO/TS 12025: 2012; ISO/TR 13014: 2012). Some deliverables relate to health and safety issues (e.g. ISO/TR 12885), as well as toxicity testing issues (e.g. ISO 29701: 2010). In addition, with topics such as labeling entering within the TC 229 agenda (e.g. publication of the new TS on labeling - ISO/TS 13830: 2013), it appears that this Committee is taking also an active role in the debates related to the labeling of consumer products containing manufactured nano-objects. In this way, TC 229 deliverables are expected to provide the “best available options to industries requested to demonstrate product compliance with regulation” (EC, 2008a: 17). Therefore, in comparison to other arrangements, TC 229 deliverables seem to address a broader range of products, settings and activities. Furthermore, because the information in these deliverables is practical, complete and concrete they are considered to make important contributions in the field of nanotechnologies (Abbott et al. 2012: 311).

2.6. Conclusions

This chapter aimed to explain the role of different TGAs in the field of nanotechnologies and to discuss the key factors that drive the emergence of these arrangements. To answer the second sub-research question - *What are the current transnational governance arrangements for nanotechnologies and how can we assess their role in regulating this field?* - this chapter highlighted the growing importance of five key TGAs, such as: TC 229, OECD/WPMN, IRGC, ICON and IFCS.

In addition, building upon the current debates on the modes of governance and transnationalization, the chapter developed a typology to determine the main characteristics of nanotechnology TGAs. The typology focuses on six attributes and distinguishes governance arrangements on the basis of *actors involved, functions, degree of institutionalization*, the *regulatory stages* in which these arrangements contribute, as well as the *normative scope* and the *substantive depth* of transnational outcomes. This typology proved to be very useful to understand the main features and the role of different TGAs to contribute to the regulatory governance of nanotechnologies.

The analysis on nanotechnology TGAs suggest that IRGC and ICON have managed to gather a wide range of actors to contribute to the transnational governance of nanotechnology risk regulation. However, the impact of these arrangements in practice seems to be marginal. There is no evidence that the outcomes of these TGAs are followed in practice. The role of IFCS is less promising given that the Committee of this Forum (i.e. FCS) agreed to suspend its work on nanotechnology related issues. In comparison to these TGAs, OECD/WPMN and TC 229 have ensured the political support and collaboration with key actors in Europe, established higher level of institutional structure, and engaged in various functions and activities. Furthermore, evidence suggests that stakeholders (even though limited in numbers) have already started to implement the outcomes of these arrangements (such as the OECD/WPMN Recommendation, as well as some TC 229 deliverables). However, the strategies developed by TC 229 to establish strong linkages with a wider range of private and non-private stakeholders, as well as the *normative scope* of TC 229 deliverables, place this arrangement in a better position to take a lead on the transnational regulatory governance of nanotechnologies.

The potential of this transnational organization that operates beyond the state level and is characterized with complex structures and transnational actors, brings forward many questions of legitimacy. In TC 229 the rule-making authority rests on the hands of those who are "neither elected nor managed by elected officials" (Thatcher and Sweet, 2011: 2). In addition, the structure of TC 229 emphasizes that this Committee is a clear example of TPGA, characterized by the interaction of various public and private actors, where industrial actors are dominating. As such, this governance arrangement raises many questions over the clear lines of accountability and inclusiveness, sources of decision-making, as well as reasons for social acceptability. I address these questions in the next chapters.

Chapter 3

3. Conceptualization of the Legitimacy of Transnational Private Governance Arrangements Related to Technology Regulation[66]

3.1. Introduction

In this chapter I address the second sub-research question: *How can the legitimacy of transnational private governance arrangements related to nanotechnologies be conceptualized and operationalized?* The chapter begins with a reflection on the main legitimacy challenges characterizing technology related TPGAs (Section 3.2). Since these arrangements differ from the traditional state-based developments, I firstly reflect on the challenges that TPGAs pose to the traditional concepts of legitimacy, such as national sovereignty, state-centric conceptions of constitutional and democratic governance, as well as accountability and deliberation. However, given that technology related TPGAs are operating in a dynamic environment characterized by rapid technological developments, socio-environmental changes, transdisciplinary research, as well as uncertainties surrounding contemporary science, I also reflect on other legitimacy challenges. These challenges relate mainly to the quality of expert knowledge and the scientific evidence underlying transnational decision-making.

In Section 3.3 I review the debate on the main legitimacy perspectives. I reflect on the normative and empirical accounts of legitimacy by discussing the core legitimacy ideas of Weber (1964 & 1978), Habermas (1979 & 1988), Beetham (1991), Suchman (1995), Scharpf (1999) and Schmidt (2010), to mention just a few. Afterwards, I explain the main legitimacy approach that is followed in this thesis. Building upon the challenges identified in Section 3.2 as well as the legitimacy perspectives identified in Section 3.3 the chapter proceeds to address how the legitimacy of technology related TPGAs can be conceptualized and evaluated in practice. In Section 3.4 an analytical framework to understand the legitimacy of TPGAs is developed by reconceptualizing the notions of input, throughput and output legitimacy. I explain the interaction between these notions diagrammatically. Important elements for developing the analytical framework are also the procedural and substantive norms of legitimacy, which guide

[66] A previous version of this chapter was presented at the 5th Annual Conference Meeting of Society for the Study of NanoScience and Emerging Technologies (S.NET), October 27-29, 2013 Northeastern University, Boston; and the INTERNORM Workshop - When civil society joins technical diplomacy: prospects and limits of participation in international standardization, March 19, 2013 University of Lausanne, Switzerland.

TPGAs and provide the basis for their legitimacy. In Section 3.5 I operationalize the main legitimacy norms that are used in the analytical framework, such as: *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes*. An operationalization is provided for each performance indicator as well. Following this operationalization, in Section 3.6 I develop an evaluative matrix for assessing the legitimacy of technology related TPGAs by using the legitimacy norms and performance indicators described in Section 3.5. In Section 3.7 I provide some concluding remarks.

3.2. TPGAs Related to Technology Regulation and the Challenges of Legitimacy

One of the main legitimacy challenges accompanying technology related TPGAs is that these arrangements do not build on legislative competences. They involve soft regulatory frameworks, such as industry guidelines, standards, benchmarks, recommendations, as well as certification schemes (Majone, 1999; Davies, 2005; Thatcher and Sweet, 2011). Traditional concepts of legitimacy focus on the exclusive authority of the nation state to make collectively binding decisions and provide for public goods. Key principles of these concepts are national sovereignty, constitutionality and democracy. However, TPGAs pose challenges to these principles. They are not established through legal mandates nor involve the components of parliamentary representation. In this way, many challenges arise in determining who should participate in the decision-making processes of these arrangements or ensuring a deliberative decision-making that responds to the requests of all interested parties. Further legitimacy challenges relate to the involvement of experts in regulatory decision-making, as well as the quality of scientific expertise.

For many years, the traditional models of sovereignty considered the nation-state to be the single legitimate source of authority on the world stage, with exclusive power to make collective binding decisions and provide for public goods (Schapiro, 2008: 801 & 803; Papadopoulos, 2011). According to this framing, which has been called the *Westphalian notion of sovereignty*, the nation state functions as the main *locus* of interaction between local and foreign governments (Krasner, 2009). National boundaries are firm and international law consists mainly of rules governing nation states or relations amongst national governments (Schapiro, 2008). However, the transnationalization of technologies, trade and communication, as well as environmental concerns have transformed the national boundaries of the *Westphalian* model. As a consequence of transnationalization, the “authoritative domain” of transnational technology regulation and its sphere of influence does not coincide anymore with territorial boundaries

(Schepel, 2005; Jayasuriya, 2005:82). As mentioned in Chapter 1 (Section 1.2) and Chapter 2 (Section 2.5), new forms of governance arrangements build on (loosely) structured networks beyond the state level. These arrangements are established through the cooperation of a wide range of private actors and NGOs, which do not constitute legally sovereign entities. As a result, sovereignty is no longer nested in the state level (Jayasuriya, 2005; Slaughter, 2004).

The emergence of TPGAs has also put pressure on the traditional state-centric conceptions of constitutional governance. Constitutions have been traditionally designed to frame the functioning of the state on the basis of hierarchic sets of competences that are attributed by law (Joerges at al., 2004; Rosenfeld, 2001; Scott et al. 2011). However, TPGAs do not function within such a constitutional framework (Black, 2008). They instead function within a heterarchic and "open constitution" that builds on various sources of regulatory authority (Backer, 2012). At transnational level, and specifically with TPGAs (e.g. international standards), different models of rule formation and enforcement are used. In these arrangements, the rule-making takes place at transnational level, whereas rule enforcement and/or monitoring are performed at national level (Caffaggi, 2010). As such, the application of the traditional constitutional criteria based on the rule of law becomes difficult. In particular, it is challenging to determine what legal principles to be followed or what "global" values to be pursued (Weiss, 2000).

TPGAs pose challenges to the state-centric conceptions of democratic governance. This principle means that citizens should be bound only by laws, which build on democratic procedures (Schepel, 2005; Dorbeck-Jung, 2008). However, at transnational level the existence of global *demos* is absent and the remaining challenge is to determine who should be involved in the decision-making processes of these arrangements (Black, 2008). TPGAs are established, implemented and enforced by private actors and experts (Black, 2008; Schmidt, 2010; Mayntz, 2010; Hinsch, 2008; Thatcher and Sweet, 2011; Hachez and Wouters, 2011; Steffek and Pereira, 2011). For instance, transnational standardization bodies usually consist of industry representatives, top-level bureaucrats, societal organizations or policy experts (Abbott and Snidal, 2008; Black, 2008; Djelic and Sahlin-Andersson, 2006; Papadopoulos, 2007; Cadman, 2011; Hallström and Boström, 2010). Most of these actors are not mandate holders or "constrained by electoral pledges" (Papadopoulos, 2007:476). While some of them may be authorized to represent certain (social) interest groups, others may justify their participation by virtue of their expertise or economic interests. In this way, the state-centric conceptions of democratic governance have become questionable.

TPGAs have also put pressure on the traditional conceptions of accountability (Kumm, 2004). According to Bovens (2007: 450), accountability refers to the "relationship between an actor and a forum, in which the actor has an obligation to explain his or her conduct, the forum can pose questions and judgments and the actor may face consequences". As such, accountability can serve as a precondition for the rulers to be responsible for their actions and convince the ruled that they "have lived up to justified expectations" (Dorbeck-Jung, 2008: 56).

At transnational level, governance structures do not build on a single relationship between the regulator and the regulatees, but on several interconnections between the decision-makers and different constituencies (Benz and Papadopoulos, 2006). In these arrangements the responsibility for decision-making often is dispersed amongst a large number of actors (Papadopoulos, 2007), and their involvement can change during the regulatory process (e.g. some stakeholders can be more active during the initial stages of agenda setting, and some others during the decision-making and enforcement processes) (Kica and Bowman, 2012). Often, many actors from national and international level participate to argue on the "good" that transnational regulation should pursue (Black, 2008). This leads to the "problems of many hands" (Bovens, 2007:457). Contrary to the unitary structures of domestic regulation, at the transnational level the obligations of each actor are not strictly formulated, and there is a lack of clear understanding on who participates and influences the outcomes of the governance arrangement (Benz and Papadopoulos, 2006). This in turn creates serious implications for determining who should be held responsible for the decisions made.

A further challenge related to the legitimacy of technology related TPGAs is that of deliberation. Given the non-binding nature of the transnational rules, deliberative decision-making processes have become crucial to underpinning the authority of transnational rules (Beisheim and Dingwerth, 2008; Benz and Papadopoulos, 2006). However, TPGAs build on the complex interaction of state and non-state actors, who are likely to perceive technology, risk and policy developments differently (Koskenniemi, 2007). For instance, what may be a reasonable choice for an environmental expert, it may not be reasonable choice for a chemical manufacturer or a representative of the population (Koskenniemi, 2007). As a result, it becomes difficult to reconcile these divergent perspectives or utilize shared interests so that a consensus is achieved.

With the pace of technology developments and the high degree of scientific uncertainties, new modes of engagement have emerged. These modes propose the inclusion of all relevant stakeholders from the earlier stages of technology research and development (Sciencewise-ERC, 2010). However, questions remain about the proper knowledge and resources that stakeholders need to ensure a meaningful inclusion (NCB, 2012; Wynne, 2006; Carrier, 2010). As Tait (2009) indicates, the asymmetric allocation of power, resources and capacities puts smaller groups in a disadvantaged position, since they often are influenced by stakeholders who have better opportunities to support inclusion in these regulatory processes. As such, many questions appear with regards to who is driving and influencing the decision-making processes? Or whether transnational rules result from the deliberative discussions among stakeholders?

Other challenges to the legitimacy of the technology related TPGAs are the quality of expert knowledge as well as the scientific evidence underlying transnational decision-making. Given that technology and science in some areas are still uncertain and incomplete, reliance on experts' decisions has been highly contested (Bäckstrand, 2004). In particular, the main issues relate to the knowledge of experts, and their skills and ability to provide an accurate contribution. The political turmoils with the Chernobyl accident in 1980s, the Britain's infamous 'mad cow' disaster of the 1990s, as well as the setting of mobile phone antennas and GMOs, illustrate clearly that scientific experts (at least in some countries) no longer have an unquestioned authority (Borrás, 2006; Borraz, 2011).

Furthermore, there is the internal institutional challenge for technology related TPGAs to ensure that experts provide for trustworthy scientific judgments (Bäckstrand, 2004; Carrier, 2010; Weingart, 2008). TPGAs assemble various actors, who volunteer to set regulatory rules and are free to select their own evidence to contribute to the debates of technology regulation. As these actors are not elected through traditional democratic processes, there are high expectations that they would contribute merely by virtue of their "acknowledged intellectual capital" (Papadopoulos, 2007: 8). However, research in other techno-scientific areas indicates that the volunteer contribution of experts may often be susceptible to a range of "cognitive or motivational biases", including various personal and political beliefs (McBride et al. 2012; Papadopoulos, 2007: 8).

A further challenge relates to the robustness of evidence (Carrier, 2010; Weingart, 2008). Different from other regulatory fields with low level of uncertainty, TPGAs, and specifically those related to emerging technologies, are occurring at a stage when the technology is characterized with a lack of mature scientific knowledge and evidence. This has created an anxious situation, with many actors questioning the prerogatives of experts in making informed decisions on transnational technology regulation (Cantelli et al. 2011).

However, concomitant to these challenges have been the expectations on the potential of technology related TPGAs to foster technological innovation (Breggin et al. 2009; Groves et al. 2008; Quack, 2010). As such, the remaining dilemmas relate to how the exercise of power at the transnational level can be justified; how compliance or obedience with transnational rules can be explained; or what the main sources of legitimacy are. I provide detailed analysis on these questions in the forthcoming sections. First I reflect on the normative and empirical conceptions of legitimacy and afterwards provide a framework for analyzing the legitimacy of TPGAs in practice.

3.3. The Normative and Empirical Perspectives on Legitimacy

When developing a framework to analyze the legitimacy of collective action a preliminary step is to decide upon whether the research will take a normative or an empirical perspective. The normative perspective aims to justify why a certain rule should be regarded as binding (Steffek, 2003). An important element of this perspective is the recognition that a governance arrangement has a moral authority to impose obligations. According to this framing, the governed obey to a valid order that conforms to the principles that can be morally justified (Beetham, 1991). It focuses on the objective criteria that an arrangement must meet in order to be considered as legitimate (Hinsch, 2010; Zürn, 2004). Similar arguments can be traced back to the work of Jürgen Habermas (1979: 178-179), who claimed that "legitimacy means that when there are good arguments for a political order's claim to be recognized as right and just - a legitimate order deserves recognition". Following this framing, the normatively justified validity depends on the basic norms that justify the authority of the ruler (e.g. democratic pedigree, values that the ruler is pursuing, transparency, expertise) (Bodansky, 2011; Dingwerth, 2007; Habermas, 1988). In this way, as Steffek (2003: 253) argues, legitimacy is a "normative quality that is attributed by theorists to a particular system […] on the basis that it is established in accordance to certain principles". However, the normative perspective does not explain the attitudes or the perceptions of individuals on whether they accept and support the domination of a political order or arrangement in practice.

Max Weber made the first steps towards conceptualizing legitimacy as an empirical fact (Weber, 1964). The empirical approach focuses on explaining how legitimacy is experienced in practice, and to what social action this experience leads. In Weber's view legitimacy in practice is based on the authority to govern, i.e. "to find obedience" (Weber, 1964:123-124). Therefore, a governmental action, or in Weber's words "a command with a given specific content", will be considered as legitimate "if it is approved or obeyed by a given group of persons" or "by those it seeks to govern" (Weber, 1978: 53). There are two key elements that comprise Weber's formulation of legitimacy: the "notions of belief" and "acknowledgment by the governed". Weber does not focus on the existing means of coercion. He holds that the existence of an enforcement staff is a sufficient precondition for authoritative legitimacy (Weber, 1964: 18;

Dorbeck-Jung, 2009). According to Weber authority is more than power; it is a relational concept. In addition to being able to exert influence on social action (power), authority requires at least a minimum of will or consent of the governed to obey (Weber,1964: 325). Therefore, the rulers also seek to gain the belief of the governed in their legitimacy. Given that coercion is not a typical feature for transnational legitimation, the beliefs of individuals or groups are of crucial importance for assessing empirically the legitimacy of these governance arrangements as well.

But, why and when shall a given rule or an arrangement be accepted as legitimate? What would be the specific types of legitimation that could justify the authority of an arrangement to govern? Weber answers these questions by referring to the sources of legitimate domination or authority. He distinguishes between three sources of legitimation that justify the power of command: the *traditional*, *charismatic* and *rational-legal* authority. The first principle of legitimation is based on *traditional* grounds. According to this framing, command and obedience are considered to be legitimate on the basis of traditions or beliefs in the sanctity of long established traditions. Legitimacy may be equally founded in *charisma*, which is based on the extraordinary trust that the ruled have for the rulers. *Rational-legal* authority (which is identified with *legality* by Weber) rests on the beliefs of the enacted rules and the assumptions that the organization seeks the good of everyone and merits support accordingly. Weber considered *rational legitimacy* as the "only type of legitimacy to survive in the modern world", since it focuses in "command which is given in the name of an impersonal norm". In this way, obedience is based to the rules that are fixed as laws, rather than to individual persons (Weber, 1978: 217-219; Steffek, 2003: 260-263).

Rational legitimacy gives an absolute priority to the valid law, which possesses its own rationality and is established through "strict judicial and administrative procedures" (Habermas, 1984:75). Luhmann (2004) also argues for the predominant role of the law in justifying authority. Under this framing, the legitimization of a system or the authority of law would be value-free and independent from the political, moral or social forces. Rules would be accepted as legitimate merely because of their *legality*. Building upon the organizational characteristics of Weber's modern bureaucracy[67], Steffek (2003: 261) argues that in "an idealized sense"-

[67] Amongst the most important part of Weber's work is his theory of bureaucracy. According to Weber (1964) bureaucracy is a particular type of administrative structure, which is developed through the rational-legal mode of authority. In the view of Weber bureaucracies are goal-oriented organizations, which are ranked in a hierarchical order (subordinates follow the orders but they have the right to appeal) and function according to impersonal rules that state responsibilities, procedures and conduct to office holders. Furthermore, in these organizations officials are appointed (not elected) based on technical (specialized) qualifications. He defines six features that characterize a bureaucracy: "1) it covers a fixed division of labour amongst participants, which is governed by rules; 2) it is organized as a hierarchy, with information flowing up the chain of command, directives flowing down; 3) action that is undertaken is based on written documents; 4) expert training is needed (specialized division of labor); 5) officials devote their full activity to their work; 6) the management of the office follows general rules which can be

international bureaucracy fulfills the criteria of modern *rational-legal* legitimation more than any other system. In this way, international bureaucracy is the perfect bureaucracy, because obedience is owed to rules/laws that are equal for everyone. However, the dilemma with the *rational* model is whether *legality* is sufficient source of legitimation or do we need other sources that will influence people's belief in legitimacy? On what grounds should these beliefs derive from?

Beetham (1991) and Habermas (1988a) take up these points by adding other elements, which are crucial for the empirical assessment of legitimacy. In his book "*The Power of Legitimacy*" Beetham (1991) suggests that Weber's three ideal types of authority build on the application of three different types of beliefs that cannot be jointly applied to define the notion of legitimacy. Beetham goes on to develop three main criteria, which together define the notion of legitimate power or authority. According to Beetham, power is considered legitimate to the extent that:

1) it conforms with established rules (*legality*),
2) is justifiable according to the shared norms and beliefs (*normative justifiability*), and
3) is confirmed through actions expressing consent (*expressed consent*) (Beetham, 1991: 20 & 38).

In this way, similar to Weber's arguments, Beetham also views legitimacy as a relational concept. However, in contrast to Weber (1978), who conceptualized legitimacy as a matter of fact, Beetham argues that legitimacy should be a matter of degree, rather than an all-or-nothing dichotomy (Beetham,1991). The exercise of a legitimate power is not "as volatile as an opinion", but it needs to be justified on whether it resonates with the beliefs of the people or whether it confirms with their values (Beetham, 1991; Montpetit, 2007: 3; Sanders et al. 2014).

Building upon Weber's concepts of rationality and modernity, Beetham (1991) and Habermas (1996) indicate that modern legitimacy is derived from the *authority of reason*. According to this framing, rules would be accepted as legitimate if they are backed by a *rational justification* and *deliberation*. This implies that parties in the decision-making process can meaningfully communicate the reasons on which decision is based. Max Weber highlights the importance of "giving reasons" in the context of societal modernization (Weber, 1978). Nevertheless, his *rational* model seems to be detached from any substantive beliefs or principles according to which legal rules can be justified (Beetham, 1991: 24).

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learned" (See Swefberg, R and Agevall, O., 2005. *The Max Weber Dictionary: Key Words and Central Concepts*, Stanford University Press. pp. 18-21; Weber, M., 1964. *The Theory of Social and Economic Organization*. Edited by Talcott Parsons. New York: Free Press).

The fact that rules would be accepted as legitimate because they are set through legal procedures is a necessary, but not a sufficient condition for legitimacy (Grafstein, 1981). Rule-making must be based not only on reasons, but also on rationally debatable reasons (Habermas, 1996). Empirically this would require an assessment of the procedural and distributive justice. More precisely, judgments about the way authority is exercised, which includes the quality of decision-making, stakeholder treatment, fairness, equity and so on (Tyler and Fagan, 2008).

In his three-tier hierarchy of organizational legitimacy (i.e. *pragmatic legitimacy*, *cognitive legitimacy* and *moral legitimacy*), Suchman (1995) also argues about the importance of the socially accepted procedures to justify the legitimacy of a particular order. In his framing, *moral legitimacy* consists of two parts: the *procedural* and the *consequential legitimacy*. *Procedural legitimacy* argues for the importance of the procedures to justify the "good-faith efforts of the organization […] to achieve valued ends" (Suchman, 1995: 581). *Consequential legitimacy* focuses merely on the benefits and the problem solving capacity of the decision-making outcomes. It argues for the substantive rationality of the decisions made.

In addition to these normative perspectives, Suchman (1995) suggests that consent to a legitimate order may derive from other motives as well. These are to be found on the mere acceptance of a social order as inevitable "based on the taken-for-granted cultural accounts" (i.e. *cognitive legitimacy*) or because it satisfies the interests of the ruled (i.e. *pragmatic legitimacy*) (Suchman,1995:580-582). In this way, the basis for the recognition of a social order derive from different sources, which cannot be found in pure isolation from each other. However, at transnational level, institutions cannot gain an "unquestionable" right to govern (i.e. *cognitive legitimacy*) from formal legal mandates or statutes. Nor through coercion or binding mechanisms. Their functioning rests merely on institutionalized practices and norms, and on voluntary outcomes that aim to contribute to technological and/or regulatory complexities and uncertainties. In this way, procedural legality and substantive rationality have become the main sources for analyzing the legitimacy of transnational regulatory developments (Mayntz, 2010).

In this thesis, as indicated in Chapter 1, legitimacy is used as a concept that describes an empirical fact. Legitimacy is considered as a relational concept between the transnational governance arrangement (in this case TPGA) and stakeholders. In particular, with the term legitimacy I aim to describe the fact that a certain group of people (in this case stakeholders) perceive a TPGA and its outcomes as legitimate, on the grounds that they:

1) believe that the legitimacy norms, which guide TPGAs and promote the setting of transnational rules are effectively taken up in practice,
2) perceive the outcomes of TPGAs to present effective regulatory solutions, and

3) voluntary comply with these outcomes.

Therefore, the aim of this study is to make an assessment of the extent to which stakeholders perceive a governance arrangement and its outcomes as legitimate. In the absence of the global *demos* at transnational level, in this thesis the concept of stakeholders is associated with that of a sectoral *demoi*. The concept of sectoral *demoi* refers to actors who are likely or willing to participate in an arrangement in order to regulate the issue at stake (Hachez and Wouters, 2011), because they "have an interest on the issue under consideration, are affected by the issue or have an active influence in the decision-making and implementation processes" (Varvasovszky and Brugha, 2000: 341).

Following this approach, I have identified many stakeholders interested in the activities of the nanotechnology TPGAs, such as TC 229. These stakeholders include, for example*:*

- *policy makers* (such as government agencies, beaurocrats, national and international regulatory authorities, regulatory agencies);
- *research institutions* (such as universities, public/private research centers, laboratories); *industry associations*; *business and professional organizations* (including lobbyists, many of the Fortune 500 companies);
- *users* (downstream manufacturers, who are affected by standards; organizations that use standards for their production purposes; as well as end users such as consumers);
- *certification agencies and small and medium enterprises* (SMEs);
- *NGOs*; *public health*, as well as *environmental* and *labor organizations* (e.g. "green" associations and large transnational labor organizations) (Arnaldi et al. 2010; Mantovani and Porcari, 2009; Mantovani et al. 2009).

Building on the work of Rip and Kulve (2008), Forsberg (2012) indicates that within TC 229 we can observe two types of stakeholders: the "*technology enactors*" and "*technology selectors*". *Technology enactors* are the technology developers and promoters. Developers and promoters include scientists, business managers and governmental agencies responsible for technological developments. In contrast, *technology selectors* include regulatory agencies working on EHS issues, with new stakeholders such as consumers, environmental groups and spokespersons for society (Forsberg, 2012; Kica and Bowman, 2012; Rip and Kulve, 2008).

In Section 3.4 I develop a framework that serves to analyze the legitimacy of TPGAs related to technology regulation in practice. Afterwards, I identify the key legitimacy norms and performance indicators that provide the basis for the legitimacy of these governance arrangements (Section 3.5), and develop an evaluative matrix against which the legitimacy of TPGAs can be assessed (Section 3.6).

3.4. A Theoretical Framework for Analyzing the Legitimacy of TPGAs in Practice

In the analysis of the legitimacy of transnational governance many scholars refer to the model of Fritz Scharpf, which was originally developed to address the "democratic deficit" of the EU. In the following paragraphs, the core ideas of Scharpf will be discussed and extended. Scharpf, distinguishes between the dimensions of input and output legitimacy (Scharpf, 1999). Both dimensions build on the norms of "good governance". Input-oriented legitimacy refers to governance "*by the people*", whereas output-oriented legitimacy addresses governance "*for the people*" (Scharpf, 1999: 2). The underlying normative assumption of governance "*by the people*" is that it reflects the "will of the people"; the political choices are derived from "the authentic preferences of the members of the community" (Scharpf, 1999: 6). According to Scharpf, input legitimacy is oriented towards legitimation through the "participation" and "consensus" of the citizens (or citizens' representatives) affected by a decision. Output legitimacy focuses on the substantial quality of the outcomes. Scharpf connects output legitimacy with the capacity of the governing authority to produce outcomes that "effectively solve problems requiring collective actions" or "effectively promote the common welfare of the constituency in question" (Scharpf, 1999: 11). Both input and output legitimacy are considered necessary. However, Scharpf indicates that input legitimacy is achieved by a "pre-existent collective identity" and the belief in "essential sameness" (Scharpf, 1999:8). Given that in the EU there is little collective European identity and no European *demos*, Scharpf argues that EU should be legitimized in output terms. One of the main reasons put forward by Scharpf is that for output legitimacy the existence of "common interests" is more important than "common identity" (Moravcsik and Sangiovanni, 2003).

According to Thomas Risse (2004), Scharpf's arguments on supranational policy can be valid for TPGAs, because these arrangements similarly lack a transnational *demos* and a transnational identity. Risse (2004: 16) argues that if the arguments of Scharpf on legitimacy are followed in the context of transnational governance arrangements that would mean that the increase in output legitimacy or more specifically the effectiveness of transnational rules to tackle global issues (e.g. in international security, human rights, environment etc) could compensate for the lack of "participatory input" by actors affected by the rules.

However, the main issue with TPGAs is that it is difficult to measure the effectiveness of transnational rules to solve global issues. For instance, in the case of TPGAs related to new technologies, transnational rules have a very brief lifespan (e.g. nanotechnology standards are established recently) and there is a lack of certainty about the application of these rules in practice (Forsberg, 2012; Kica and Bowman, 2012). Furthermore, TPGAs do not regulate on the basis of binding decisions and their outcomes are not universally accepted. As a result, it is difficult to rely only on the effectiveness that these outcomes have or will have on relevant issues (Börzel and Risse, 2005; Risse, 2004).

Recognizing these difficulties, institutionalist theorists and scholars of deliberative democratic theory argue that TPGAs may ensure a wider acceptance of their rules and justify that they are trustworthy by increasing the validity of the procedures by which rules are developed and implemented (Black, 2009; Hachez and Wouters, 2011; Papadopoulos, 2007; Schmidt, 2010; Suchman, 1995). According to this framing, the belief in the legitimacy of governance arrangement relies on the so-called "logic of appropriateness" according to which actors will follow rules "to the extent that rules have come into being in accordance with the right process" (Beisheim and Dingwerth, 2008:9; Hurd, 1999&2011). The reasoning behind this is that the more those affected by transnational governance are involved in rule-making processes to discuss and communicate the reasons on which decisions are based, the better compliance will be. These arguments for the justification of decisions by argument link closely to the ideas of Jürgen Habermas on *deliberation* - which often is accepted as a significant means for the legitimation of TPGAs (Habermas, 1979; Mayntz, 2010:10). Contrary to the traditional aggregative approaches of democracy in which voting is the primary mechanism for selecting preferences and determining outcomes, in transnational arrangements a deliberative decision-making is required to promote a communicative consensus amongst all parties (Cadman, 2011:14-16).

Building upon similar arguments related to deliberative decision-making processes, Vivien Schmidt (2010)[68] adds another dimension of legitimacy, specifically the throughput legitimacy. In Schmidt's words, throughput legitimacy relates to the notions of governance "*with the people*". It refers to the quality of the processes by which decisions are made. According to throughput legitimacy, the decisions of a governing authority are legitimate if they result from processes that have assured a fair consultation with the people and exchange of plural visions (Schmidt, 2010). Schmidt goes on to connect throughput legitimacy with transparency, and the responsiveness of policy makers for the decisions made. According to Schmidt the three dimensions of legitimacy (i.e. input, throughput and output) can be analyzed

[68] It is important to note that throughput legitimacy has been used previously by Michael Zürn to analyze legitimacy of governance beyond the state. See: Zürn, M.,1998. *Regieren jenseits des nationalstaates: Globalisierung und denationalisierung als chance*, Suhrkamp 1. Aufl Edition (pp. 236-240).

from an *institutionalist* and *constructivist* perspective. The first perspective relates to the formal institutions, mechanisms and procedures that a governance arrangement establishes to provide for a realistic chance that its decisions are made "*by the people*", "*with the people*" and "*for the people*". The *constructivis*t approach, on the other hand, focuses on the beliefs of the citizens that "input politics, throughput processes and output policies […] are morally authoritative and they therefore voluntary comply with government acts" (Schmidt, 2010: 9).

The analytical dimensions of Fritz Scharpf and Vivien Schmidt are useful starting points for the broader model of legitimacy that this thesis aims to develop. They provide for various norms that are important to analyze and understand the legitimacy of governance arrangements beyond the state level. However, in their conceptualization of legitimacy, Scharpf and Schmidt consider representative democracy as the key basis for input legitimacy. The issue is that TPGAs related to technology regulation are not dealing with "citizens expressing demands through representative politics, while providing support via their sense of identity and community" (Schmidt, 2010: 8). In contrast, these TPGAs are dealings with the representatives of organized groups of stakeholders, who are likely to join a governance arrangement in order to influence a sector-specific issue. As such, participation by representatives of organized groups of stakeholders has become an alternative for input legitimacy at transnational level (Maytnz, 2010).

Another issue with the analytical approaches of Scharpf and Schmidt is that their conceptualization of legitimacy focuses primarily on democratic principles. Their focus on the role of expertise as a specific criterion in the legitimacy of governance arrangements is marginal. As Mayntz indicates, the main drawback of democratic legitimacy is that it finds representative democracy and deliberative processes as sufficient conditions for generating acceptable outcomes, without explicating on the role of expertise (Maytnz, 2010:11). At the transnational level, engagement with key stakeholders and attempts to ensure that regulatory processes are guided by appropriate procedural norms are the main basis for ensuring transnational legitimacy (Forsberg, 2012). However, the problem solving capacity of TPGAs and their rules depends largely on expert knowledge (Mayntz, 2010; Quack, 2010). According to Willke (2007) and Carrier (2010), one of the silent derivatives of legitimacy in cases of complexity and uncertainty is expertise (Carrier, 2010; Willke, 2007). At this point, the knowledge of experts and trust in experts' judgments have become important basis for decision-making, which complement the traditional norms of throughput legitimacy (Carrier, 2010; Take, 2012; Willke, 2007). In the legitimacy framework that I provide in this chapter (see Section 3.5), trustworthy expertise is considered as an important norm for the legitimacy of TPGAs, along with other norms of legitimacy.

Following Kees Van Kersbergen and Frans Van Waarden (2004), I develop a different view on input legitimacy.[69] In my view, input legitimacy refers to the "rules of the game", which do not include only the legitimacy norms aligned with the dimensions of the governance "*for the people*", but also include a variety of legitimacy norms aligned with the dimensions of the governance "*with the people*" and "*of the people*". In this way, I expand the concept of input legitimacy by focusing on these norms of legitimacy (i.e. rules of the game): *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes*.[70] These "rules of the game" guide TPGAs and provide the basis for their legitimacy. In the next section , I explore in more details the content of these norms.

Building on the idea that throughput legitimacy aims to assess the interdependencies of the different legitimizing mechanisms and their reinforcing potential (Schmidt, 2010), I propose to assess in this part the extent to which stakeholders believe that the legitimacy norms or the "rules of the game" are effectively taken up in practice. My main focus is to understand stakeholders' beliefs with regards to the norms that promote the setting of legitimate transnational rules, such as: *meaningful participation, deliberative decision-making, effective process control* and *trustworthy expertise*. In this way, throughput legitimacy emphasizes what goes on inside the TPGA. This understanding enriches the research model with an exploration of the use of the legitimacy norms in practice, which is essential to assess the output of a governance arrangement.

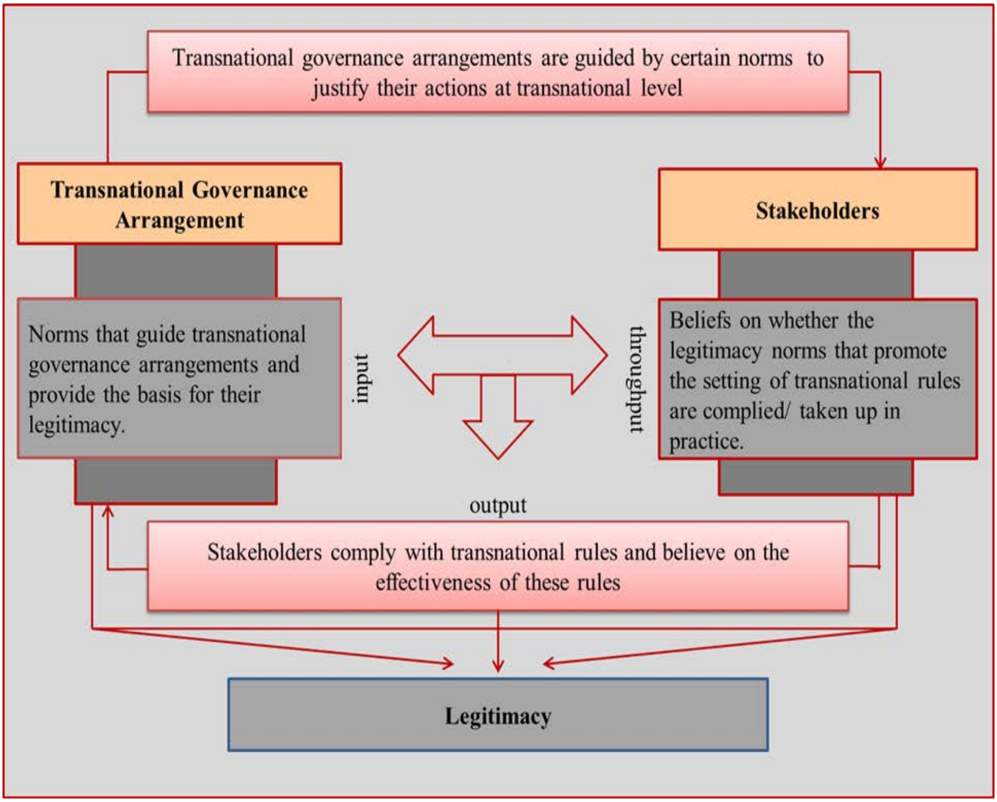
In my view, output legitimacy refers to the capacity of the governance arrangement to provide *implementable outcomes*. Outcomes which have high potential to work in practice because of their effectiveness and capacity to influence the behaviour of rule addresses. This understanding is closely related to what Scharpf and Schmidt frame as "outcome-effectiveness" and "outcome-compliance" (Scharpf, 1999; Schmidt, 2010). As mentioned earlier, Scharpf associates output legitimacy with the effectiveness in problem solving capacity, but over the past years new categorizations adding to output legitimacy have been presented. Output legitimacy is

[69] Van Kersbergen and Van Waarden (2004:148-158) provide important discussions on the legitimacy of new arrangements of governance. They relate the concept of input legitimacy to the "rules of the games"-which are negotiated and agreed by network participants to guide or control their behaviour in the network. Van Kersbergen and Van Waarden (2004) consider the process by which specific policies are established as an additional element that remains outside of the "rules of the game". In our view, input legitimacy is broader and the norms related to the process of decision-making are also part of the "rules of the game" (see the main text above).

[70] Bäckstrand, 2004; Baldwin and Black, 2008; Beisheim and Dingwerth, 2008; Cadman, 2011; Carrier, 2010; Forsberg, 2012; Vinkhuyzen and Vihma, 2009; Lövbrand et al. 2011; Mayntz, 2010; and Take, 2012, reflect on various norms that promote the setting of transnational rules. See Chapter 4 (pp. 113-114) for detailed explanation on the selection of these norms.

associated also with the effectiveness of the governance arrangements to generate outcomes that satisfy the interests of the ruled and demonstrate clarity or determinacy (Maytnz, 2010; Suchman, 1995; Franck, 1998; Finnemore and Toope, 2001). In addition, the implementation potential of transnational rules depends largely on whether affected parties are willing to adhere or act in accordance to these rules (Beisheim and Dingwerth, 2008; Vinkhuyzen and Vihma, 2009). My conceptualization of output legitimacy builds on similar concepts. Output legitimacy is determined by stakeholders through: a) beliefs on the effectiveness of transnational rules, and b) compliance with these rules. Figure 3.1 depicts the framework I use to explore the legitimacy of TPGAs related to technology regulation.

Figure 3.1: A Framework for Analyzing the Legitimacy of Technology Related TPGAs in Practice



3.5. Explaining the Key Legitimacy Norms Relevant for TPGAs Related to Technology Regulation

As mentioned in Section 3.4 scholars have identified various norms that are relevant for the legitimacy of technology related TPGAs. These norms are important as they act as a means to guide the legitimate behaviour and the decisions of these arrangements. The main focus in this thesis is on five key legitimacy norms :

1) *meaningful participation,*
2) *deliberative decision-making,*
3) *effective process control,*
4) *trustworthy expertise,* and
5) *implementable outcomes*.

Next to these norms I have identified certain performance indicators, which serve as parameters for demonstrating compliance with the legitimacy norms. In the following sub-sections, the operationalization of the norms and performance indicators is provided on the basis of the relevant literature.

3.5.1. Meaningful Participation

In the discussion of the legitimacy dimensions, participation is seen as the key component of the “good governance”. Here the main norm is that participation should be *meaningful* - meaning that the governance arrangement provides appropriate opportunities and resources for the interested parties to participate actively in developing transnational rules. *Meaningful participation* is comprised of three performance indicators:

1) *inclusiveness,*
2) *representation,* and
3) *resources.*

Inclusiveness refers to the scope of stakeholder participation. In particular, to the possibility for as many stakeholders as possible to get involved in a governance arrangement. *Representation* refers to the quality of participation. At transnational level, stakeholders come from various countries and sectors, with different power and resources (Dingwerth, 2007; Take, 2012). This may lead certain actors to be under represented in the process or participate on *ad-hoc* basis only. As a result, actions need to be made by respective authorities to correct these asymmetric allocation of power and ensure that all stakeholders have equal participation rights to be actively represented. *Representation* is also considered an important performance indicator. It denotes the commitment of the transnational governing authority to ensure that the active participation of a wide range of stakeholders is guaranteed in practice, regardless of their differences. However, *meaningful participation* requires that participants have a significant level of financial or technical resources to represent their interests in these arrangements (Cadman, 2011; Forsberg, 2010). As a result, the element of *resources* is important at the indicator level to assess the allocation of resources provided to participants to support their inclusion in relevant arrangements of technology regulation.

3.5.2. Deliberative Decision-Making

Deliberative decision-making occurs when stakeholders have appropriate opportunities to contribute to the decision-making process, communicate and discuss the reasons on which decisions are based, and develop solutions through cooperation and joint agreements (Benz and Papadopoulos, 2006; Bekkers and Edwards, 2007). *Deliberative decision-making* is comprised of four performance indicators:

1) *participatory decision-making*,
2) *comprehensive agreements*,
3) *communicative agreements*, and
4) *effective dispute settlement.*

Participatory decision-making demonstrates the extent to which participants have the appropriate opportunities to present and amend proposals during the setting of transnational rules (Benz and Papadopoulos, 2006; Dingwerth, 2007; Bekkers and Edwards, 2007). *Comprehensive agreements* refer to the extent to which a governance arrangement provides for the sincere consideration of the arguments of the participants. *Communicative agreements* refer to the quality of interaction amongst participants to achieve acceptable regulatory outcomes (Cadman, 2011; Beisheim and Dingwerth, 2008).

However, transnational decision-making is also characterized by various conflicts amongst interested parties. Newly emerging technologies are characterized by many uncertainties and preferences over the final regulatory outcomes. Therefore, the performance indicator of *dispute resolution* is considered important to demonstrate the ability of the governance arrangement to manage conflicts amongst participants in cases when agreements are not achieved (Beisheim and Dingwerth, 2008; Cadman, 2011).

3.5.3. Effective Process Control

Effective process control relates to the responsiveness of the governing authority to ensure that appropriate mechanisms of transparency and accountability are embedded, to provide for the democratic control of the process and ensure that actors have a realistic chance of being heard (Bekkers and Edwards, 2007; Schmidt, 2010). *Effective process control* consists of four performance indicators:

1) *transparency,*
2) *internal accountability,*
3) *external accountability,* and
4) *domestic accountability*.

Transparency refers to the readiness of the rule-maker to share information and open up the process to affected stakeholders (Dingwerth, 2007). *Accountability* refers to the mechanisms that ensure the control of the governing authority and its decision-making processes (Bekkers and Edwards, 2007; Dingwerth, 2007). Scholars of transnational governance consider *transparency* as a precondition for ensuring *accountability* (Risse, 2006; Take, 2012). They assume that an open and timely access to the relevant information enables stakeholders to be well-informed about the overall stages of the decision-making process, including its structure, subject matter and status (Dingwerth, 2007).

Accountability is a broader concept than transparency. It refers to the principal-agent or to the forum-actor relationship (Bovens, 2007). In particular, *accountability* refers to the extent to which the behaviour of the agent can be called into account by an individual, group or other entity both inside and outside of the governance arrangement (Keohane, 2003). In this way, transnational *accountability* consists of several complex and interrelated performance indicators.

Keohane (2003) and Risse (2004) distinguish between *internal* and *external* accountability. *Internal accountability* refers to the internal institutionalized procedures that compel the agent to inform and justify their actions, and be held into account by individuals or groups with whom the agent is institutionally linked. *External accountability* focuses on possibilities provided to individuals or groups acting outside the governance arrangements to keep decision-makers accountable for their conduct. In addition to these performance indicators, Risse (2004) argues that participants in TGAs most often are delegated by national bodies to participate and negotiate on transnational rules. Therefore, these participants also need to provide feedback into the "domestic and other environments" to which they are accountable (Risse, 2004:18). I frame this indicator - the *domestic accountability*. It indicates the extent to which national bodies are able to hold their delegates accountable for the decisions made at transnational level.

3.5.4. Trustworthy Expertise

Trustworthy expertise relates to the ability of the governance arrangement to ensure that transnational rules derive from highly-qualified experts, and are based on accurate and reliable scientific information, as well as robust evidence. *Trustworthy expertise* is comprised of four performance indicators:

1) *competent expertise,*
2) *robustness,*
3) *scientific validity*, and
4) *objective judgments*.

Competent expertise refers to the familiarity, the skills and the experience of the rule makers/participants with the technicalities of the relevant domain (Hilligoss and Rieh, 2008; Funtowicz and Strand, 2011). *Robustness* and *scientific validity* relate to the evidence that participants provide in the decision-making process. These indicators are usually treated together in the literature. *Robustness* demonstrates the extent to which the decisions of the participants are based on scientifically robust evidence that remains largely constant even in cases when the factual conditions change or are unknown (Carrier, 2010:204-205). *Scientific validity* refers to the ability of participants to provide for reliable and verified results, which are scientifically relevant to the issue at stake (Carrier, 2010; Lövbrand et al. 2011). The last indicator - *objective judgments* - relates to the independency of participants from politics or other individual interests. In particular, it demonstrates the ability of the participants to present or appraise the scientific facts in an independent manner (Papadopoulos, 2007).

3.5.6. Implementable Outcomes

Implementable outcomes demonstrate the ability of the governance arrangement to provide outcomes that solve collective problems, are understandable, beneficial and followed by relevant actors. *Implementable outcomes* consist of four performance indicators:

1) *problem solving capacity,*
2) *rule benefits,*
3) *rule clarity*, and
4) *compliance.*

Problem solving capacity relates to the capacity of transnational rules to solve the problems they were created (or are expected) to address (Scharpf, 1999; Scharpf, 2006; Gunningham, 2010). The second performance indicator, *rule benefits,* is closely related to the first indicator because it also refers to the potential of the transnational rules. However, this indicator is more narrow in content, since it aims to demonstrate the extent to which transnational rules correspond to the individual interests of stakeholders (Mayntz, 2010). *Rule clarity* indicates the extent to which transnational rules are clearly drafted and understandable, and *compliance* relates to the willingness of the ruled to act in accordance with transnational rules (Finnemore and Toope, 2001; Keller, 2006; Mayntz, 2010). Table 3.1 provides an overview of the legitimacy norms and performance indicators relevant for transnational legitimacy.

Table 3.1: Norms and Performance Indicators Relevant for Transnational Legitimacy

Norms	***Performance Indicators***
Meaningful Participation	*Inclusiveness* *Representation* *Resources*
Deliberative Decision-Making	*Participatory Decision-Making* *Comprehensive Agreements* *Communicative Agreements* *Effective Dispute Settlement*
Effective Process Control	*Transparency* *Internal Accountability* *External Accountability* *Domestic Accountability*
Trustworthy Expertise	*Competent Expertise* *Robustness* *Scientific Validity* *Objective Judgments*
Implementable Outcomes	*Problem Solving Capacity* *Rule Benefits* *Rule Clarity* *Compliance*

3.6. A Matrix for Evaluating the Legitimacy of TPGAs Related to Technology Regulation

In this thesis, I use an evaluative matrix to understand the extent to which stakeholders believe that the legitimacy norms and performance indicators identified in Table 3.1 are followed in practice. As we shall see in Chapter 4, there are 76 stakeholders surveyed for this study. The perceptions of stakeholders on each performance indicator are evaluated by using a Likert scale ranked from 1 (very low) to 5 (very high). Following this hierarchical division, the degree to which legitimacy norms are taken up in practice is determined by the total values of the performance indicators. Consequently, the values of each legitimacy norm determine the overall rating of the legitimacy of the TPGA. In Table 3.2 I provide the evaluative matrix for assessing the legitimacy of the technology related TPGAs in practice.

Table 3.2: Evaluative Matrix for the Legitimacy of TPGAs Related to Technology Regulation[71]

Norms	***Performance Indicators***	***Values***				
		V. High	High	Medium	Low	V. Low
Meaningful Participation	*Inclusiveness*	5	4	3	2	1
	Representation	5	4	3	2	1
	Resources	5	4	3	2	1
Sub-total: 15 (Highest possible score: 15; lowest possible score: 3).						
Deliberative Decision Making	*Participatory Decision Making*	5	4	3	2	1
	Comprehensive Agreements	5	4	3	2	1
	Communicative Agreements	5	4	3	2	1
	Effective Dispute Settlement	5	4	3	2	1
Sub-total: 15 (Highest possible score: 20; lowest possible score: 4).						
Effective Process Control	*Transparency*	5	4	3	2	1
	Internal Accountability	5	4	3	2	1
	External Accountability	5	4	3	2	1
	Domestic Accountability	5	4	3	2	1
Sub-total: 15 (Highest possible score: 20; lowest possible score: 4).						

[71] For similar matrixes developed to evaluate legitimacy of transnational developments see also : Cadman, T., 2011. *Quality and Legitimacy of Global Governance*. US: Palgrave Macmillan, pp. 23.

Trustworthy Expertise	*Competent Expertise*	5	4	3	2	1
	Robustness	5	4	3	2	1
	Scientific Validity	5	4	3	2	1
	Objective Judgments	5	4	3	2	1
Sub-total: 15 (Highest possible score: 20; lowest possible score: 4).						
Implementable Outcomes	*Problem Solving Capacity*	5	4	3	2	1
	Rule Benefits	5	4	3	2	1
	Rule Clarity	5	4	3	2	1
	Compliance	5	4	3	2	1
Sub-total: 15 (Highest possible score: 20; lowest possible score: 4).						
Total: Final Score: 95						

3.7. Conclusions

Building upon the political, legal and sociological thoughts of legitimacy, in this chapter I have explored the normative and empirical perspectives of legitimacy. From the literature it was observed that a wide range of scholars and stakeholders have commented on various attributes of “good governance”. They focus on the broader inclusion of stakeholders, the processes of decision-making, or compliance. However, there is less focus on evaluating the perceptions of stakeholders on whether these attributes are effectively taken up in practice. Even in cases when a comment is made on particular criteria (such as participation, deliberation or accountability), the discussions are mostly related to the experience and/or viewpoint of the authors than to the perceptions of stakeholders.

To complement the current stream of research on transnational legitimacy and to answer the second sub-research question - *How can the legitimacy of transnational private governance arrangements related to nanotechnologies be conceptualized and operationalized?* - which was the main objective of this chapter, I have developed an analytical framework. This framework serves to understand the legitimacy of TPGAs related to technology regulation in practice. The framework consists of two steps: a) bringing together the procedural and substantive norms of legitimacy that guide TPGAs and provide the basis for their legitimacy, and b) defining how legitimacy of transnational technology regulation can be measured in practice by reconceptualizing the notions of input, throughput and output legitimacy. I have extended the notion of input legitimacy to include not only the legitimacy norms aligned with the dimensions of the governance “*for the people*”, but also the norms aligned with the dimensions of the governance “*with the people*” and “*of the people*”. As such, input legitimacy includes *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes*. Several performance indicators were identified to explain the content of these norms in details.

Throughput legitimacy refers to the extent to which stakeholders believe that the legitimacy norms that guide the setting of transnational rules are taken up in practice. Output legitimacy focuses on stakeholders’ compliance with transnational rules and their beliefs on the effectiveness of these rules. In my view, a complete attempt to study the legitimacy of technology related TPGAs should consider both the norms of legitimacy (or as we frame them the “rules of the game”), as well as the perceptions of stakeholders on how these norms are taken up in practice. Therefore, in this thesis legitimacy is viewed as a relational concept between the governance arrangement and stakeholders.

Now that I have proposed an analytical framework and a matrix for exploring the legitimacy of technology related TPGAs, in the forthcoming chapters (Chapter 4 and 5) I focus on the research design and the case study (i.e. TC 229), to gather evidence on whether it is accurate to conceptualize and evaluate legitimacy in this way. For instance, of crucial importance is to see whether the analytical framework developed in this chapter serves as a useful tool to explain the perceptions of stakeholders on the legitimacy of TC 229; or how stakeholder rate TC 229 in terms of the legitimacy norms and performance indicators. These issues are addressed through an empirical investigation of stakeholder perceptions on the legitimacy of TC 229.

Chapter 4

4. Research Design

4.1. Introduction

In this chapter I explain the methods used to investigate the legitimacy of international nanotechnology standardization, in particular the legitimacy of the process of creating nanotechnology standards at the international level, and describe the key stages that comprised the investigation process (Section 4.2). I explain the different types of data that were collected in this study, and describe specifically the process that was used to collect the data related to the case study - TC 229. In Section 4.3, I explain the analytical strategy that has guided this study.

4.2. Research Methods, Process and Data Collection

Several methods were used in this study to empirically investigate the different dimensions of the legitimacy of TC 229. First, I undertook a mapping exercise to collect information on the various transnational governance arrangements that have emerged in the field of nanotechnologies, in order to understand their potential to contribute to these emerging technologies. The mapping exercise was done through desk research in the first stages of this study (i.e. between 2011-2012), but as the debate on nanotechnology transnational governance arrangements evolved the information on these arrangements was updated accordingly. I conducted the mapping exercise primarily by reviewing different documents, such as research reports, newsletters, policy documents, reports written by the EU Commission, as well as journal articles of various IR and transnational governance scholars. These documents contained discussions on the attributes that characterized and distinguished different governance arrangements at transnational level. In this regard, my main focus was firstly, to determine which were the attributes that were mostly used in various documents to distinguish and characterize governance arrangements at the transnational level, and secondly, to provide a typology for understanding the main features and the role of transnational governance arrangements in the regulatory governance of nanotechnology. The comprehensive review of various documents helped me to identify six attributes according to which transnational governance arrangements can be understood and distinguished, such as the *actors involved*, *functions*, *degree of institutionalization*, the *regulatory stages* in which governance arrangements contribute, as well as *the normative scope* and *the substantive depth* of transnational outcomes.

Second, I conducted a literature review of existing discourse related to the legitimacy of TPGAs.[72] This was performed by using the Web of Science, Google Scholar and PubMed. I reviewed peer-reviewed literature, several expert reports and strategy papers. The key terms used for searching documents were transnational legitimacy AND transnational governance OR regulatory governance OR global governance OR standard-setting OR private governance OR institutions OR stakeholder engagement OR technical expertise OR experts OR decision-making process OR good governance. In addition, I also analyzed the key official documents guiding the functioning of ISO and TC 229, such as the ISO/IEC Directives, TC 229 business plan, white papers (such as those developed by the IRGC and EC on the governance of nanotechnologies), as well as mandates provided by the EU Commission to the standardization bodies (e.g. M/409).

To broaden my understanding about the legitimacy of TPGAs, and more specifically about the legitimacy of international nanotechnology standardization and relevant issues that mattered on this point, I visited the Netherlands Standardization Institute (NEN) (the Committee on Nanotechnology) and participated in one TC 229 meeting in Stresa. During my first visit at NEN in May 2012, I got introduced to the Dutch delegates that were involved in nanotechnology standardization. I spent the whole day observing the discussions and preparations of the Dutch delegated for the later TC 229 meeting that was held in June 2012. This meeting gave me also the opportunity to observe the technical work on standardization and discuss with various delegates on the decision-making processes at TC 229. Following this meeting, in June 2012 together with other Dutch delegates, I participated as an observer at the international week-long meeting organized by TC 229 in Stresa. As an observer in the Dutch delegation I was able to attend all the discussion meeting held by this delegation during the week and participate in the meetings held by the TC 229 working groups (e.g. WG3 and WG1) and task groups (e.g. the Task Groups on Consumer and Societal Dimensions). During coffee breaks and lunch, I was able to discuss with various delegates coming from other countries (e.g. US, Iran, Germany, Italy, France, Canada) and stakeholder groups (e.g. industry, trade unions, consumers, regulatory agencies, academia), which helped me understand what the process of setting nanotechnology standards involved in practice.

Following these meetings, in September 2012 and June 2013, I revisited NEN to discuss my observations at the TC 229 meeting with the secretary of NEN, as well as the questions that I

[72] This was performed mainly in 2012, however the information with regards to the legitimacy of TPGAs was updated accordingly to include relevant literature that was published in later years as well (i.e. in 2013 and 2014).

was preparing for the survey questionnaire. These visits were supplemented with many telephone conversations and email exchange with the secretary of NEN, as well as archive studies. In particular I had access to the NEN archive where I could access and analyze documents related to the TC 229 meetings, project proposals, as well as technical and/or administrative work on nanotechnology standardization. More thorough discussions with two key experts that have contributed extensively to the work of TC 229 were held at this time and included an interview with the former chairman of TC 229 as well as of NT-001.[73] These methods were used to explore the main legitimacy issues accompanying the development of international nanotechnology standards, and to find out the underlying norms and principles that these actors considered as the basis of a legitimate governance.

Third, I started with the pilot survey (September - November 2012) with stakeholders from NEN. There were two main reasons why I chose to do the pilot with the NEN actors. First, because of its geographic location, i.e. in the Netherlands, I could easily access the organization. Second, given that I have participated in many face-to-face meetings and discussions organized by NEN delegates, I was able to know their involvement in TC 229 process. I invited surveyees by sending an invitation letter through email.[74] The letter explained the research objectives and the aim of the survey questionnaire. The main aim of the questionnaire was to examine how different actors are engaged in the development of international nanotechnology standards, and what are their perceptions in regards to TC 229 standards, as well as the process of developing these standards. Furthermore, the invitation letter explained that the responses would be treated as confidential and that only aggregate data will be published (see Appendix 1). In this letter I also sent the link to the survey, which directed the surveyees (who wanted to participate in the pilot survey) to the survey questionnaire.

The selection of participants was not random, I selected participants whose profile indicated that they had expertise on nanotechnology standardization issues and have participated in TC 229 meetings and discussions. Initially I sent 13 survey requests and received nine responses. The main aim of the pilot survey was to validate the findings made in the Second step related to the legitimacy norms and principles, and to test the survey questionnaire for the Fourth step (See Table 4.1).

Finally, I conducted the main survey questionnaire (January - November 2013) with representatives of other member countries participating in TC 229.[75] The questionnaire was designed on the basis of the findings made in Step Two and Three (see Table 4.1). The pilot

[73] See Appendix 2. Interview Questions: Genesis of ISO/TC 229, the role of international nanotechnology standards in te governance of nanotechnology and principles of “good governance”.
[74] See the Letter of Invitation in Appendix 1.
[75] See The Study Questionnaire for ISO/TC 229 in Appendix 1.

study, and more specifically, the responses of the surveyees in the pilot survey suggested that there was no need and/or request by the respondents to make (substantial) changes in the design of the survey questions. Table 4.1 provides an overview of the main steps and methods used in this study.

Table 4.1. Methods for Investing Legitimacy and Following Steps

Steps	**Time**	**Methods & Activities**
1. Mapping exercise of the transnational governance arrangements in the field of nanotechnologies.	2011-2012	- Documentary research - (review of documents, research reports, newsletters, policy documents, journal articles).
2. Review of existing discourse related to the legitimacy of TPGAs (and nanotechnology standardization more specifically).	January 2012 - September 2012	- Documentary research - (literature review of existing discourse, analyzing official documents) - Discussions with NEN delegates and observations of the meetings; - Attending a TC 229 meeting, observations of the TC 229 WG meetings and discussions with delegates; - Analyzing official documents from the NEN archive; and - Conducting interviews with the former chairman of the TC 229 as well as of NT-001.
3. Conducting the pilot survey with the key stakeholders from the NEN.	September 2012 - November 2012	- Survey research - (sent the questionnaire to the representatives of NEN).
4. Conducting the main survey questionnaire with the key stakeholders involved in the work of TC 229.	January 2013 - November 2013	- Survey research - (sent the questionnaire to the representatives from ISO member countries, and representatives from the liaison organizations).

Similar to the pilot survey questionnaire, the aim of the main survey questionnaire was to explore the perceptions of the stakeholders on the legitimacy of TC 229. I targeted actors whose job profile indicated that they had expertise on nanotechnology standardisation issues, were involved in the work of respective standardization committees at national level (e.g. participating in delegation meetings, organizing events/workshops at national level related specifically to nanotechnology standardization) and participated in the work of TC 229 (e.g. by attending and/or chairing meetings, participating in discussions).

To determine these actors, I studied firstly the TC 229 biannual meetings as well as their public profile.[76] The documents of TC 229 biannual meetings were analyzed to find the actors that have participated in international nanotechnology standardization activities. As of October 2014, TC 229 has had 16 biannual meetings.[77] There are more than a hundred - now closer to two hundred - participants involved in these meetings (Kica and Bowman, 2013).[78] By analysing the actors that have participated at the TC 229 biannual meetings I could observe that the participation of actors ranged from attending more than eight meetings to actors attending one or two TC 229 meetings. Certainly this emphasizes that there is a high difference on how actors are involved in TC 229, but in order to present the perspectives of various actors in the process, the questionnaire was also sent to actors that have participated in one or two TC 229 meetings and whose profile indicated that they have been actively engaged at national standardization bodies. Given their experience in nanotechnology standardization processes (both at NSBs and TC 229), I concluded that these actors were in a better position to provide information on what is going on inside this Committee, and on whether the legitimacy norms and performance indicators are effectively taken up in practice. As a result, actors who have not participated in any TC 229 meetings were not invited to participate in this survey.[79]

After analyzing 11 TC 229 biannual meeting (out of 16 meetings), I contacted representatives from 28 (out of 35) ISO member countries, as well as representatives from the *liaison* organizations.[80,81] Similar to the pilot survey, the invitations were sent through email where the aim of the survey questionnaire was explained. A follow-up reminder was sent one week after the first invitation and a second reminder two weeks after the first invitation.

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[76] After sending the survey questionnaire, some respondents also recommended potential actors that I could approach for this study.
[77] A detailed overview of the TC 229 biannual meetings is provided in Table 5.8 in Chapter 5.
[78] See Chapter 5 - Table 5.8., for a detailed discussion and overview of TC 229 biannual meetings.
[79] It must be noted that I deliberately did not invite in the survey actors who have not been active in the work and/or the meetings of TC 229, including those who might in fact be impacted by the TC 229 outcomes. This may include, for example, individual consumers or workers or other companies (e.g. SMEs) working with nanomaterials, which might be impacted by TC 229 standards, but have not participated in the meetings and/or discussions of this Committee. One of the main reasons is that I was interested to see what goes inside TC 229, and this required knowledge and practical experience with the Committee and with the standardization process in general. To cover the interests of some of these groups I invited actors working to promote the environmental and labour interests in the development of standards (e.g. ANEC, ECOS). With this approach I was able to receive information from the key experts in the field on what goes on inside TC 229, but one of the limitations could arguably be that it does not present the perceptions of those (external) stakeholders who have not participated directly in the setting of international nanotechnology standards, but may be impacted by them. As such the responses of the surveyees involved in this study cannot be easily generalized for these stakeholders.
[80] *Liaison* organizations are those who are not connected with ISO through national bodies, see Chapter 5 (Section 5.2.1.b) for a detailed overview on the *liaison* organizations.
[81] See Chapter 5 (Tables 5.2 and 5.8 for a detailed overview of the participants and their country of origin).

According to the rules of ISO there is no limit in the number of delegates/representatives that NSBs can send at the international level (Hatto, 2010). However, after analyzing the TC 229 biannual meetings, I was able to observe that NSBs were mostly represented at the international level by three to seven delegates/representatives. To ensure that representatives from various ISO member countries were included in the survey, I sent three to seven invitations to the representatives of each member country, depending on the number of delegates that I could identify.

4.2.1. The Case of ISO/TC 229

Initially I sent a total of 136 survey invitations requesting participation in the case of TC 229. In particular, I sent 13 invitations for the pilot study (during the period of January - September 2012) and 125 invitations for the main study (during the period of January - November 2013). I received 67 full responses and 9 incomplete responses from the main survey questionnaire. In my analysis of stakeholder perceptions (see Chapter 5), I consider only the full responses of the surveyees. Since the questionnaire was not modified for the main study, in the main analysis the data from the pilot study are also included.[82] Therefore, the total number of full responses received and considered for the case of TC 229 is 76, representing a response rate of 56%.

In this study I received responses from the representatives of: Australia, Belgium, Canada, China, France, Germany, Japan, Italy, India, Iran, *Liaison* Organizations, Malaysia, Mexico, Norway, South Africa, South Korea, Spain, Switzerland, the Netherlands, US, and UK (see Table 4.1). I could not identify any person that has been involved in the work of TC 229 for these countries: Brazil, Bulgaria, Ireland, Kenya, Poland and Jamaica. Representatives from Austria, Czech Republic, Denmark, Finland, Indonesia, Israel, Russia, Sweden and Singapore were also contacted but no replies were received.

[82] When the "pilot study […] mimics the main study in a small scale employing all the methods and instruments planned for the main study"(Smith, 2002: 73), and the data are collected using the same equipment and accuracy it is considered reasonable/acceptable to include the data of the pilot study to the main study (see alsoThabane et al., 2010;). See: Smith, F., 2002. *Research Methods in Pharmacy Practice*, UK: Lambeth High Street (pp. 43-76); Thabane et al., 2010. A Tutorial on Pilot Studies: The What, Why and How, *BMC Medical Research Methodology*, 10(1): 1-10.

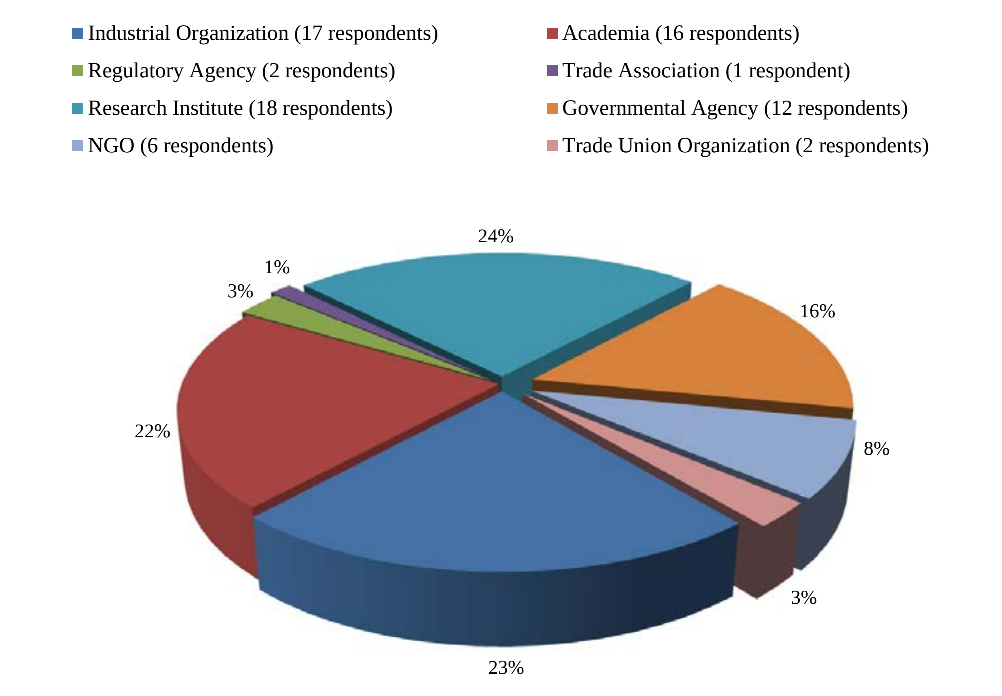
Table 4.1: Overview of the Stakeholders in the Survey Questionnaire and their Country of Origin

Country	Number of respondents
Australia	3
Belgium	4
Canada	4
China	3
France	4
Germany	4
India	2
Iran	5
Italy	5
Japan	5
Liaison EU	3
Malaysia	2
Mexico	2
Netherlands	9
Norway	2
South Africa	2
South Korea	3
Spain	1
Switzerland	2
UK	6
US	5
Total	76

The surveyees were members of the NSBs and have been involved in the work of TC 229.[83] They were mainly associated with private industrial organizations, research institutes, academia, governmental agencies, regulatory agencies, NGOs, trade union organizations and trade associations (See Figure 4.1).

[83] See Chapter 5-Table 5.2. and 5.7 on the involvement of respondents in the work of TC 229.

Figure: 4.1: Overview of the Stakeholders in the Survey Questionnaire and their Organizational Background



4.3. Analytical Strategy

The survey questionnaire of this study was formulated on the basis of the research questions. To implement and run the survey I used *LimeSurvey*, which is an open online-survey application. The survey questionnaire consists of 51 questions and it took on average 30-35 minutes for surveyees to respond to the survey questions. The survey questionnaire is divided in seven parts. To obtain data that are rich in context, in the survey I used both scaled questions and open-ended questions (see Appendix 1). For data analyses I used the SPSS social science statistical software. The first part of the questionnaire was titled *General Information* and consisted of six questions. The aim of this part was to get general information from surveyees about their country of origin, the type of the organizations with which they are associated, as well as the main activities in relation to nanotechnology. The second part of the survey was titled *Participation in ISO/TC 229* and consisted of eight questions. The aim here was to extract the perceptions of stakeholders on whether they feel that the *performance indicators* (i.e. *inclusiveness*, *representation* and *resources*) constituting the norm of *meaningful participation* are effectively taken up in practice at TC 229.

The third part of the survey was titled *Decision-making over ISO/TC 229 standards* and consisted of six questions. The aim here was to extract the perceptions of stakeholders on whether they feel that the *performance indicators* (i.e. *participatory-decision making; comprehensive agreements; communicative agreements and effective dispute settlement*) constituting the norm of *deliberative decision-making* are effectively taken up in practice at TC 229. The fourth part of the survey was titled *Transparency and Accountability* and consisted of eight questions. The aim here was to extract the perceptions of stakeholders on whether they feel that the *performance indicators* (i.e. *transparency, domestic accountability, internal accountability and external accountability*) constituting the norm of *effective process control* are effectively taken up in practice. The fifth part of the survey was titled *Scientific Robustness and Expertise* and consisted of six questions. The aim here was to extract the perceptions of stakeholders on whether they feel that the *performance indicators* (i.e. *expert knowledge, scientifically verified results, robust evidence and objective judgments*) constituting the norms of *trustworthy expertise* are effectively taken up in practice at TC 229.

The sixth part of the survey was titled *ISO/TC 229 Outcomes* and consisted of nine questions. The aim here was to extract the perceptions of stakeholders on whether they feel that the *performance indicators* (i.e. *compliance, rule clarity, problem solving capacity* and *rule benefits*) constituting the norm of *implementable outcomes* are effectively taken up in practice at TC 229. In this part I also asked surveyees to indicate which legitimacy norms they consider to be most important for TC 229, and to recommend any other norm or performance indicator that they feel it needs further consideration. In addition, in each part of the survey questionnaire, surveyees were asked to provide recommendations (if any) on how to improve/enhance the legitimacy of TC 229 process and outcomes. Information on these aspects were helpful to validate the findings in Step Two of the research related to the legitimacy norms and principles

The last part (the seventh part) of the survey consists of eight questions. In this part surveyees were asked to evaluate the survey questionnaire and provide recommendations (if any) on how to improve the survey in the future.

Chapter 5

5. Case Study: Exploring the Legitimacy of ISO/TC 229[84]

5.1. Introduction

In this chapter I present the results of the survey and analyze the perceptions of stakeholders related to the legitimacy of TC 229. The chapter aims to respond to the third and the fourth sub-research questions. These questions are: *To what extent is international nanotechnology standardization perceived as legitimate by stakeholders* (sub-research question 3) and *How can international nanotechnology standardization enhance its legitimacy* (sub-research question 4). Section 5.2 provides detailed analyzes on the legitimacy performance of TC 229 from the perspective of the respondents that were surveyed in this study. In particular, I reflect on the the perceptions of stakeholders and analyze the extent to which they perceive that the legitimacy norms and performance indicators, identified in Chapter 3 of this thesis, are effectively taken up in practice at TC 229. However, given that TC 229 functions within the ISO, the legitimacy of this Committee cannot be viewed in isolation from the ISO procedures. As such, background information is provided on the formal procedures that these bodies have undertaken to provide for legitimate standardization.

To analyze the perceptions of respondents, I have followed the evaluative matrix developed in Chapter 3, according to which the perceptions of stakeholders are measured by using a five-point Likert scale. For the actual calculation of stakeholders' perceptions on legitimacy norms the mean values of each performance indicator are used. Taking into account the explorative approach of this research, in this chapter I have searched for different explanations of the results. In particular, while discussing the perceptions of respondents on the performance of TC 229, in Section 5.2 I analyze how other factors, such as the respondents' country of origin, backgrounds, competencies, expertise and other interests, shape or impact the individual perceptions of respondents. This Section also provides the main recommendations, which in the view of respondents, can enhance the performance of TC 229 on each legitimacy norm.

In Section 5.3 specific attention is paid to the internal consistency and correlation of all legitimacy norms and performance indicators used to construct the overall score on the

[84]A previous version of this chapter is published at: Kica, E and DM Bowman., 2012. Regulation by Means of Standardization: Key Legitimacy Issues of Health and Safety Nanotechnology Standards. *Jurimetrics: The Journal of Law, Science and Technology*, 53*:*11-56.

legitimacy of TC 229. I measured the internal consistency of the scores given on each performance indicator and legitimacy norm by using the Cronbach's Alpha test.[85] To see whether there is a statistically significant relationship between performance indicators, I used the Kendall's tau_b correlation test (τ).[86] Statistics are calculated by using the SPSS software package. In Section 5.4, I provide some concluding remarks.

5. 2. Empirical Data from ISO/TC 229

In this section I analyze the perceptions of the respondents on the legitimacy of TC 229. A total of 76 survey responses was received and analyzed for this purpose. As indicated in Chapter 3, the perceptions of stakeholders on each performance indicator are evaluated by using a Likert scale ranked from 1 (very low) to 5 (very high). The overall rating of the legitimacy of TC 229 is determined by the total values of legitimacy norms and performance indicators (see Section 3.6). Figure Table 5.1 displays the legitimacy norms and performance indicators, which guided the survey questions.[87]

Table 5.1: Legitimacy Norms and Performance Indicators

Norms	***Performance Indicators***
Meaningful Participation	*Inclusiveness* *Representation* *Resources*
Deliberative Decision Making	*Participatory Decision Making* *Comprehensive Agreements* *Communicative Agreements* *Effective Dispute Settlement*
Effective Process Control	*Transparency* *Internal Accountability* *External Accountability* *Domestic Accountability*

[85] Cronbach's alpha test is a technique which measures the extent to which individual variables are measuring the same underlying construct. It measures the internal consistency of individual variables considering the number of items and their magnitude of intercorrelation (Cronbach, 1951; Clark and Watson, 1995).

[86] Kendall's tau_b correlation coefficient measures the strength of dependence between two or more variables. In particular, it measures the extent to which a change in one variable leads or causes a change in another variable. Because in this thesis most variables (or in this case the legitimacy norms and performance indicators) consist of numerical scores that exist in an ordinal scale (i.e. from 1- very low to 5 - very high), a nonparametric measure of correlation (such as Kendall's tau_b) was considered more appropriate. The Kendall's rank correlation coefficient can be in the range of $-1.00 \leq \tau \leq 1.00$, depending on the extent to which variables relate to each other.
See also: Weisberg, H.F., J.A., and Bowen, D.D., 1996. *An Introductory to Survey Research, Polling, and Data Analysis*. Newbury Park, CA: Sage Publications.

[87] For detailed description of these norms of legitimacy and performance indicators see Chapter 3 (Section 3.5 and 3.6).

Trustworthy Expertise	*Competent Expertise* *Robustness* *Scientific Validity* *Objective Judgments*
Implementable Outcomes	*Problem Solving Capacity* *Rule Benefits* *Rule Clarity* *Compliance*

5.2.1. Meaningful Participation at ISO/TC229

To understand the performance of TC 229 on *meaningful participation*, the survey explored the perceptions of stakeholders on *inclusiveness*, *representation* and *resources*. In the following paragraphs, I first provide background information related to the structure and the functioning of TC 229, which is received from documentary analysis, such as the Directives of ISO, reports and observations. Afterwards, I provide detailed analyzes on the perceptions of stakeholders on each performance indicator.

5.2.1.a. Inclusiveness

International standards are developed by groups of experts under the overarching TC umbrella (ISO/IEC, 2012). ISO applies the principle of national delegation according to which NSBs send delegates at the international level to discuss new projects. Countries participating in TC 229 have established mirror committees at national level to keep the interested parties informed and develop a national consensus on standardization proposals. In ISO, national bodies have the same rights to participate in the work of the committees and subcommittees (ISO/IEC, 2012).

Under the ISO rules, NSBs are expected to take into account the interests of all actors that are relevant to the development of particular standards (ISO, 2010). In practice, however, it is the responsibility of the national bodies to determine what kind of experts they send in ISO and to ensure that the national position on particular item proposal is established. Experts have important roles with respect to approving and shaping new projects (Hatto, 2010). They participate at ISO TC meetings in negotiations and consultations that are intended to lead to the development of an international consensus. Usually, standardization proposals are developed and discussed on specific PGs, which are established within ISO WGs. The official spokespersons - *the heads of the delegations* - are expected to ensure that the position of their national bodies is represented at ISO. Afterwards, they are expected to report at the national level about the outcomes of the ISO meetings. As of October 2014, TC 229 has had 16 biannual plenary meetings, followed by many other teleconference meetings held amongst experts of relevant PGs.

NSBs can act either as Participating (PI) or as Observing (OB) members. Whereas ‘PI’ members participate actively in the work and vote on all standardization proposals, ‘OB’ members have the right to attend the meetings, but not to vote. In TC 229 there are 35 ‘PI’ and 13 ‘OB’ members.[88] Participation in standardization activities is voluntary and non-compensated (Jakobs, 2010; Forsberg, 2012). For instance, the NSI has the status of a private legal body. In principle, participation in the standardization process is open only to the representatives of recognized parties of interest,[89] who must also be willing to contribute to the funding of NEN. Standardization bodies at the national level also differ on the way they engage with different actors (Cadman, 2012). Some standardization bodies (such as, for example, the Austrian Standards Institute) work under the principle of “neutral teamwork”, which provides for the consultation and participation of representatives from consumers, science, employees, environmental groups and business world (Josef and Schepel, 2000: 27). Other NSBs, such as, for example, the Norwegian Standardization Institute, do not exclude trade unions, consumer organizations or environmental organizations, but there are no obligations for the Standardization Institute to consult with them (Josef and Schepel, 2000).

To understand the perceptions of stakeholders on *inclusiveness*, surveyees were asked to indicate the extent to which they are able to participate actively in the nanotechnology standardization activities of their NSBs. 75 respondents answered this question. The empirical results indicate that respondents have mixed perceptions on *inclusiveness*. In particular, 19 respondents indicate that their participation at nanotechnology standardization activities at national level is *very high*, followed by 33 respondents indicating a *high* level of participation, 13 respondents a *medium* level of participation, 5 respondents - a *low* level of participation and 5 respondents - a *very low* level of participation. One respondent did not answer to this question (see Table 5.2 and Figure.5.1). Overall, respondents perceive that they have relatively good

[88] The participating members in ISO/TC229 are: Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Czech Republic, Denmark, Finland, France, Germany, India, Indonesia, Islamic Republic of Iran, Ireland, Israel, Italy, Jamaica, Japan, Kenya, Republic of Korea, Malaysia, Mexico, Netherlands, Norway, Poland, Russian Federation, Singapore, South Africa, Spain, Sweden, Switzerland, United Kingdom and United States. Observing members are: Argentina, Egypt, Estonia, Greece, Hong Kong, Kazakhstan, Mongolia, Morocco, Portugal, Romania, Serbia, Sri Lanka and Thailand.

[89] These actors include: organizations and institutions of manufacturers; organizations and institutions of trade; institutions of science; organizations and institutions of professional users; research and examination institutions; government and semi-government institutions, See: Schepel, H and Falke, J., 2000. Legal Aspects of standardization in the Member States if the EC and EFTA: Volume 1 Comparative Report 76-78, pp.557-625.

opportunities to participate in nanotechnology standardization activities at national level as indicated by the mean of 3.7 on a scale of 1 (very low) to 5 (very high) (see Table 5.13).

Figure 5.1: The Distribution of Stakeholders' Perceptions on *Inclusiveness*

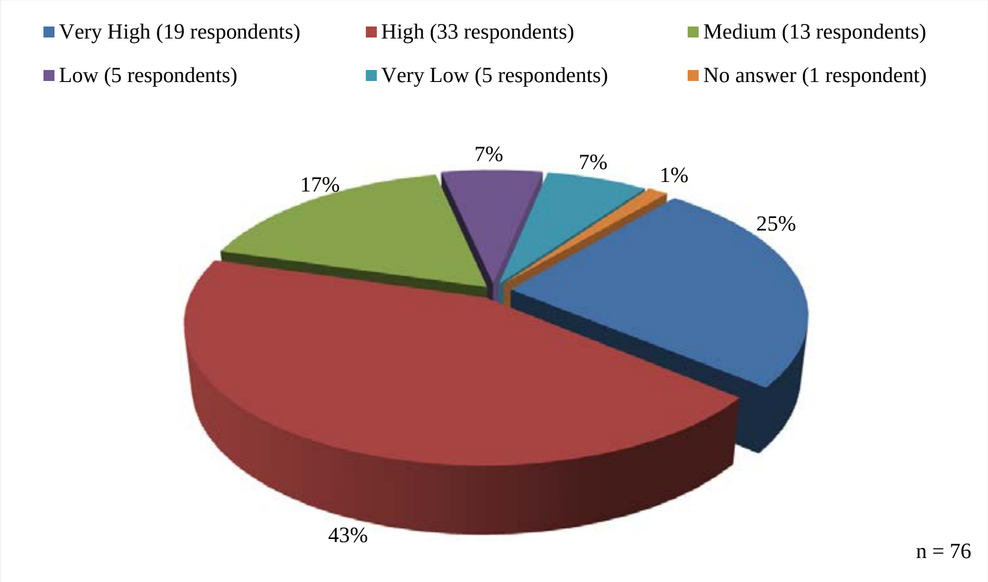


Table 5.2 presents the scores given on *inclusiveness* by different stakeholders based on their *country of origin*. By looking at Table 5.2 we can see that respondents from Belgium, Canada, Liaison Organizations, Norway, Switzerland and India appear less satisfied with their level of involvement at the NSBs as compared to the rest of the respondents.

On the question on inclusiveness, there were 55 respondents from developed countries and 18 from less developed countries (LDCs).[90] The mean scores in Table 5.2 emphasize that there is a higher variation on the perceptions of respondents coming from developed countries with responses ranging between 2.0 to 4.5, that is between "very low" to "high" level of *inclusiveness*. The perceptions of respondents from LDCs range between 3.0 to 5.0, that is between "medium" to "very high" level of *inclusiveness*. In general, however, there is not much difference between the mean scores of stakeholders coming from developed and LDCs. For instance, the mean scores of respondents from US (mean = 4.4), France (mean = 4.5), Japan (mean = 4.4), are not highly different from the mean scores of respondents from Malaysia (mean = 4.0), China (mean= 4.3), Iran (mean = 4.0) or Mexico (mean = 5.0).

[90] LDC countries (or as formerly known newly industrialized counties) are those nations that are undergoing a rapid economic growth and industrialization. In the literature South Africa, Mexico, Brazil, China, India, Iran, Malaysia, Philippines, Thailand and Turkey are the countries that are consistently considered as LDCs. See: Bozyk, P., 2006. Globalization and the Transformation of Foreign Economic Policy, Ashgate:UK.

Table 5.2. The Perceptions of Stakeholders on *Inclusiveness* and *the Country of Origin*

	Very Low	Low	Medium	High	Very High	Mean
	Number of respondents					
Australia	0	0	0	3	0	4.0
Belgium	3	0	0	0	1	2.0
Canada	0	1	2	1	0	3.0
China	0	0	0	2	1	4.3
France	0	0	0	2	2	4.5
Germany	0	0	1	1	2	4.3
India	0	0	2	0	0	3.0
Iran	0	0	1	3	1	4.0
Italy	1	0	0	3	1	3.6
Japan	0	0	0	3	2	4.4
Liaison EU	0	1	0	1	0	3.0
Malaysia	0	0	1	0	1	4.0
Mexico	0	0	0	0	2	5.0
The Netherlands	0	2	2	2	3	3.7
Norway	0	0	2	0	0	3.0
South Africa	0	0	0	2	0	4.0
South Korea	0	0	0	2	1	4.3
Spain	0	0	0	1	0	4.0
Switzerland	0	1	0	1	0	3.0
UK	1	0	2	3	0	3.2
US	0	0	0	3	2	4.4

The views of the respondents on *inclusiveness* seemed to vary also with the extent to which they were associated with industrial organizations, governmental and regulatory agencies, or organizations representing civil society. In the survey respondents indicated that they come from industrial organizations (IO) (17 respondents), research institutes (RI) (18 respondents), governmental agencies (Gov.) (12 respondents), academia/university (16 respondents), NGOs (5 respondents), regulatory agencies (2 respondents), trade associations (1 respondent) and trade union organizations (TUOs) (2 respondents). As illustrated by Table 5.3 respondents coming from industry, research institutes and academia appear generally more satisfied with their level of involvement at the NSBs. Respondents coming from NGOs and TUOs seem to have more issues with inclusiveness at NSBs. This is indicated by the lower mean scores that NGOs (mean = 2.6) and TUOs (mean = 2.0) have in comparison to other respondents (see Table 5.3).

Table 5.3. The Perceptions of Stakeholders on *Inclusiveness* and the *Type of the Organization*

	Inclusiveness					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	0	1	0	8	8	4.3
RI	2	3	2	6	5	3.6
Acad.	1	0	5	9	1	3.5
Gov.	0	0	3	6	3	4.0
NGO	1	1	2	1	0	2.6
Reg.	0	0	0	1	1	4.5
TA	0	0	0	0	1	5.0
TUO	1	0	1	0	0	2.0

The activities of respondents emphasize that respondents that appeared more satisfied with their level of involvement at the NSBs were mostly involved in the manufacturing of nanotechnology artifacts (e.g. nanopowders, nanotubes, nanofibers etc), manufacturing of products containing nanotechnology artifacts (e.g. particle loaded materials or goods), research directed at nanotechnology, regulatory issues directed at nanotechnologies, as well as in the analysis/characterization of components or products at the nanoscale (see Table 5.4). Similar trends have been observed in other standardization areas as well. For instance, while discussing the development of ICT standards, Jakobs (2010) observed that manufacturers were the most active actors in the standardization process, mainly because they had higher interests in the technology and more powerful resources to support their involvement in these processes. These factors, as we shall see in the next paragraphs, seem to be important in the nanotechnology standardization process as well.

Table 5.4. The Organizational Background and the Activities of Stakeholders

	IO	RI	Acad.	Gov.	NGO	Reg.	TA	TUO
	Number of respondents							
A manufacturer of NT artifacts	8	2	0	0	0	0	0	0
A manufacturer of products containing NT	6	2	0	0	0	0	0	0
A user of NT artifacts in any manufacturing	4	2	0	1	0	0	0	0
Engaged in research directed at NT	4	8	6	1	1	0	0	0
Engaged in regulatory issues directed at NT	6	3	1	4	3	2	1	0
Engaged in the analysis or characterization of components or products at the nanoscale	5	8	4	4	0	1	0	0
Engaged in safety issues related to NT	7	9	5	4	5	1	1	2
Engaged in academic research related to NT	2	6	13	2	0	1	0	1

The views of respondents on *inclusiveness* seemed to vary also on the basis of the technical expertise they had in standardization work for nanotechnologies.[91] In the survey respondents were asked to specify their level of technical expertise ranging from awareness, basic, intermediate, advanced to specialist.[92] The majority of respondents (54 out of 73) claimed to have advanced levels of technical expertise. These respondents came mainly from the industry, research institutes, academia, governmental and regulatory agencies.

By looking at Table 5.5 we can see that the higher the technical expertise of stakeholders on nanotechnology standardization issues the higher their satisfaction for involvement at the NSBs. Stakeholders having advanced and specialist technical expertise are more satisfied with their level of involvement on nanotechnology standardization activities at national level. The results of the Kendall's tau_b correlation test also verify that there is a positive and statistically significant relationship between respondents' technical expertise on nanotechnology standardization issues and their level of involvement at the NSBs (τ = 0.48; significant level = 0.00) (see Appendix 3).

[91] *Technical expertise* : in the survey questionnaire respondents were asked to specify the level of technical expertise - i.e. awareness, basic, intermediate, advanced or specialist- in the international standardization work for nanotechnologies.
[92] *Awareness* - respondents are only aware with the technicalities of nanotechnology standardization; *Basic* - respondents have a basic understanding of the main techniques and concepts; *Intermediate* - respondents have a good understanding of the process and policies in the area of nanotechnology standardization; *Advanced* - respondents have abilities to participate in senior level discussions regarding nanotechnology standardization; and *Specialist* - respondents have a high level experience in the area of nanotechnology and are able to apply this knowledge across multiple projects.

Table 5.5: The Perceptions of Stakeholders on *Inclusiveness* and the *Level of Technical Expertise*

Level of Technical Expertise	Number of respondents	**Mean**
Basic	3	3.3
Intermediate	19	3.0
Advanced	29	3.7
Specialist	25	4.4

Looking further at the characteristics of the respondents, I was able to observe that respondents from smaller organizations (i.e. organizations that have less than 100 employees or 100-999 employees) were generally less satisfied with the level of *inclusiveness* at the NSBs, as compared to other respondents from larger organizations (i.e. organizations that have more than 1000 employees). This is indicated by the lower mean scores that respondents from smaller organizations have as compared to those associated with larger organizations (see Table 5.6). By looking at Table 5.6 we can observe that as the size of the organization increases so do the perceptions of respondents on *inclusiveness* at the NSBs. These data suggest that maybe respondents that are associated with larger organizations have more opportunities to support their involvement at the national standardization activities. The results of the Kendall's tau_b correlation test also verify that there is a positive and statistically significant relationship between the size of the organization with which respondents are associated and their level of involvement at the NSBs ($\tau = 0.25$; significant level = 0.01) (see Appendix 4).

Rainess (2003) and Cadman (2012) observe similar trends in other TCs, and in particular in the TC 207 that works on the development of the environmental management standards. They indicate that respondents from larger organizations are more satisfied with their level of involvement on standardization activities mainly because these actors (in comparison to those coming from small organizations such as NGOs for example), have more financial resources to support their participation. Focusing on the development of ICT standards, Werle and Iversen (2006), as well as Jakobs (2010), argue that since standardization process is resource intensive, time consuming and requires technical expertise, participants of larger organizations are most likely to dominate the process as compared to those coming from small organizations. The responses of the surveyees reveal similar explanations for the case of nanotechnology standardization as well.

Table 5.6: The Perceptions of Stakeholders on *Inclusiveness* and the *Size of the Organization*

Size of the Organization	Number of respondents	**Mean**
< 100	17	3.2
100 - 999	24	3.7
1000 - 5000	18	3.8
5001 - 10,000 or more	16	3.9

The situation at the international level (i.e. at the TC 229) is similar. In the survey respondents were asked about their level of participation at the TC 229 plenary-week meetings. These meetings are face-to-face and bring experts together to discuss on relevant standardization issues. 76 respondents answered this question. The survey results show that 29 respondents (out of 76) have had *low* participation at TC 229 meetings, attending 1- 4 TC 229 meetings. 25 respondents have been able to participate in 5-8 TC 229 meetings and 22 respondents in more than 8 TC 229 meetings[93] (see Table 5.7).

The characteristics of the respondents emphasize that respondents participating in more than four TC 229 meetings came mostly from industry (12 out of 17 respondents), research institutes (11 out of 18 respondents), governmental agencies (8 out of 12 respondents) and academia (8 out of 16 respondents). Other respondents (i.e. coming from NGOs, TAs, TUOs) indicate a lower level of participation at the TC 229 meetings.

Table 5.7. Participation at TC 229 Meetings

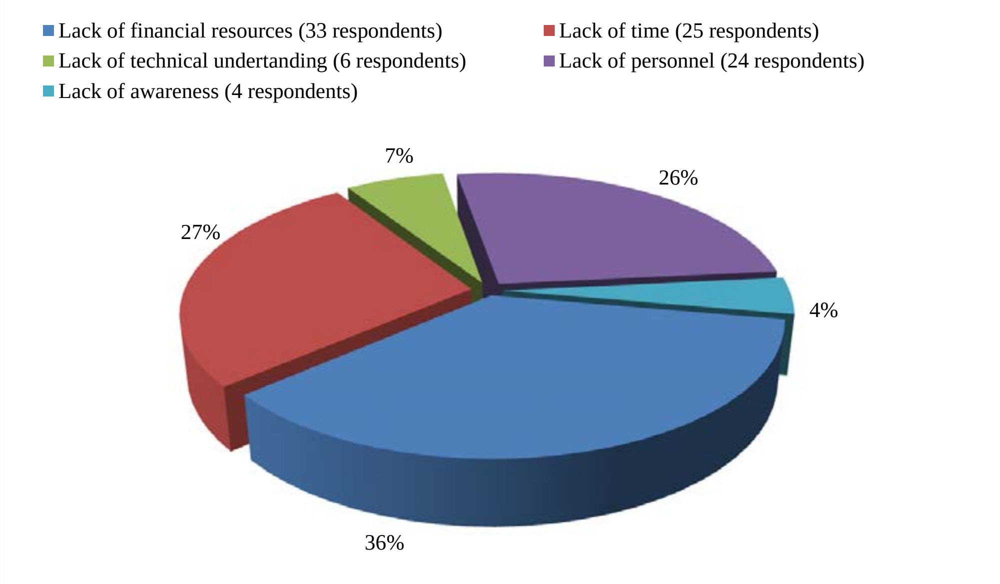
Meetings	Number of respondents	Percentage
1-4 meetings	29	38.1%
5-8 meetings	25	32.8%
9-13 meetings	22	28.9%

In the survey respondents identified several barriers, which as they argue, impacted their participation in nanotechnology standardization activities. Respondents from all stakeholder groups considered the travelling expenses (33 respondents), lack of human resources/personnel (24 respondents) and lack of time (25 respondents), to be the major barriers to their participation

[93]At the time when the survey was conducted TC 229 had organized 13 biannual meetings.

at nanotechnology standardization activities.[94] However, respondents from NGOs, academia, governmental agencies and TUOs seemed to face additional barriers. These included, for example, lack of awareness and accessibility to information on TC 229 standards (4 respondents), as well as the lack of technical understanding on nanotechnology (6 respondents) (see Figure. 5.2).

Figure 5.2. Barriers to Active Participation in Nanotechnology Standardization Activities



5.2.1.b. Representation

As part of its outreach strategy TC 229 has taken several steps to establish close relationship with a broader range of stakeholders, including those who are not connected with ISO through national bodies. These stakeholders are known as *liaison* members, and include manufacturer associations, commercial and professional associations, user groups, industrial consortia and social societies. *Liaison* organizations may have different status within ISO. These organizations may be:

1) invited to nominate experts that will participate in WGs and are given access to all relevant documents (i.e., *Liaison* A);

[94] Similar barriers to participation have been observed by other scholars as well. For instance when analyzing the involvement of the (non) industrial researchers in nanotechnology standardization activities in Germany, Blind and Gauch (2009) argue that financial costs are amongst the main barriers for recruiting these actors to participate in these activities. Werle and Iversen (2006), as well as Jacobs (2010) observe similar barriers on ICT standardization as well.

2) allowed to participate and access the reports of the TCs and WGs (i.e., *Liaison* B); or
3) allowed to participate as full members and make a technical contribution in a particular WG through the approval of the TMB (i.e., *Liaison* D).

There are 28 TCs with which TC 229 liaises, as well as with ANEC, ECOS and ETUI (see Figure 2.1). Furthermore, ISO has created several committees to foster the representation of less developed countries, such as the Committee on Developing Country Matters (DEVCO), which provides travel assistance to the technical meetings of ISO and focuses on setting training programmes and publishing training manuals for developing countries, to increase their informational capacity on standardization activities (ISO, 2011). In ISO there are also committees created to enhance the representation of consumers, such as the Committee on Consumer Policy (COPOLCO), which develops strategies to increase the participation of consumers in standardization processes. The ISO/IEC Directives does not place limits on the number of delegates that NSBs can send at the international level. However, the Directives indicate that WGs need to comprise of a restricted number of experts appointed by P-members, A-*liaisons*, and D-*liaison* organizations (ISO/IEC, 2012).

The documents of the TC 229 biannual meetings indicate that even though the process is formally open to a wide range of actors, their representation differs largely. As agreed in 2006 (on the third TC 229 meeting in Seoul), this Committee has met twice a year.[95] Evidence indicates that a variety of stakeholders have participated at the biannual plenary meetings. In the following 11 meetings are analyzed that were held between 2006 and 2013. These meetings were held in in South Korea, Germany, Singapore, China, US, Israel, the Netherlands, Malaysia, Russia, Italy and Mexico. The delegates that have participated in each of these meetings are analyzed, as well as the organizations with which they are affiliated and their background (see Table 5.8).

[95] In the beginning of 2012, TC 229 decided to hold one plenary meeting every ten months.

Table 5.8. Representation of Stakeholder Groups in TC 229 Plenary Meetings from 2005–2013[96]

Meeting	Measurement Institute	Gov't Agency	Research Institute	Accident Prevention Agency	University	Private Companies	Other	Total number of Participants
	(% of the total number of participants)							
United Kingdom 2005	NDA	NDA	NDA	NDA	NDA	NDA	NDA	**NDA**
Japan 2006	NDA	NDA	NDA	NDA	NDA	NDA	NDA	**NDA**
S. Korea 2006	7	7.8	28.1	8.5	14	21	13.2	**128**
Germany 2007	9.4	13	21.4	4	15.2	21	13	**138**
Singapore 2007	8.2	7.4	29.5	3.2	17.5	22.2	12	**122**
France 2008	NDA	NDA	NDA	NDA	NDA	NDA	NDA	**NDA**
China 2009	8.5	6.2	35.5	4.1	18	20.7	7	**223**
US 2009	11.5	8.5	30.5	4.2	14	22.1	9.2	**164**
Israel 2009	8.3	6.8	26.2	4.1	16.6	27.6	10.4	**145**
Netherlands 2010	12.3	6.1	25.6	5.5	15.5	25	10	**180**
Malaysia 2010	13	10.4	33.8	3.9	6.4	13	19.5	**77**
Russia 2011	10.7	5.1	25.7	3.4	22.3	21.3	11.5	**179**
South Africa 2011	NDA	NDA	NDA	NDA	NDA	NDA	NDA	**NDA**
Italy 2012	13	12.3	24.1	6.2	11.2	23.6	9.5	**178**
Mexico 2013	9.4	14.1	21.6	5.4	6	35.1	8.1	**148**
Brazil 2013	NDA	NDA	NDA	NDA	NDA	NDA	NDA	**NDA**

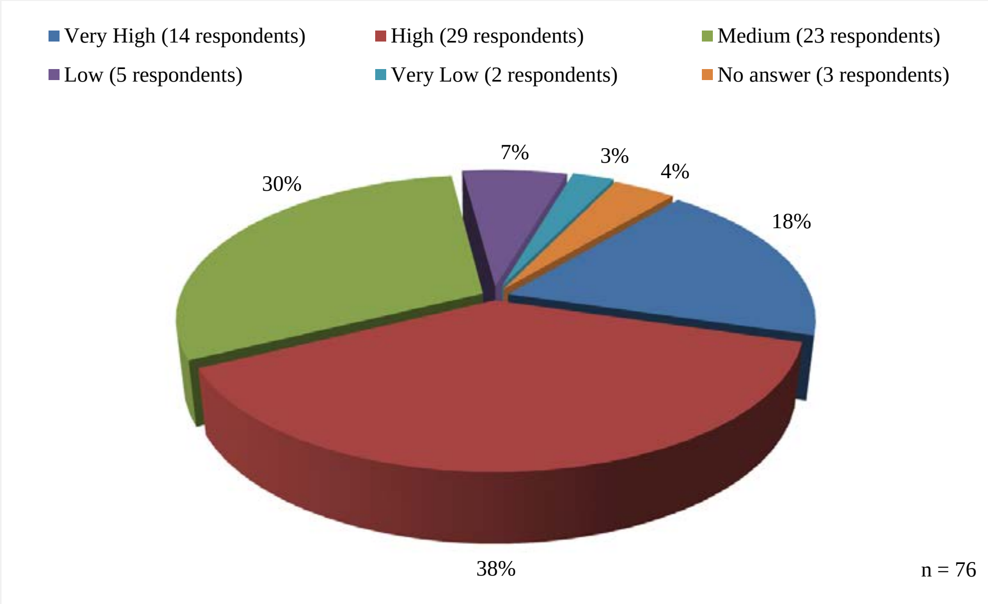
[96] It is important to note that in Table 5.8:
a) *most of the measurement/metrology institutions*: are funded by the government, whereas others are private institutions; b) *governmental agencies*: refer to agencies responsible for research and making recommendations for the prevention of work-related injury and illness; as well as institutes funded by the government to work on issues of health and consumer protection, as well as with industry to develop and apply technology; c) *research institutes*: involve public and private research and laboratory institutes working on, for example, ceramic and engineering research and design; nanoscience and technology; solar energy; metallurgical, nanomedicine and chemical research; materials and research testing; and occupational health and safety; d) *other*: refers to stakeholders that were associated only with the standardization bodies (such as secretaries or administrative assistants), as well as members from other *liaison* technical committees; e) *NDA*: means "No Data Available."

Documents from the TC 229 biannual meetings emphasize that the initiatives of this Committee to hold the plenary meetings in different countries have contributed to increase the access of developing countries in the standardization process. For instance, the meetings held in China, Malaysia, Singapore and Russia, have resulted in an increased participation of delegates coming from these countries, as well as from Thailand and India. However, the majority of delegates present at the biannual meetings have been drawn increasingly from developed countries (such as, for example, Japan, South Korea, US, Canada, UK, Germany, and France). Since the fifth meeting, newly industrialized countries, such as China, have been increasingly active on issues of measurement and metrology (Kica and Bowman, 2012; Delemarle and Throne-Holst, 2012).

The institutional origin of the actors involved at the TC 229 biannual meetings emphasizes also that the majority of delegates come from the private sector (including consulting and testing companies), industrial research centers, laboratories, universities, and metrology institutes, with regulatory and insurance-industrial accidental prevention agencies having a lower representation. In this way, the development of international nanotechnology standards seems to go through similar difficulties observed in the development of other international standards (e.g. environmental and quality management standards, labour standards, ICT standards) in which an imbalanced representation of actors from developed and less developed countries is observed (see Morikawa and Morrison, 2004; Werle and Iversen, 2006; Hallström and Boström, 2010; Jakobs, 2010, Cadman, 2012).

To understand the perceptions of stakeholders on *representation*, surveyees were asked to indicate the extent to which they feel that TC 229 is committed to ensure the representation of a wide range of stakeholders in the standardization process. 73 respondents answered to this question. The results of the survey indicate that 14 respondents perceived *representation very high*, followed by 29 respondents perceiving the *representation* of stakeholders - *high*, 23 respondents perceiving *representation* - *medium*, 5 respondents - *low* and 2 respondent - *very low*. Three respondents did not answer on this question (see Table 5.9 and Figure 5.3). These results emphasize that the majority of the respondents (i.e. 43 out of 73) are highly satisfied with the work that TC 229, and ISO in general, are doing to ensure the representation of a wide range of stakeholders in the process. This is also indicated by the mean score of 3.6 on a scale of 1 (very low) to 5 (very high) (see Table 5.13).

Figure 5.3: The Distribution of Stakeholders' Perceptions on *Representation*



The characteristics of stakeholders provide several explanations about their mixed perceptions on *representation*. Table 5.9 presents the scores given on *representation* by different respondents based on their *country of origin*. By looking at Table 5.9 we can see that respondents from Belgium, Malaysia, Norway and Switzerland appeared to be generally less satisfied with the issue of *representation* as compared to other respondents. This is indicated by the lower mean scores that respondents from these countries have. On the question on *representation* there were 58 respondents from developed countries and 15 from the LDCs. The mean scores in Table 5.8 emphasize that the variation on the perceptions of respondents coming from developed countries ranges between 2.5 to 4.4, that is between "very low" to "high" level of *representation*. A lower variation is observed on the perceptions of respondents from LDCs ranging between 3.0 to 4.5, that is between "medium" to "high" level of *representation*. In general, however, the overall mean scores of the respondents from developed countries and LDCs are not significantly different. This could be due to the low number of responses for each individual country.

Table 5.9. The Perceptions of Stakeholders on *Representation* and *the Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	1	1	0	3.5
Belgium	1	0	2	1	0	2.8
Canada	0	1	1	1	1	3.5
China	0	0	2	0	1	3.7
France	0	0	0	3	1	4.3
Germany	0	0	2	0	2	4.0
India	0	0	0	2	0	4.0
Iran	0	0	1	3	1	4.0
Italy	0	1	0	2	2	4.0
Japan	0	0	3	2	0	3.4
Liaison EU	0	0	0	2	0	4.0
Malaysia	0	0	2	0	0	3.0
Mexico	0	0	1	1	0	3.5
The Netherlands	1	0	4	3	1	3.3
Norway	0	1	1	0	0	2.5
South Africa	0	0	0	1	1	4.5
South Korea	0	0	0	2	1	4.3
Spain	0	0	0	1	0	4.0
Switzerland	0	1	1	0	0	2.5
UK	0	1	0	4	0	3.6
US	0	0	1	1	3	4.4

The institutional origin of respondents emphasizes that respondents from industry, research institutes and governmental agencies are more satisfied with the issue of *representation* at the international level (see Table 5.10). This is indicated by the higher mean scores that representatives from industry (mean = 3.8), research institutes (mean = 3.7) and governmental agencies (mean = 4.0) have in comparison to other respondents. Respondents from NGOs and TUOs appeared less satisfied with the efforts made at the international level to ensure the representation of stakeholders. These respondents commented on the issue of *representation* arguing that financial expenses and the lack of acknowledgement on the contribute that civil society organizations can make at TC 229, remain major barriers to their representation at the international level. These factors, in the view of the respondents, have led to an imbalance of interests being presented at the Committee. The problem of *representation* was mentioned across all the WGs of TC 229, including WG1, WG2 and WG3.

Table 5.10. Stakeholder Perceptions on *Representation* and the *Type of the Organization*

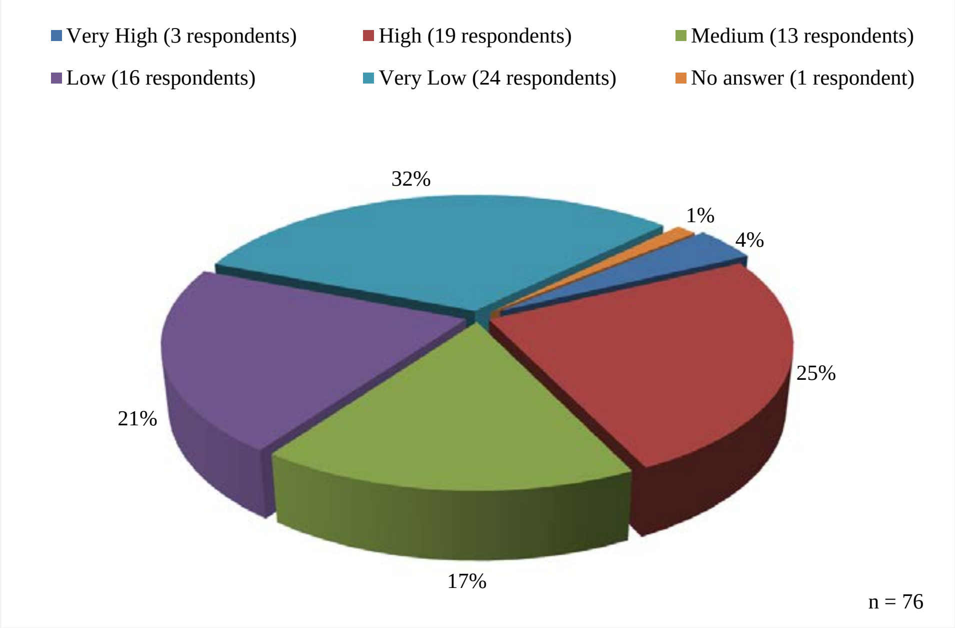
	Representation					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	0	6	4	5	3.8
RI	0	0	7	7	4	3.8
Acad	0	2	3	10	1	3.6
Gov.	0	1	1	6	3	4.0
NGO	0	2	2	1	0	2.8
Reg.	0	0	1	1	0	3.5
TA	0	0	1	0	0	3.0
TUO	1	0	1	0	0	2.0

5.2.1.c. Resources

As mentioned earlier, participation in TC 229 is opened to a variety of stakeholders. However, ISO does not provide any financial resources or technical training for these actors to get involved in standardization processes. National members pay the membership fees in proportion to the gross national income and trade figures of their countries (ISO Central Secretariat, 2014). The fees are used by ISO to cover the operational costs for running the ISO Central Secretariat. For instance, as of 2011, the Central Secretariat has a budget of around 57 million Swiss francs (Steele, 2011). Membership fees generate two thirds of the income, while the rest is provided through the sales of publications and services. The ISO TC secretariats are financed directly by the hosting members (Cadman, 2011; ISO/IEC, 2012).

To understand the perceptions of stakeholders on *resources*, surveyees were asked to indicate the extent to which they feel that their respective NSBs provide sufficient resources for them to participate actively in the activities of TC 229. 75 respondents answered this question. The empirical results reveal that only 3 respondents (from South Korea, South Africa and Iran) believe that their NSBs provide *very high* financial resources to support the participation of national delegates in TC 229 (see Figure 5.4). However, 19 respondents rate the level of resources - *high*, followed by 13 respondents rating the level of resources - *medium*, 16 respondents - *low* and 24 respondents - *very low.* One respondent did not answer to this question (see Table 5.11 and Figure 5.4). Overall respondents evaluate the provision of resources to participate at the TC 229 *low* as indicated by the mean of 2.4 on a scale of 1 (very low) to 5 (very high) (see Table 5.23).

Figure 5.4: The Distribution of Stakeholders' Perceptions on *Resources*



At the country level there were mixed perceptions amongst respondents on *resources* (see Table 5.11). By looking at Table 5.11, we can see that respondents from Belgium, Malaysia, Switzerland, US and the Netherlands appear generally less satisfied with the resources that NSBs provide to ensure participation at the international standardization activities. Respondents from South Africa, South Korea and Japan appear generally more satisfied with the resources provided at the national level. This could be because NSBs differ in the financial support they provide for industry, consumer organizations, trade unions, environmental groups and public interest actors, to become involved in the process. NSBs fund themselves in a different way, such as industry, government as well as from the sale of standards. For example, some SDOs (such as in South Korea for example) are public bodies that are regulated by a law covering general standards and operate as part of a particular Ministry-Department. At the other end of the spectrum, there are entirely private bodies that are funded merely by the subscription from industry, NGOs or other groups (such as in US for example). Between these extremes, there are a number of SDOs that serve as an advisory board to the competent ministries in charge, but have also established closer linkages with other organizations to share human resources on nanotechnology related issues (such as in Japan for example) (see also Schepel and Falke, 2000).[97]

Table 5.11: The Perceptions of Stakeholder on *Resources* and *the Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	1	1	0	1	0	2.3
Belgium	3	0	1	0	0	1.5
Canada	2	1	0	1	0	2.0
China	0	1	0	2	0	3.3
France	2	0	2	0	0	2.0
Germany	0	4	0	0	0	2.0
India	0	0	2	0	0	3.0
Iran	0	2	1	1	1	3.2
Italy	2	1	1	1	0	2.2
Japan	0	0	1	4	0	3.8
Liaison EU	0	0	1	1	0	3.5
Malaysia	1	1	0	0	0	1.5
Mexico	1	0	1	0	0	2.0
The Netherlands	6	0	1	2	0	1.9
Norway	0	1	0	1	0	3.0
South Africa	0	0	0	1	1	4.5
South Korea	0	0	1	1	1	4.0
Spain	0	1	0	0	0	2.0
Switzerland	1	1	0	0	0	1.5
UK	1	2	2	1	0	2.5
US	4	0	0	1	0	1.6

The institutional origin of the respondents emphasizes also that respondents of all stakeholder groups were not satisfied with resources provided by NSBs to support their participation at the international level. As we can observe in Table 5.12, their mean scores range between 1.0 to 2.9, that is between "very low" and "low" level of resources. The comments provided by respondents are in many ways similar to the comments mentioned earlier, particularly in terms of the financial barriers they face to participate in ISO meetings. Multiple respondents, from all stakeholder groups, emphasize that the costs of active participation at the international

[97] The Japanese standardization body (JSB) has made linkages with other organizations to share human resources on nanotechnology related issues. Representatives of the Japan's National Institute of Advanced Industrial Science and Technology (AIST) have a leading role in the JSB. AIST is the core R&D organization in Japan involved in research and development projects on metrology and test methods for nanotechnology, and is funded by the New Energy and Industrial Technology Development Organization.

standardization activities are too high for them to support their involvement in these processes. Industrial actors (and specifically those coming from SMEs) indicate that resources remain a problematic issue even in cases when NSBs provide subsidies to support their traveling costs to ISO meetings, but not their working hours. In this regard, a Dutch delegate indicated that he had to quit his activities on nanotechnology standardization because his company could not afford the unpaid hours he spent on standardization issues.

Table 5.12. The Perceptions of Stakeholders on *Resources* and the *Type of the Organization*

	Resources					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	6	3	3	5	0	2.4
RI	6	5	3	4	0	2.3
Acad	3	3	4	4	2	2.9
Gov.	2	4	2	3	1	2.7
NGO	4	0	1	0	0	1.4
Reg.	0	1	0	1	0	3.0
TA	1	0	0	0	0	1.0
TUO	1	0	0	1	0	2.5

In sum, the data suggest that respondents from developed countries and LDCs seem relatively satisfied with their level of participation and representation on nanotechnology standardization activities. However, the provision of resources remains a major barrier for all respondents. The institutional origin of respondents revealed several explanations about the mixed and different perceptions of stakeholders. Actors coming from industry, research institutes and governmental agencies appear more satisfied with their level of participation and representation at standardization activities. However, respondents coming from NGOs and TUOs seem to struggle more with the issue of participation and representation, mainly because of the insufficient funds.[98] The fact that some NSBs finance themselves through membership fees has caused many concerns amongst actors coming from these groups, who fear that these practices may lead to the participation gap of under-resourced groups. In fact, financial resources have challenged the ability of some businesses to participate as well, such as SMEs for example.

At the international level, ISO and its TCs, including TC 229, are reliant on harnessing technical expertise and building consensus between the different sectors and jurisdictions that make up its constituency. However, for the most part, TC 229 is open to members who pay their

[98] Similar barriers for this group of stakeholders have been observed in the development of the ISO 14000 and ISO 14001 (Cadman, 2012; Raines, 2002) as well as ICT standards (Jacobs, 2010).

own membership fees. This “pay-to-play” requirement, as observed at the biannual plenary meetings, has led to the under-representation of actors coming from smaller organizations, including those from the not-for-profit arena. ISO has taken several initiatives to assist the participation of developing countries in the standardization process, including for example the establishment of the DEVCO and COPOLCO committees. The data from the survey suggest that developing country respondents seem relatively satisfied with these initiatives, but recommend that more needs to be done on the way how these actors are involved in the process. In the next Section we discuss these recommendations in more details. Given these mixed results on inclusiveness, representation and resources the overall rating for *meaningful participation* is *medium*. This is indicated by the mean of 3.2 on a scale of 1 (very low) to 5 (very high) (see Table 5.13).

Table 5.13: The Perceptions of Stakeholders on *Meaningful Participation*

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Inclusiveness	19	33	13	5	5	3.7
Representation	14	29	23	5	2	3.6
Resources	3	19	13	16	24	2.4
Overall Rating						**3.2**

Scale: 1 (very low) to 5 (very high).

5.2.1.d. Recommendations to Improve Meaningful Participation at ISO/TC 229

In an open-ended question surveyees were asked to provide recommendations on how TC 229 can enhance the legitimacy of its processes and outcomes. In this section, I provide the main recommendations of respondents on *meaningful participation*. As mentioned earlier (Section 5.2.1.a) the participation of all relevant stakeholders in nanotechnology standardization process is perceived to come with many challenges, mainly because some stakeholders lack the financial resources, technical means and expertise to afford an active involvement in these processes. The openness of the NSBs and ISO to allow all interested parties to be involved in the process is considered an important, but not a sufficient strategy for ensuring the active engagement of these parties in the process. Building upon these challenges, respondents recommend that both NSBs and ISO are more active in recruiting the participation of underrepresented stakeholder groups so that a proactive stakeholder engagement and a more dynamic representation of actors is ensured throughout the process. However, ensuring such a representation requires that standardization bodies provide funding and training to organizations presenting the interests of actors that are impacted by nanotechnology standards, but cannot afford active involvement in these processes (e.g. consumer representatives, NGOs, SMEs etc.). More specifically, respondents recommend that several activities are undertaken at the national and international level.

At the national level, based on the recommendations of respondents, NSBs need to:

- provide more financial support for NGOs, SMEs and consultancies to support the time spent at national standardization bodies and ISO;
- improve the training schemes for consumers to understand the standardization issues related to nanotechnology as well as their impact on the process;
- use internet based activities to attract participants more productively (e.g. establish more interactive websites at the national mirror committees that allow members to add their comments and contributions);
- ensure that relevant actors are included from the early stages of standardization;
- foster the cooperation between the government and industry with regards to the importance of the ISO work, so that the government supports financially NSBs (national bodies could learn from the strategies of other NSBs on how to establish close collaboration with government. For example one could also learn from the experience of the NSBs in S.Africa or Singapore).

At the international level, based on the recommendations of respondents, ISO and TC 229 need to:

- improve the funding schemes to support the inclusion of knowledgeable and dedicated experts in the process and not “tourist experts” (i.e. experts who participate on *ad-hoc* basis);
- establish new ways for stakeholders to be included in the standardization process (i.e. participation through video conference, Skype etc);
- raise awareness about the social and economic benefits of TC 229 standards;
- foster the cooperative culture within the TC by encouraging the active participation of the developing countries in standardization activities; and

- commit more time and resources to coordinate work with government on the development and benefits of standards.

5.2.2. Deliberative Decision-Making at ISO/TC 229

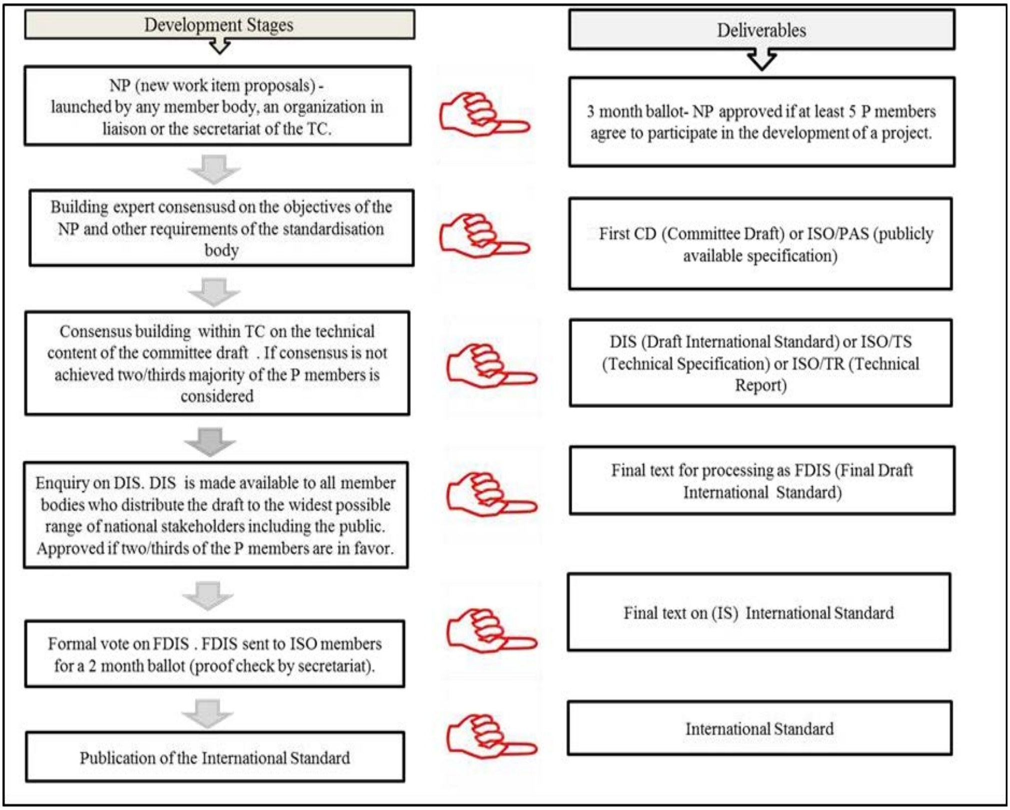
To understand the performance of TC 229 on *deliberative decision-making*, the survey explored the perceptions of stakeholders on *participatory decision-making*, *comprehensive agreements*, *communicative agreements* and *effective dispute settlement*. In the following paragraphs I first provide background information on TC 229 and afterwards analyze the perceptions of stakeholders on each performance indicator.

5.2.2.a. Participatory Decision-Making

There are several stages in the development of standards, each of which is important in shaping the development of standards and provides an opportunity for firms, experts, and other social drivers (e.g. NGOs, consumer representatives, trade unions) to influence the technical specifications and the final draft of a standard. Figure 5.5 illustrates the development progress for international standards. According to ISO/IEC Directives, the new work item proposals (NP) at TC 229 are launched by any member body, an organization in *liaison* or the secretariat of the TC (ISO/IEC, 2012). NPs contain the purpose and justification for developing a standard, which are reviewed and balloted by the 'PI' members through simple majority voting. A new proposal is approved in ISO/TC if 50% of the 'PI' members support the proposals and five or more agree to participate in the development of the project (Hatto, 2010). The aim of this preparatory stage is to develop a consensus document that satisfies the objectives of the proposal and other requirements of the standardization body (i.e. compliance with ISO/IEC Directives). Afterwards, the project proposal is allocated to a respective WG and 'PI' members nominate the experts that will be involved in the project group responsible for the development of the particular work item. In the third stage, members discuss the technical content of the committee draft standard (CD). Besides face-to-face meetings, the work of the project group is also undertaken by correspondence (e.g. e-mail, telephone, web conferencing). For the CD to be circulated as an enquiry draft a consensus and support of all members is required. When consensus is not achieved, a two-thirds majority of the 'PI' members is considered sufficient. Following the enquiry stage, the registration of a project as a proposed Draft International Standard (DIS) is made (ISO, 2008).

In the next stage, DIS is made available to all member bodies, which have an obligation to distribute the draft to national stakeholders including the public. This stage is of crucial importance in the consensus building process because 'PI' members have to consult relevant national stakeholders and study their comments before submitting the national vote on DIS. 'OB' members and *liaisons* are also free to submit comments. The enquiry draft is approved if two-thirds of the 'PI' members are in favor and no more than one-quarter of the total number of votes are negative. Only when 100% of the members approve DIS - it may proceed directly to the publication of the standard. In the contrary, the enquiry stage ends with the registration of the Final Draft International Standard (FDIS). The final draft is then send to the approval stage, where the translation (in French or English) and the final editions are done by ISO staff to ensure compliance with ISO/IEC Directives (ISO, 2008; ISO/IEC, 2012). The FDIS text then is send to ISO member bodies for a two month vote. Following this stage the publication of the international standard (IS) is made.

Figure 5.5 : Development of the International Standards [99]



[99] Figure 5.5. is adapted from : ISO., 2008. *My ISO Job: Guidance for Delegates and Experts*, ISO Central Secretariat.

The process of developing standards indicates that inclusion in the decision-making is important for various actors to communicate their interests and shape the development of international standards. At this point it is important to note that 'PI' members play an active role in the work of their TC. They are expected to comment on the proposals from the initial to the final stages, and exercise full voting rights on any TC and policy committee of ISO. The 'OB' members and *liaison* members are usually those organizations who want to follow the development of a standard and are interested to make a contribution to the work item proposals. These members are allowed to nominate experts to work on projects, but have no right to vote (ISO, 2008 & 2012a; ISO/IEC, 2012). Therefore, the ability of the 'OB' members and *liaisons* to initiate new proposals and influence the final standardization outcomes seems to be more limited.

To understand the perceptions of stakeholders on *participatory decision-making*, surveyees were asked to indicate the extent to which they feel that in TC 229 there are fair opportunities for them to influence the content of the standards. 74 respondents answered this question. The results of the survey indicate that respondents perceive the process of decision-making relatively participatory. In particular, 8 respondents indicated that they have had *very high* opportunities to influence the content of TC 229 standards. 34 respondents indicated that they have *high* opportunities to influence the content of TC 229 standards, followed by 22 respondents having *medium* opportunities, 9 respondents - *low* opportunities and one respondent - *very low* opportunities. Two respondents did not answer to this question (see Table 5.14 and Figure 5.6). The characteristics of the respondents are discussed in below. Overall these data emphasize that respondents are relatively satisfied with the *participatory decision-making* in TC 229. This is indicated by the mean of 3.5, which corresponds to a "medium" level of *participatory decision-making* on scale of 1 (very low) to 5 (very high) (see Table 5.23).

Figure 5.6: The Distribution of Stakeholders' Perceptions on *Participatory Decision-Making*

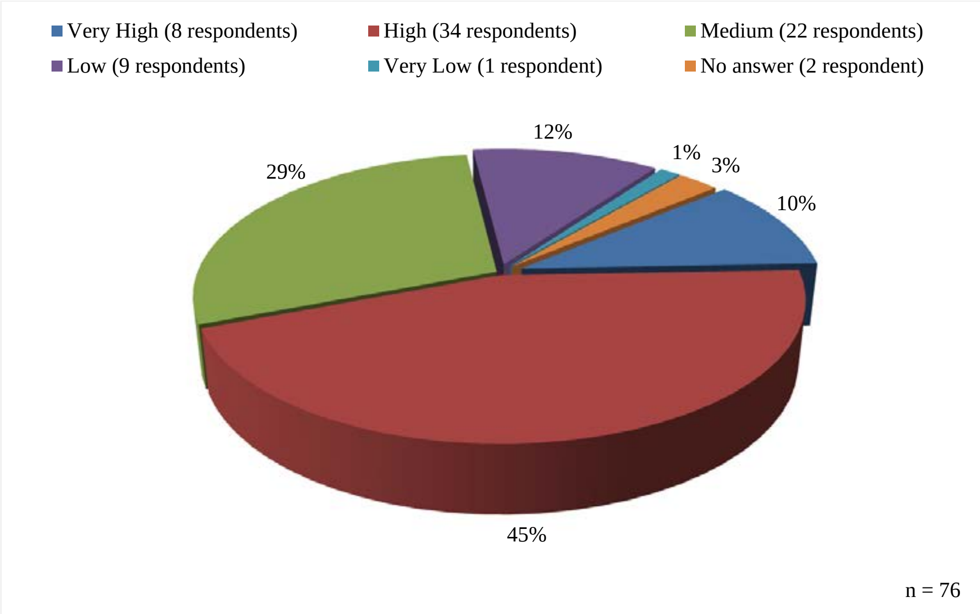


Table 5.14 presents the scores given on *participatory decision-making* by different stakeholders based on their country of origin. By looking at Table 5.14, we can see that respondents from India, Iran, Malaysia, South Africa, South Korea, Norway and Switzerland, appear less satisfied with the opportunities they have had to influence the content of TC 229 standards as compared to other respondents. Respondents being highly satisfied with *participatory decision-making* came mainly from China, France, Germany, Japan, Spain followed by respondents coming from US, UK and Canada. On the question on *participatory decision-making* there were 59 respondents from developed countries and 18 from LDCs. The mean scores in Table 5.14 emphasize that there is a higher variation on the perceptions of stakeholders coming from developed countries with responses ranging between 2.5 to 4.2, that is between "low" and "high level" of *participatory decision-making*. The perceptions of respondents from LDCs range between 3.0 to 4.0, that is between "medium" and "high level" of *participatory decision-making*. An explanation for the lower variation on the perceptions of respondents from LDCs could be the small number of responses received from these countries.

Table 5.14. The Perceptions of Stakeholders on *Participatory Decision-Making* and *the Country of Origin*

	Very Low	Low	Medium	High	Very High	Mean
	Number of respondents					
Australia	0	0	1	2	0	3.7
Belgium	0	1	1	2	0	3.2
Canada	0	0	2	1	1	3.8
China	0	0	1	1	1	4.0
France	0	0	1	2	1	4.0
Germany	0	0	1	2	1	4.0
India	0	0	1	0	0	3.0
Iran	0	2	1	2	0	3.0
Italy	1	0	1	2	1	3.4
Japan	0	0	2	0	3	4.2
Liaison EU	0	1	0	2	0	3.3
Malaysia	0	0	2	0	0	3.0
Mexico	0	0	1	1	0	3.5
The Netherlands	0	1	1	6	0	3.6
Norway	0	1	1	0	0	2.5
South Africa	0	0	2	0	0	3.0
South Korea	0	2	0	1	0	2.7
Spain	0	0	0	1	0	4.0
Switzerland	0	0	2	0	0	3.0
UK	0	1	0	5	0	3.7
US	0	0	1	4	0	3.8

For the respondents of the LDCs, financial resources have generally played an important role on how they are involved in the standardization processes. For instance, one respondent from LDCs indicated that the financial difficulties to participate actively in TC 229 meetings often create a situation in which a country is represented by various experts throughout the development cycle of one standard. In this way, as the respondent argues, some experts end up participating on ad-hoc basis, which reduces the chances for particular member countries to influence the development of an international standard. Furthermore, five respondents seemed concerned with the number of delegates that developed counties sent at the TC 229. These respondents argued that since some developed countries send more delegates at the TC 229, they get to influence much more the final standardization decisions. This, in the view of respondents, have impacted the entire process of standardization, which often feels poorly represented.

The views of the respondents on *participatory decision-making* seemed to vary also with the extent to which they were associated with industrial organizations, governmental agencies or organizations representing civil society. By looking at the mean scores provided in Table 5.15, we can observe that respondents coming from industry, research institutes, governmental agencies and trade associations, generally appear more satisfied with the influence they have to the development of international nanotechnology standards. Respondents coming from NGOs and TUOs appear less satisfied. These respondents have participated mostly in the WG3 and WG4 of the TC 229, and have a background on occupational health and safety, as well as on consumer and societal issues. In comparison, actors coming from industry, research institutes and governmental agencies are involved mostly in WG1, WG2 and WG3. These respondents have an expertise on chemistry, physics, toxicology and materials science, and appear more satisfied with the influence they have had in the development of standards on each WG.

This data seem to suggest that the expertise of respondents may have also played a role on how they have influenced the development of standards. Another explanation for the lower mean scores of respondents coming from NGOs and TUOs could be also the status that these respondents have when participating in the standardization process. In particular, some of these respondents come from Liaison Organizations and have an observatory status in the standardization process. This, according to the ISO rules, means that these actors do not have voting rights in the standardization process. Therefore, as one respondent argues, it is difficult for NGOs and related actors to influence the content of the standards.

Table 5.15. The Perceptions of Stakeholders on *Participatory Decision-Making* and *the Type of the Organization*

	Participatory Decision-Making				**Mean**
	Low	**Medium**	**High**	**Very High**	
	Number of respondents				
IO	1	4	10	2	3.8
RI	1	6	8	3	3.7
Acad	5	4	5	1	3.1
Gov.	0	2	7	1	3.6
NGO	1	4	1	0	3.0
Reg.	0	1	1	0	3.5
TA	0	0	1	0	4.0
TUO	1	1	0	0	2.5

5.2.2.b. Comprehensive Agreements

As illustrated in Figure 5.5, technical committees in ISO function under the consensus agreement of the member states. Decisions on committee draft proposals and their technical content are taken through consensus, whereas approvals on enquiry drafts and final drafts depend on member ballots. In ISO each country has one vote. The process of achieving consensus on the purpose and the technical content of the standard involves a mixture of bargaining and arguing amongst participants until a resolution of all significant technical disagreements is achieved (ISO, 2012). Under its agreement with WTO, ISO must implement the principles of "good governance" including consensus. According to ISO/IEC Directives consensus is considered "a general agreement, characterized by the absence of sustained opposition to substantial issues […] and by a process that involves seeking to take into account the views of all parties concerned" (ISO/IEC, 2012: 28). The ISO procedures indicate that the chair of the WG or TG decides whether consensus is obtained on a specific decision (Hallström and Boström, 2010: 155).

To understand the perceptions of stakeholders on *comprehensive agreements*, surveyees were asked to evaluate the extent to which their interests are taken into account when agreements on setting nanotechnology standards are made. 75 respondents answered this question. In particular, 8 respondents indicated that their interests were taken *very highly* into account, 39 respondents indicated that their interests were *highly* taken into account, 24 respondents indicated that their interests were *somewhat* taken into account and 4 respondents indicate that their interests were *poorly* taken into account. One respondent did not answer to this question (see Table 5.16 and Figure 5.7). According to this data, the overall rating for *comprehensive agreements* is relatively high, as indicated by the mean of 3.6 on a scale of 1 (very low) to 5 (very high) (see Table 5.23).

Figure 5.7: The Distribution of Stakeholders' Perceptions on *Comprehensive Agreements*

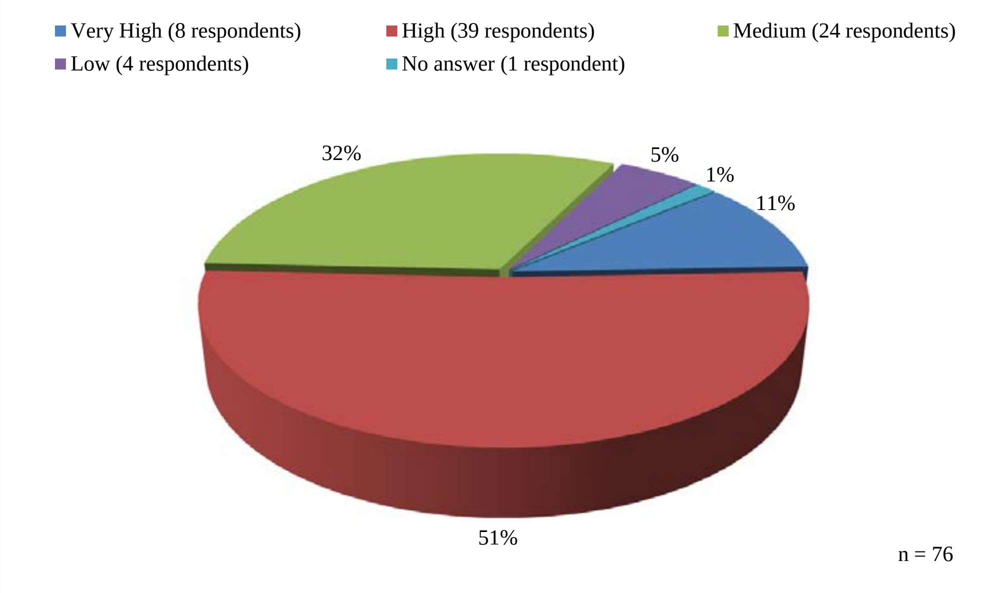


Table 5.16 presents the scores given on *comprehensive agreements* by different stakeholders based on their *country of origin*. The data indicate that respondents from Belgium, India, Iran, Liaison Organizations, Malaysia, Mexico, Norway and Switzerland, generally appear less satisfied with the extent to which their interests are taken into account when decisions on nanotechnology standards are made. Therefore, similar to the scores given on participatory decision-making, the majority of respondents rating *comprehensive agreements* as being low, are coming from LDCs. This, as we shall see in Section 5.4, suggests that there may be some correlation between these indicators. In particular, those that are less involved in influencing the content of standards are most likely to argue that their interests are not taken into account in the setting of nanotechnology standards.

Jakobs (2010) has observed similar trends in the ICT standardization area, arguing that participation in the meetings is a crucial "non-technical factor" for respondents to ensure that their views are taken into account. Lack of physical participation at the TC meetings, as Jakobs argues while reflecting on stakeholder responses, often impacts the influence of stakeholders on the decisions made about standards regardless of how technically correct their arguments may be.

At the country level the mean scores suggest that there is a higher variation on the perceptions of respondents coming from developed countries. In particular, the perceptions of respondents from developed countries range between 2.5 to 4.2, which is between "low" and "high" level of *comprehensive agreements*. On the other hand, the perceptions of respondents from LDCs range between 3.0 to 4.0, which is between "medium" and "high" level of *comprehensive agreements*.

Table 5.16. The Perceptions of Stakeholder on *Comprehensive Agreements* and the *Country of Origin*

	Low	Medium	High	Very High	Mean
	Number of respondents				
Australia	0	1	2	0	3.7
Belgium	1	2	1	0	3.0
Canada	0	2	1	1	3.7
China	0	1	1	1	4.0
France	0	0	3	1	4.2
Germany	0	1	2	1	4.0
India	0	1	0	0	3.0
Iran	0	3	2	0	3.4
Italy	0	1	3	1	4.0
Japan	0	2	1	2	4.0
Liaison EU	1	0	2	0	3.3
Malaysia	0	2	0	0	3.0
Mexico	0	1	1	0	3.5
The Netherlands	0	2	6	1	3.9
Norway	1	1	0	0	2.5
South Africa	0	0	2	0	4.0
South Korea	0	1	2	0	3.7
Spain	0	0	1	0	4.0
Switzerland	1	0	1	0	3.0
UK	0	2	4	0	3.7
US	0	1	4	0	3.8

Seven respondents, from both developed and LDCs, commented on the comprehensiveness of agreements at TC 229. These respondents appear very critical on the way new work item proposals are approved within the Committee. For example, one respondent argued that developed countries have often the "lion's share" and dominate to get their views accepted and the standards made on the way which suits them. This, in the view of the respondent, has led the process to be influenced more by politics rather than the priorities for the work that needs to be done.[100] Other respondents argued that this had to do also with how the meetings in TC 229 are

[100] In earlier work, Forsberg (2012) while reflecting on anecdotal evidence from TC 229 WGs, also indicates that standardization outcomes in nanotechnologies are not always resulting from processes based on argumentation and deliberation, but they also are based on negotiations and politics.

chaired. In particular, the fact that WGs in TC 229 are chaired mostly by developed countries (e.g. WG1 on Terminology and Nomenclature is chaired by Canada; WG2 on Measurement and Characterization is chaired by Japan; WG3 on Health, Safety and Environment is chaired by US), was considered to be an important factor for these actors to gain additional influence in the process and increase the chances for the standards to made on the way which suits the interests of these countries. Similar observations on this issue have been made by Delemarle and Throne-Holst (2012), when discussing the objectives and the work of the WGs in TC 229.

While commenting on the comprehensiveness of the agreements in TC 229, one respondent was concerned that bargaining and lobbying were often used as mechanisms for reaching consensus amongst delegates on nanotechnology standardization issues. As argued by various scholars, power politics and lobbying seem to be the way for reaching agreements in other standardization areas as well. For instance, Jakobs (2010: 9) argues that the development of the ICT standards is often about the "distribution and the use of power," and in many cases negotiations occur outside the official meetings. Cadman (2012) when discussing the development of environmental standards compares the inappropriate use of consensus" in TC 207 to a government cheating on election. The main argument here is that a consensus that serves as the basis for decision-making and does not represent all relevant actors, is similar to establishing a democratic system that is based on cheated elections.

In TC 229, the use of consensus also seems to have impacted the way standardization documents are produced. According to one respondent, achieving consensus on the content of the documents is often very challenging and difficult within the WGs of TC 229. This, as the respondent argued, has cost the Committee to establish few documents which are actual technical standards with requirements. The majority of documents in the Committee are TRs and TSs, which are established when there is a lower level of consensus amongst participants. The comments of the respondents on the deliverables of TC 229 can be divided in two groups. There were some respondents, for example, that argued that technical standards for nanotechnology are not established because of the uncertainties of the field, and more specifically, because of the absence of relevant expertise.[101] These issues seem to have been similarly acknowledged by the former Chairman of the TC 229, arguing that unless the experts nominated in the projects have the appropriate knowledge there can be no real contribution to achieving consensus (Forsberg, 2010). Four respondents alternatively argued, that the production of TRs and TSs is the result of the difficulties to reach agreement amongst experts on the technical issues that these documents should cover. Because of the difficulties to reach

[101] In an earlier study, Delemarle and Holst (2012) also emphasize that the lack of scientific knowledge is experienced as a practical problem in the working groups.

consensus, the content of these documents in some WGs (e.g. WG1 on terminology and nomenclature) seems broad and not very substantial (see also Forsberg, 2010; Hatto,2010).[102] As Blind and Gauch (2009) argue, the heterogeneous standardization community and the various backgrounds that experts have, are the main factors that generate problems amongst experts to find a consensus towards a common terminology.

The views of the respondents on *comprehensive agreements* seemed to vary also with the extent to which they were associated with industrial organizations, governmental agencies, organizations representing civil society and so on. By looking at the scores in Table 5.17, we can observe that respondents coming from industry, research institutes and governmental appear generally more satisfied with the way their interests are taken into account when setting nanotechnology standards. Respondents from trade associations and regulatory agencies appear also satisfied, but the number of respondents is very limited for these groups. The mean scores in Table 5.17 emphasize that NGOs and trade unions appear generally less satisfied with the way their interests are taken into account when setting nanotechnology standards.

An explanation for the low influence that these stakeholders have in the development of standards could be the liaison status that they have in TC 229. As mentioned earlier, this status gives these organizations an opportunity to participate and observe the process, but they have no voting rights. However, the ISO Directives specify that the TCs should seek the "full and […] formal backing" of liaison organizations on the documents in which they have an interest (ISO/IEC, 2012: 20). According to some respondents (i.e. 18 respondents) this does not seem to work in practice, which is also the reason why they argue that within the TC 229, and in ISO more generally, the rules for engagement should be more flexible. In particular, they argue, that representatives of the civil society should not only be part of the "consultative schemes" in the TCs, but they should have the "status of experts" and have more "voice" in the setting of standards. These and other recommendations are discussed in Section 5.2.2.e.

[102] ISO/TC 229 N 812- 11th meeting of ISO/TC 229, December 2010, Kuala Lumpur Chairman's speech at the opening ceremony.

Table 5.17: The Perceptions of Stakeholders on *Comprehensive Agreements* and *the Type of the Organization*

	Comprehensive Agreements				**Mean**
	Low	**Medium**	**High**	**Very High**	
	Number of respondents				
IO	0	4	11	2	3.9
RI	0	5	11	2	3.8
Acad	1	8	6	1	3.4
Gov.	0	2	7	2	4.0
NGO	2	3	1	0	2.8
Reg.	0	1	1	0	3.5
TA	0	0	1	0	4.0
TUO	1	1	0	0	2.5

5.2.2.c. Communicative Agreements

The best opportunities for experts to meet with delegates and make rapid progress in developing a particular document are the plenary-week meetings of TC 229 (Hatto, 2010). These meetings are face-to-face and are held every tenth month in various countries of the world. The meetings aim to bring experts together to discuss on relevant standardization issues that have come up in previous teleconference discussions, to meet with colleagues from different projects, or discuss on future work. The discussions take place during the WG and PG meetings, in which experts interested in particular area participate to contribute to the debate. When decisions are not made the discussions continue through teleconferencing.

To understand the perceptions of stakeholders on *communicative agreements*, surveyees were asked to indicate the extent to which they feel that the exchange of arguments amongst participants in TC 229 meetings is effective. 74 respondents answered this question. In particular, 13 respondents perceived the interaction with other participants in TC 229 *very highly* effective, followed by 32 respondents perceiving it *highly* effective, 26 respondents - *somewhat* effective and 3 respondents - *poorly* effective. Two respondents did not answer to this question (see Table 5.18 and Fig.5.8). Overall these data emphasize that respondents are relatively satisfied with the extent to which they have been able to exchange arguments with other participants in TC 229. This is indicated by the mean of 3.7, which corresponds to a “medium” level of *communicative agreements* on a scale of 1 (very low) to 5 (very high) (see Table 5.23).

Figure 5.8: The Distribution of Stakeholders' Perceptions on *Communicative Agreements*

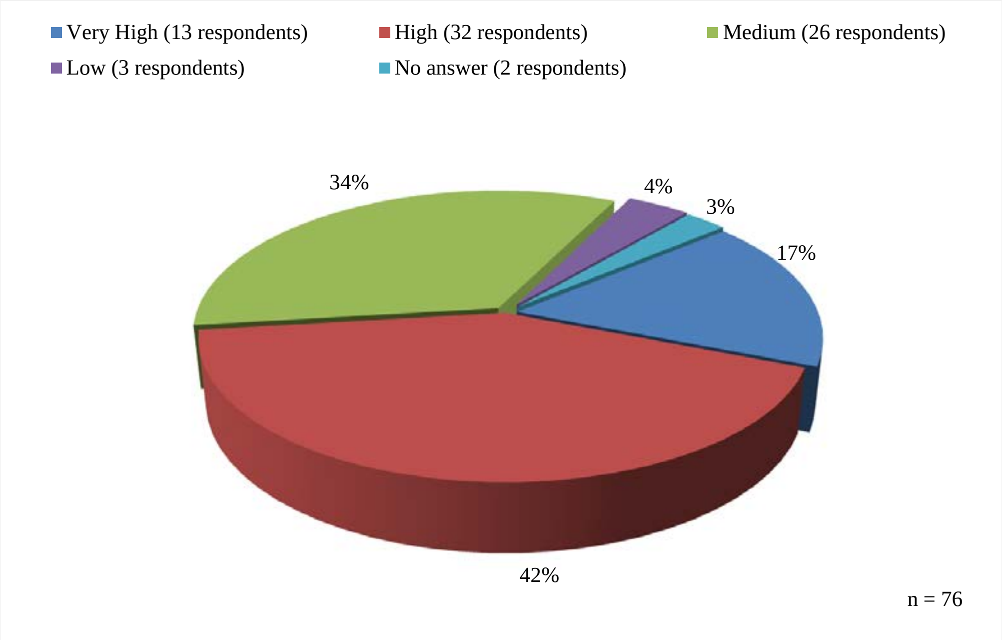


Table 5.18 presents the scores given on *communicative agreements* by different stakeholders based on their *country of origin*. By looking at Table 5.18 we can see that respondents of both developed countries and LDCs appear relatively satisfied with the interaction they have with other participants in TC 229. In fact when looking at the mean scores of some respondents, such as for example of those coming from Switzerland, Norway, Malaysia and South Africa, which had lower scores on the aforementioned indicator, we can observe that the scores for *communicative agreements* are higher. This data seem to suggest that whereas these actors may be satisfied with the way they interact with other delegates, the difficulties arise when they have to reach an agreeement or decide which arguments and solutions are the best to proceed when setting standards.

Table 5.18. The Perceptions of Stakeholders on *Communicative Agreements* and the *Country of Origin*

	Low	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents				
Australia	0	2	1	0	3.3
Belgium	1	1	2	0	3.2
Canada	0	2	1	1	3.7
China	0	1	0	2	4.3
France	0	0	3	1	4.2
Germany	0	2	2	0	3.5
India	0	0	1	0	4.0
Iran	0	2	3	0	3.6
Italy	0	1	3	1	4.0
Japan	0	1	1	3	4.4
Liaison EU	1	0	2	0	3.3
Malaysia	0	0	2	0	4.0
Mexico	0	1	0	1	4.0
The Netherlands	0	4	3	1	3.6
Norway	0	1	1	0	3.5
South Africa	0	1	0	1	4.0
South Korea	0	2	1	0	3.3
Spain	0	0	1	0	4.0
Switzerland	1	1	1	0	3.5
UK	1	3	1	1	3.3
US	0	1	3	1	4.0

The views of the respondents on *communicative agreements* seem to vary also with the extent to which they are associated with industrial organizations, governmental agencies, organizations representing civil society and so on. By looking at the scores in Table 5.19 we can observe that respondents coming from industry, research institutes and governmental appear more satisfied with the way their interests are taken into account when setting nanotechnology standards. The institutional origin of the respondents emphasizes that respondents from NGOs, TUOs and regulatory agencies appear to have more problems with the way they have been interacting with other participants in TC 229. The main challenges brought forward by respondents were the cultural and language barriers. According to one respondent, different languages often cause problems amongst participants in relation to understanding each other.

The official language in the Committee is English[103], and because of the domination of Western and European Countries, the negotiation process or interaction amongst participants seems to rely mostly on Western customs. Experts involved in the work of TC 229 argue that another factor contributing to difficult communication is also the diversity of background of the delegates involved in nanotechnology standardization (see Blind and Gauch, 2009; Delemarle and Throne-Holst, 2012). In fact, delegates have a background on chemistry (25 out of 74), physics (12 out of 74), material science (25 out of 74), toxicology (13 out of 74), OHSH (18 out of 74), environmental safety (8 out of 74), as well as consumer and societal dimensions (12 out of 74). NGOs and TUOs belong to the last group of respondents. In this way, these various backgrounds may generate difficulties for delegates to communicate and agree in the standardization process, because what may be, for example, an appropriate definition or specification for an academic it may not be for an industrialist or NGO.[104]

Table 5.19: The Perceptions of Stakeholders on *Communicative Agreements* and *the Type of the Organization*

	Communicative agreements				**Mean**
	Low	**Medium**	**High**	**Very High**	
	Number of respondents				
IO	0	7	8	2	3.7
RI	0	5	9	4	3.9
Acad	1	5	6	3	3.7
Gov.	0	4	5	2	3.8
NGO	1	4	1	0	2.6
Reg.	1	1	0	0	3.5
TA	0	0	1	0	4.0
TUO	0	2	0	0	3.0

The views of the respondents on *communicative agreements* seem to vary also with the extent to which they have participated in the TC 229 meetings and understand the nanotechnology standardization process. As emphasized in Table 5.20, respondents that have participated in more than five TC 229 meetings, and have advanced level of knowledge on nanotechnology standardization issues, are more satisfied with the way they have been interacting with other

[103] See also Hatto, P., 2010. European Commission Directorate – General for Research & Innovation, *Standards and Standardization: A practical guide for researchers* 4-5, *available at*: http://ec.europa.eu/research/industrial_technologies/pdf/practical-standardisation-guide-for-researchers_en.pdf

[104] Delemarle and Throne-Holst (2012: 12) have observed that in JWG1-working on terminology and nomenclature, delegates face many difficulties to communicate and agree on the terms and definitions for nanotechnology. These difficulties seem to emerge mainly, as the authors argue, because "[…] the scientific definition of a term X may not be the same as the definition of the same term X used by industrialists leading to hard debates".

participants. This is indicated by the higher mean scores that these respondents have on communicative agreements.

When discussing the development of environmental management standards in TC 207, Raines (2001 & 2003), argues that it takes up to 2-3 meetings until respondents get deep understanding in the standardization process. Furthermore, Raines observed that those that were more involved in these meetings had better chances to develop close relationships and negotiate with delegates from other countries (Raines, 2001: 65). The results of the Kendall's tau_b correlation verify that in TC 229 similar trends can be observed. In particular, that there is a positive and statistically significant relationship between the perceptions of the respondents on *communicative agreements* and their *level of participation at TC 229 meetings* (τ = 0.38; significant level = 0.00), as well as their *level of expertise on nanotechnology standardization issues* (τ = 0.16; significant level = 0.10) (see Appendices 5 and 6).

Table 5.20: Stakeholder Perceptions on *Communicative agreements*, the *Level of Technical Expertise*, and *Participation at TC 229 meetings*

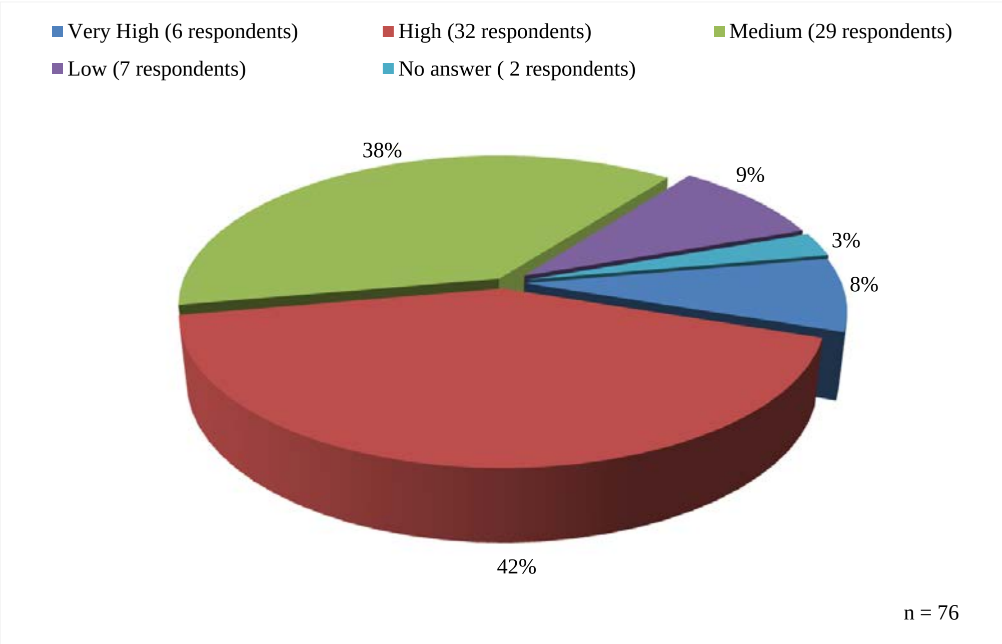
Level of Technical Expertise	Number of respondents	**Mean**	***Participation at TC 229 meetings***	Number of respondents	**Mean**
Basic	3	3.3	1- 4 meetings	27	3.3
Intermediate	18	3.4	5-8 meetings	25	3.7
Advanced	29	3.8	9-13 meetings	22	4.2
Specialist	25	3.9			

5.2.2.d. Effective Dispute Settlement

Given that nanotechnology standardization is developing at a stage when the field has not achieved its maturity and when there are still many uncertainties, it is reasonable to expect that stakeholders have different arguments over the technical issues that standards should cover. ISO Directives clearly indicate that the reconciliation of conflicting arguments amongst national delegates is crucial to determine the technical content of the standard (ISO/IEC, 2012). However, when tensions cannot be solved through consensus, a two-third of majority voting of the 'PI' members of the Committee is acquired. In cases when no agreement is achieved amongst members, the chair of the TC may also consider the publication of an intermediate deliverable in the form of a Technical Specification (TS) (ISO/IEC, 2012).

To understand the perceptions of stakeholders on *effective dispute settlement*, surveyees were asked to indicate the extent to which they feel that TC 229 is successful in settling the disputes amongst participants in cases when agreements are difficult. 74 respondents answered this question. In particular, 6 respondents perceived the effectiveness of TC 229 to solve disputes - *very high*, 32 respondents - *high*, 29 respondents - *medium* and 7 respondents - *low*. Two respondents did not respond to this question (see Table 5.21 and Figure 5.9). As we shall see in Table 5.22, respondents from developed countries (e.g. US, UK, Netherlands, France, Germany, Australia) appear to be more satisfied with the way disputes are settled in TC 229. Only few respondents (i.e. 7 out of 74) seem to have more issues with dispute settlement. Overall these data emphasize that respondents perceive TC 229 to be relatively successful in settling the disputes amongst participants. This is indicated by the mean of 3.4, which corresponds to a "medium" level of *effective dispute settlement* on a scale of 1 (very low) to 5 (very high) (see Table 5.23).

Figure 5.9: The Distribution of Stakeholders' Perceptions on *Effective Dispute Settlement*



At the country level there were mixed perceptions amongst respondents on dispute settlement (see Table 5.21). The variation of responses for both developed counties and LDCs was similar. In particular the responses for developed countries ranged between 3.0 to 4.0, and for LDCs between 3.0 to 4.5, which in both cases is between "medium" and "high" level of effective dispute settlement. By looking at Table 5.21, we can observe that respondents from France, China, Mexico, Spain, US, Germany and Japan have higher mean scores. This suggests that these respondents are most likely to perceive TC 229 as being successful in settling disputes amongst participants. Respondents from Belgium, India, Malaysia, Norway, Netherlands and Switzerland, appear generally less satisfied with the way disputes are settled in the Committee. As discussed in Section 5.2.2.a and 5.2.2.b, respondents from these countries were most likely to be less satisfied with other performance indicators as well (e.g. *participatory decision-making*, *comprehensive agreements*). This suggests that there may be a correlation amongst these indicators, in particular that the lower the involvement and influence of actors in the negotiation processes, the lower their satisfaction on how disputes are solved at the international level. As we shall see in Section 5.3 the correlation between the perceptions of respondents on these performance indicators is also statistically significant.

Table 5.21. The Perceptions of Stakeholders on *Dispute Settlement* and the *Country of Origin*

	Low	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents				
Australia	1	0	2	0	3.3
Belgium	1	2	1	0	3.0
Canada	1	2	0	1	3.2
China	0	1	1	1	4.0
France	0	0	3	1	4.2
Germany	0	1	3	0	3.7
India	0	1	0	0	3.0
Iran	1	2	1	1	3.4
Italy	0	3	2	0	3.4
Japan	1	1	2	1	3.6
Liaison EU	1	0	2	0	3.3
Malaysia	0	2	0	0	3.0
Mexico	0	0	1	1	4.5
The Netherlands	0	4	4	0	3.5
Norway	0	2	0	0	3.0
South Africa	0	1	1	0	3.5
South Korea	0	2	1	0	3.3
Spain	0	0	1	0	4.0
Switzerland	0	2	0	0	3.0
UK	1	2	3	0	3.3
US	0	1	4	0	3.8

The views of the respondents seemed to vary also with the extent to which they were associated with industry, research institutes, academia, NGOs and other organizations. By looking at Table

5.22, we can observe that respondents coming from NGOs, TUOs and academia appear less satisfied with the way the disputes are settled in TC 229. However, looking in details at the mean scores of other respondents, it seems that some of them appear less satisfied with this indicator. For instance, respondents from industry and research institutes were more likely to perceive the effectiveness of TC 229 to settle the disputes amongst participants much lower than other performance indicators.

Table 5.22: The Perceptions of Stakeholders on *Dispute Settlement* and the *Type of the Organization*

	Dispute Settlement				**Mean**
	Low	**Medium**	**High**	**Very High**	
	Number of respondents				
IO	1	7	8	1	3.5
RI	0	5	11	2	3.8
Acad	1	9	5	0	3.2
Gov.	1	3	4	3	3.8
NGO	3	3	0	0	2.5
Reg.	0	1	1	0	3.5
TA	0	0	1	0	4.0
TUO	1	1	0	0	2.5

The deliverables that TC 229 has published, such as international standards, TR and TSs, reflect also the success or ability of the Committee to settle disputes amongst participants and cope with various interests and/or arguments. As mentioned in Section 2.4.1 and 5.2.2.b, the majority of outcomes from TC 229 are in the form of TSs, which are usually set when “there is the future but not immediate possibility of an agreement to publish an International Standard” (ISO/IEC Directive, 2012:33). As of September 2014 most of the documents published in TC 229 are in the form of TSs and TRs, which emphasizes that a lower level of consensus or agreement is achieved amongst participants (see also Forsberg, 2012). In this regard, some respondents argued that the difficulties to reach agreements on nanotechnology standards often occurred due to the high level of uncertainty and insufficient information to support the setting of standards. However, one respondent was more concerned that the review process of the new work item proposals was not very stringent in the Committee, which led to many projects being disputed on later stages. Similar trends have been observed by Forsberg (2010), which suggests that the Committee has not made many changes on the way it solves the disputes amongst participants.

In summary, the formal procedures of the ISO emphasize that there are several stages in the development of standards, which provide an opportunity for various stakeholders to influence the technical specifications and the final draft of a standard. However, the survey data suggest that respondents from LDCs, as well as those associated with NGOs, TUOs, academia and regulatory agencies, are less likely than respondents from developed countries and those associated with industry, research institutes, governmental laboratories and agencies, to view TC 229 decision-making process as deliberative. The responses of the surveyees emphasize that LDCs are most likely to be absent in the meetings. Often LDCs are represented by smaller delegations and have fewer resources, which seems to have impacted the possibilities for these actors to influence the content of the standards and create closer relationship with delegates from other countries. Similar to what has been observed in other standardization areas,[105] many respondents also admit that in nanotechnology standardization process power politics and negotiation tactics seem to play an important role on how powerful actors (mostly coming from developed countries, industries and research institutes) gain important positions in the WGs (such as chair, convenor etc), and push forward proposals in which they are interested.

As part of its agreement with the WTO, consensus remains one of the main principles guiding the development of international standards. ISO has also established other meachnisms for reaching agreements, such as simple and qualified majority voting. In TC 229 consensus seems to be the main mechanism used for reaching agreements on standardization proposals. However, as te respondents argue, the lack of sufficient knowledge and the various backgrounds of experts in the WGs, have often led to hard debates and no agreements to publish international standards.

Following the perceptions of the respondents on each performance indicator the overall score for the norm of deliberative decision-making is 3.6 (see Table 5.23). This means that respondents are relatively (but not highly) satisfied with the deliberation of the decision making process in TC 229. See Table 5.23 for the details of the responses.

[105] See for example: Jakobs, K.. 2010. How People and Stakeholders Shape Standards - the Case of IEEE 802.11. In Proceedings of WEBIST. Institute for Systems and Technologies of Information, Control and Communication; Hallström, T. K. and Boström, M., 2010. *Transnational Multi-Stakeholder Organization: Organizing Fragile Non-State Authority*, Edward Elgar : UK.

Table 5.23: The Perceptions of Stakeholders on *Deliberative Decision-Making*

Performance Indicators	Very High	High	Medium	Low	Very Low	Mean
	Number of respondents					
Participatory Decision Making	8	34	22	9	1	**3.5**
Comprehensive Agreements	8	39	24	4	1	**3.6**
Communicative Agreements	13	32	26	3	0	**3.7**
Effective Dispute Settlement	6	32	29	7	0	**3.4**
Overall Rating						**3.6**

Scale: 1 (very low) to 5 (very high).

5.2.2.e. Recommendations to Improve the Deliberative Decision-Making at ISO/TC 229

According to respondents a *deliberative decision-making process* in TC 229 may be established by using stronger democratic strategies. The strategies mentioned by respondents do not focus on the complete reconstruction of the ISO process, which may be very difficult and complex to be achieved, but on improving the quality of the deliberative environment in which nanotechnology standards are debated. In the view of many respondents (i.e. 40 respondents), this could be achieved by improving the quality of the decision-making process and turning it into an open, fair and participatory process. To achieve such a *deliberative decision-making process*, based on the recommendations of the respondents, TC 229 and the convenors of the working groups need to:

- enhance the quality of the deliberations in the WGs by facilitating the inclusion of participants with broader range of backgrounds;
- foster the quality of voting by discussing more thoroughly the content of the new work item proposals, the cohesion of project areas, as well as the validity of projects;

- make ballot results and comments easily accessible for all participants;
- use a checklist to identify standardization priorities and evaluate the relevance of new work item proposals;
- set limits on the number of delegates that each country can send on WGs to allow for the equal representation of stakeholders' perspectives in the decision-making process;
- upgrade the status of *liaison* and civil society organizations to "expert status" to allow them active participation at different stages of standardization development;
- adopt alternative voting structures that rely on a double-majority voting of both developed and developing countries;
- avoid language barriers by providing continuous translation in the WG and PG meetings; and
- provide support to NSBs to help them build local networks and develop more representative contributions.

5.2.3. Effective Process Control at ISO/TC229

To understand the performance of TC 229 on *effective process control*, the survey explored the perceptions of stakeholders on *transparency, domestic accountability, internal accountability* and *external accountability*. In the following paragraphs I first provide background information on TC 229 and afterwards analyze the perceptions of stakeholders on each performance indicator.

5.2.3.a. Transparency

As indicated earlier, to do justice to its key functions and deliverables, ISO assigns itself to the WTO (Miles, 2010). According to the agreement with the WTO, international standards embody "the essential principles of global openness and transparency, consensus and technical coherence […] safeguarded through its development in an ISO Technical Committee […] representative of all interested parties, supported by a public comment phase" (ISO, 2012:2).

It is important to note that TC 229 provides full access to its documents, plenary meetings and WGs to its members only. The dissemination of information is done by distributing documents for discussion through the ISO livelink website, which contains information about the Committee, including its programme of work, as well as draft work items (Hatto, 2010). Project leaders and WG secretaries use the website to display all documents relevant to the members of the WG and its constituent projects. The NSBs, on the other hand, provide access (by issuing a username and password) to their members in the area of the website devoted to the

WG in which respective projects are developed. However, even though NSBs have an important role to play on informing their members about respective projects developed at international level, it is the responsibility of ISO to ensure that all relevant parties have access to information related to the development of the international standards (see also Forsberg, 2012).

As indicated earlier, the ISO Directives provide for a different level of access and contribution that 'PI' and 'OB' members may have in the international standardization process. 'PI' members actively participate in the Committee and WGs, and vote on all formal questions, enquiry drafts, and the final draft of an international standard. 'OB' members on the other hand, have the right to attend the meetings, receive the committee documents, and vote on the proposals only at the enquiry stage (ISO/IEC, 2012). As such, their access and contribution to ISO documents is limited.

ISO Directives provide also for a different access for full members and liaison members. As indicated in Section 5.2.1.b, some *liaison* organizations participate in the process by invitation, but they do not have the right to vote. Their inability to participate effectively and contribute intensively in the process has created debates amongst some groups, especially groups that are concerned with the rights of consumers and workers, as well as with environmental issues (such as, for example, ANEC, ECOS and ETUI) (Forsberg 2010 & 2012; Kica and Bowman, 2012). The work of these organizations is dominantly self-funded and their ability to follow and access information depends on their capacity to pay for their inclusion in the process.

To understand the perceptions of stakeholders on *transparency*, surveyees were asked to indicate the extent to which they have been able to obtain information about the technical discussions and decisions of TC 229. 74 respondents answered this question. The results of the survey emphasize that 19 respondents believe that they have had *very high* opportunities to access and obtain information on TC 229 discussions and decisions, followed by 31 respondents indicating *high* opportunities, 18 respondents - *medium* opportunities, 3 respondents - *low* opportunities and 3 respondents - *very low* opportunities. Two respondents did not respond to this question (see Table 5.24 and Figure 5.10). Overall the data emphasize that respondents perceive the *transparency* of TC 229 relatively high. This is indicated by the mean of 3.8, which corresponds to a "medium" level of *transparency* on a scale of 1 (very low) to 5 (very high) (see Table 5.30).

Figure 5.10: The Distribution of Stakeholders' Perceptions on *Transparency*

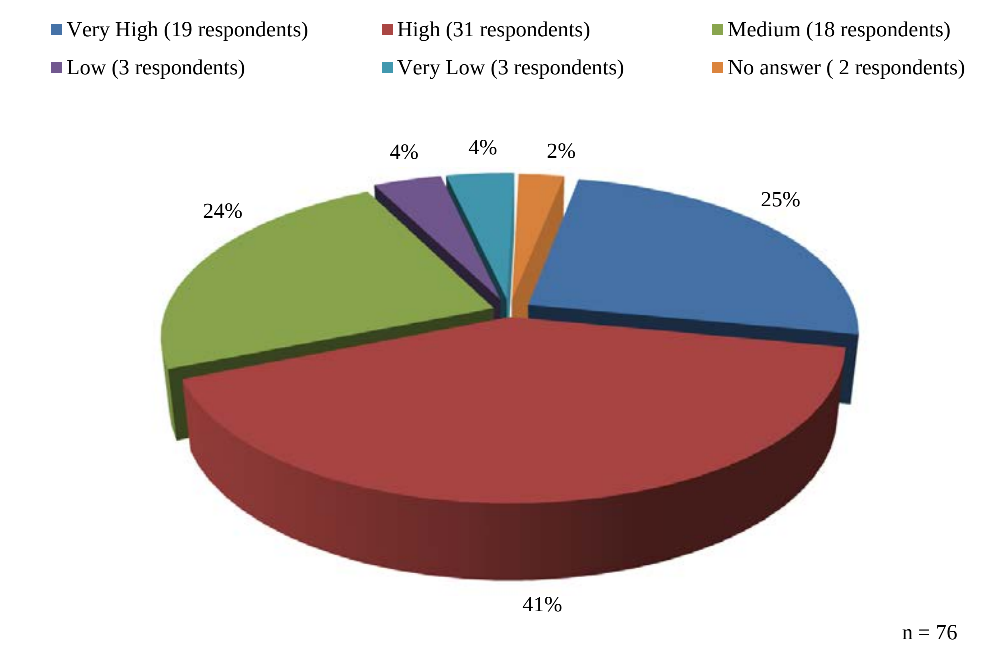


Table 5.24 presents the scores given on *transparency* by different stakeholders based on their *country of origin*. By looking at Table 5.24 we can see that respondents from Liaison Organizations as well as Norway and Belgium, appear less satisfied with the opportunities they have had to obtain information on the technical discussions and decisions of TC 229. Other respondents, from both developed and LDCs, appear relatively satisfied with obtaining these information.

It should be noted that all respondents (besides Liaison Organizations) are PI-members of TC229. Whereas this could lead us assuming that all respondents are satisfied with transparency because ISO rules indicate that they have full access to the documents of the TCs, in practice this does not seem to be the case. Some respondents (i.e. 10 respondents), argue that even though they are full members participating in TC 229, they have been able to access documents that provide only a snapshot of the discussions held, with no detailed information on the input and arguments of registered experts in the WGs and TGs. A respondent from a Liaison Organization indicated that TC 229 just like other TCs, collects and deals with the comments of the experts according to ISO rules. However, as the respondent argues, one needs to look at the internal organization of TC 229 to understand how the conveners of the WGs and JWGs, as well as the Chairman Advisory Group, deal with the issue of transparency. In this regard, the main concern was that conveners did not provide detailed information on the status of projects in-between the meetings. These practices, as evidenced in other standardization areas, may have several implications for legitimacy, impacting therefore the possibilities for stakeholders to be aware of what is going on in the Committee and react on the projects in a timely manner (see also Dingwerth, 2007).

Table 5.24. The Perceptions of Stakeholders on *Transparency* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	0	2	0	4.0
Belgium	2	0	2	0	0	2.0
Canada	0	0	2	1	1	3.7
China	0	0	2	1	0	3.3
France	0	0	1	2	1	4.0
Germany	0	0	0	2	2	4.5
India	0	0	1	0	0	3.0
Iran	0	1	1	2	1	3.6
Italy	0	0	1	2	2	4.2
Japan	0	0	0	3	2	4.4
Liaison EU	1	0	1	1	0	2.6
Malaysia	0	0	0	2	0	4.0
Mexico	0	0	0	0	2	5.0
The Netherlands	0	0	2	6	1	3.9
Norway	0	2	0	0	0	2.0
South Africa	0	0	0	0	2	5.0
South Korea	0	0	1	1	1	4.0
Spain	0	0	0	1	0	4.0
Switzerland	0	0	1	1	0	3.5
UK	0	0	3	1	2	3.8
US	0	0	0	3	2	4.4

The organizational background of the respondents also emphasizes that there are mixed perceptions on *transparency*. By looking at Table 5.25 we can observe that NGOs, TUOs and regulatory agencies appear generally less satisfied with the opportunities they have had to obtain information on the technical discussions and decisions of TC 229. This is indicated by the lower mean scores that these respondents have as compared to other respondents. An explanatory reason for this could be the fact that these respondents are associated with Liaison Organizations, which means that they do not have full access to various documents and discussions. Six respondents pointed also to the limited access that the public has on ISO documents. Except for the drafts, which are published for public comment, the general public does not have access to any information regarding the development of ISO deliverables.

These respondents contrasted/compared the position of various stakeholders in TC 229 with the position of stakeholders in the development of ISO 26000 standards on social responsibility. They argued that in the development of ISO 26000 standards members of the ISO WGs were divided in six stakeholder categories (i.e. industry, labour organizations, NGOs, consumers, governments and service support). ISO member bodies were allowed to nominate up to six delegates (all of which had an "expert status) at the international level - one for each of the six stakeholder categories. Furthermore, measures were taken to support the participation and influence of the LDCs in the development of standards (Hahn and Weidtmann, 2010; Ruwet, 2009). In this way, as one respondent argues, ISO 26000 serves as a case in point that it is "indeed possible to change the practices of ISO from within".

Table 5.25: The Perceptions of Stakeholders on *Transparency* and the *Type of Organization*

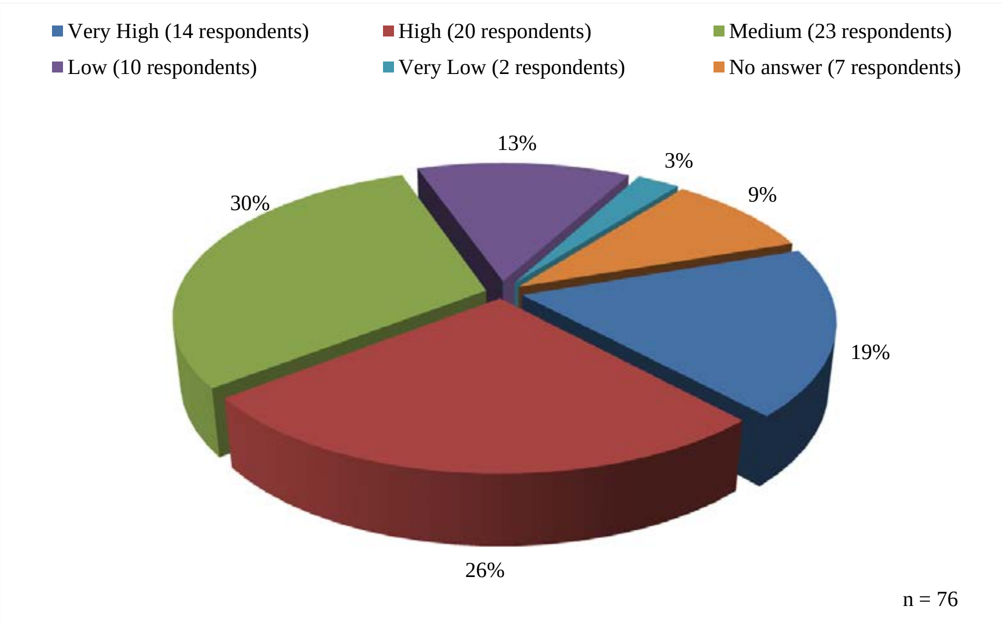
	Transparency					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	0	0	2	9	6	4.2
RI	0	0	6	8	4	3.9
Acad	0	2	4	6	4	3.7
Gov	0	0	2	6	3	4.0
NGO	1	0	3	1	0	2.8
Reg.	1	0	1	0	0	2.0
TA	0	0	0	1	0	4.0
TUO	1	1	0	0	0	1.5

5.2.3.b. Domestic Accountability

TC 229 consists of a wide range of actors, who are referred to by their country of origin rather than their organizational affiliation. In this way, it is difficult to hold a participant accountable for their actions at international level through a clear allocation of responsibilities and roles. So far ISO has not taken any specific measures to give directions to the NSBs on how they should allocate responsibilities to their members (Cadman, 2012). Therefore, it is up to member bodies to determine the range of actors participating in the setting of standards and the mechanisms used for holding them accountable.

To understand the perceptions of stakeholders on *domestic accountability*, surveyees were asked to indicate the extent to which their respective NSBs manage to hold delegates accountable for their actions at TC 229. 69 respondents answered this question. The results of the survey show that 14 respondents perceive *domestic accountability* - *very high*, followed by 20 respondents evaluating *domestic accountability* - *high*, 23 respondents - *medium*, 10 respondents - *low* and two respondents - *very low*. 7 respondents did not answer to this question (see Table 5.26 and Figure 5.11). Overall the data emphasize that respondents are relatively satisfied with the way NSBs manage to hold delegates accountable for the decisions made at the international level. This is indicated by the mean of 3.5 on a scale of 1 (very low) to 5 (very high) (see Table 5. 30).

Figure 5.11: The Distribution of Stakeholders' Perceptions on *Domestic Accountability*



By looking at Table 5.26 we can see that there are mixed perceptions amongst respondents on *domestic accountability*. The data emphasize that only in five countries, specifically in France, Germany, Japan, South Africa and Spain, NSBs are considered highly effective in holding their delegates accountable for their actions at TC 229. The rest of the respondents appear less satisfied with the way their NSBs hold delegates accountable. Five respondents, coming mainly from developed countries argue, that even though their NSBs have formally established the mechanisms for ensuring *domestic accountability*, in practice these mechanisms are rarely implemented. The main challenge for keeping delegates accountable is considered the fact that different delegates are involved in the setting of international standards, while participating in the ISO meetings and commenting on various drafts of standardization proposals. This, as the respondents argue, creates many complexities for determining who should be held accountable.

Table 5.26. The Perceptions of Stakeholders on *Domestic Accountability* and *the Country of Origin*

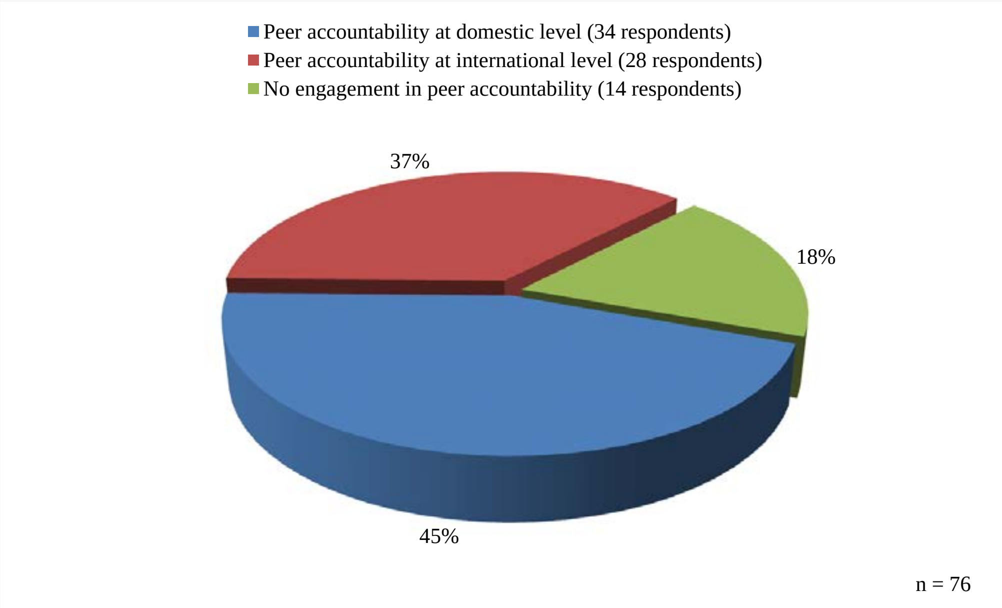
	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	1	0	2	0	3.3
Belgium	0	2	0	1	0	2.7
Canada	0	0	3	0	1	3.5
China	0	0	1	1	1	4.0
France	0	0	0	1	2	4.7
Germany	0	0	0	1	3	4.8
India	0	1	0	0	0	2.0
Iran	0	0	3	1	1	3.6
Italy	0	0	2	2	0	3.5
Japan	0	0	1	1	3	4.4
Malaysia	0	1	1	0	0	2.5
Mexico	0	0	1	1	0	3.5
The Netherlands	0	1	4	4	0	3.3
Norway	1	1	0	0	0	1.5
South Africa	0	0	0	1	1	4.5
South Korea	0	0	2	1	0	3.3
Spain	0	0	0	0	1	5.0
Switzerland	0	2	0	0	0	2.0
UK	1	1	1	2	0	2.8
US	0	0	3	1	1	3.6

Respondents that evaluated *domestic accountability* higher identified several mechanisms that NSBs have used to hold delegates accountable, such as :

- organizing regular mirror committee meetings where delegates report on their experiences and impressions from the international meetings;
- sending out comments and reminders on circulated documents;
- checking alignment of input by members; and
- discussing comments on standardization documents with other delegates before submitting them to TC 229.

The majority of respondents (i.e. 62 out of 76) also indicated that they were involved in *peer accountability* both at the domestic and international level (see Figure 5.12). There were mixed impressions amongst respondents on these mechanisms. One respondent, for example, was highly concerned that the use of some accountability mechanisms, such as checking whether delegates follow the rules of engagement at standardization processes effectively, could lead some members to resign from delegation due to repeated transgressions or departures from these rules. In this regard, *peer accountability* was considered to be the most effective mechanism by many respondents, because it pushed delegates to develop a consensus position on standardization proposals and ensure that these decisions were reported and reflected together with other peers.

Figure 5.12: Stakeholder Engagement in *Peer-Accountability*



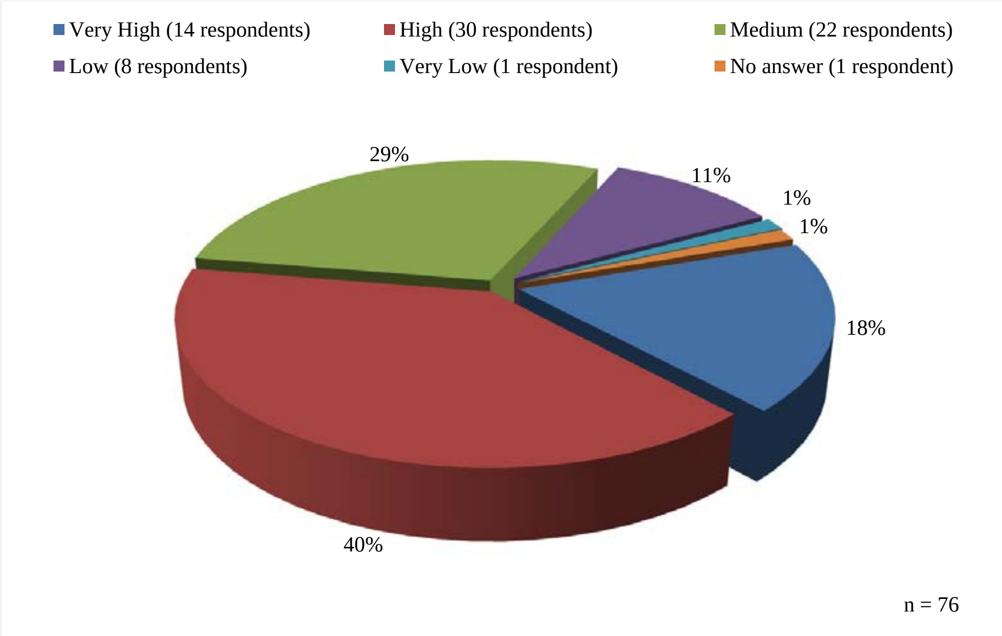
5.2.3.c. Internal Accountability

According to ISO procedures, the TMB has the highest degree of responsibility since (amongst others) it establishes the TCs, it appoints the chairmen of the TCs, it approves the programmes of work for TCs, and oversees the implementation of ISO rules related to the development of standards (ISO/IEC, 2012). However, the chair of the TC and secretariat have also key responsibilities to ensure the proper functioning of the work on the committees and inform national members for any changes within the committee. They need to ensure that the views of all members are expressed at the meetings, and that decisions are clearly formulated and made available to everyone.

As emphasized in the ISO rules, national members can hold committees or subcommittees accountable for following the formal procedures of the ISO (ISO/IEC, 2012). A 'PI' member may file an appeal against any "action or inaction on the part of the TC, in cases when the 'PI' member considers that such action or inaction is against the rules of procedure and ISO/IEC Directives", as well as against the best interest of international trade, health, safety and environment (ISO/IEC, 2012: 34).

To understand the perceptions of stakeholders on *internal accountability*, surveyees were asked to indicate the extent to which they consider TC 229 to be accountable for its performance and decision-making. 75 respondents answered this question. The empirical results of the survey emphasize that 14 respondents evaluate *internal accountability very high*, followed by 30 respondents evaluating *internal accountability* - *high*, 22 respondents - *medium*, 8 respondents - *low* and one respondent - *very low*. One respondent did not answer to this question (see Table 5.27 and Figure 5.13). Based on these data the overall rating for *internal accountability* is relatively high. This is indicated by the mean of 3.6 on a scale of 1 (very low) to 5 (very high) (see Table 5.30).

Figure 5.13: The Distribution of Stakeholders' Perceptions on *Internal Accountability*



By looking at Table 5.27 we can observe that respondents from Belgium and Liaison Organizations have the lowest mean score on *internal accountability*. This means that these organizations are, generally, less satisfied with the extent to which ISO is accountable to them. An explanation for this could be the status that these respondents have in the ISO. For example, respondents from Belgium were mainly associated with trade union organizations and NGOs, which often participate as observers in the process. In addition, as mentioned in Section 5.2.1.b and 5.2.3.a, the liaison status of the Liaison Organizations means that these organizations have no voting rights, and cannot keep the TC 229 accountable at the ballot box. Furthermore, as emphasized in the ISO Directives, participants that have a liaison or an observatory status in the process have very limited possibilities to appeal against any action or decision taken by the TC. As such, *internal accountability* remains an issue for these organizations.

Table 5.27: Stakeholder Perception on *Internal Accountability* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	2	1	0	3.3
Belgium	0	1	2	1	0	2.2
Canada	0	1	2	0	1	3.2
China	0	0	1	1	1	4.0
France	0	0	0	3	1	4.2
Germany	0	0	2	1	1	3.8
India	0	0	0	1	0	4.0
Iran	0	1	3	1	0	3.0
Italy	0	0	1	3	1	4.0
Japan	0	0	1	2	2	4.2
Liaison EU	0	2	1	0	0	2.3
Malaysia	0	0	0	2	0	4.0
Mexico	0	0	1	1	0	3.5
The Netherlands	0	0	2	5	2	4.0
Norway	0	0	2	0	0	3.0
South Africa	0	0	0	1	1	4.5
South Korea	0	0	1	1	1	4.0
Spain	0	0	0	1	0	4.0
Switzerland	0	0	0	1	0	3.0
UK	1	0	1	2	2	3.7
US	0	0	1	3	1	4.0

The extent to which TC 229 is accountable to civil society organizations, such as NGOs and TUOs was also considered unsatisfactory. By looking at Table 5.28 we can observe that respondents from these groups have the lowest mean scores. In particular, the mean score for NGOs is 2.6 and for TUOs is 2.5, which in both cases corresponds to "low" level of *internal accountability*. The creation of the TG on Consumer and Societal Dimensions of Nanotechnologies (TGCSDN) and the TG on Sustainability (TGS) may be seen as an attempt by TC 229 to increase the participation of consumer representatives, the society at large and underrepresented groups, thus making its actions accountable to a broader range of actors. In 2011, TGCSDN conducted a survey with the NSBs on the engagement of consumer and societal organizations in TC 229.[106] The results of this survey aimed, amongst others, to provide recommendations to TC 229 on how to refine its roadmaps for future development of nanotechnology standards, and engage those who want to be involved in the responsible development of nanotechnology standardization (CASD, 2011). However, as there are not any actions taken by TC 229 and CAG to respond to these recommendations, it remains to be seen to what extent the TGs will have an impact on the Committee. For now, the accountability of TC 229 to civil society organizations remains low (see Table 5.28).

Table 5.28: The Perceptions of Stakeholders on *Internal Accountability* and *the Type of Organization*

	Internal Accountability					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	0	0	5	8	4	3.9
RI	0	2	3	6	6	3.8
Acad	1	0	5	8	2	3.6
Gov	0	1	4	5	1	3.5
NGO	0	3	2	1	0	2.6
Reg.	0	0	2	0	0	3.0
TA	0	0	0	1	0	4.0
TUO	0	1	1	0	0	2.5

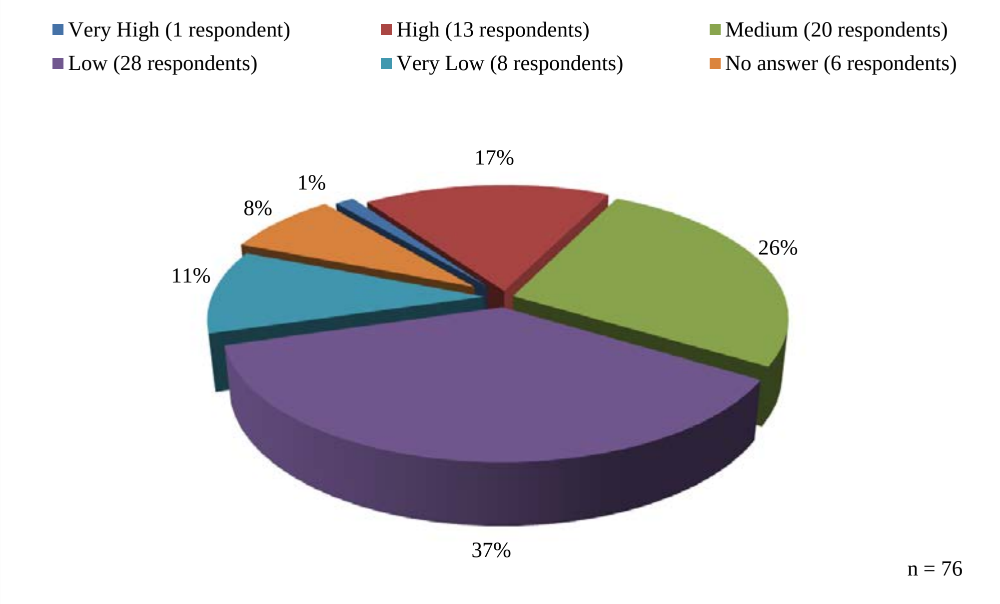
[106] See: Task Group on Consumer and Societal Dimension (CASD) of ISO Technical Committee on Nanotechnologies (ISO TC229). *Study on Engagement of Consumer and Societal Related Organizations in TC229 National Member Bodies.* Available at: http://www.iso.org/iso/casd_tg_final_report_03032014.pdf.

5.2.3.d. External Accountability

As indicated earlier, ISO/IEC Directives emphasize that external actors or the general public do not have access to any information related to the standardization process, unless they become members of the ISO (ISO/IEC, 2012). Access to TC 229 meetings is limited to ISO members only. Even in this case, the reports of the meetings provide a snapshot of the general discussions, but do not reflect the details of the meeting debates nor the reasons why, for instance, certain proposals or decisions are pushed forward (Cadman, 2012; Kica and Bowman, 2012). Furthermore, the publicly available information on the representation of stakeholders in the development of ISO standards is very limited. This not only leads to a lack of transparency on who is involved in the setting of standards, but it creates also many challenges to determine who can be held accountable for the decisions made.

To understand the perceptions of stakeholders on *external accountability*, surveyees were asked to indicate the extent to which they consider that external parties have appropriate opportunities to hold TC 229 accountable for the decisions made. 70 respondents answered this question. Referring to the possibility of the public to comment on standardization enquiry drafts, only one respondent believed that there are *very high* opportunities for external actors to hold TC 229 accountable. 13 respondents believed that there are *high* opportunities for external actors to hold this Committee accountable, followed by 20 respondents indicating that there are *medium* opportunities, 28 respondents - *low* opportunities and 8 respondents - *very low* opportunities. Three respondents did not answer to the question. Three respondents indicated that they were not aware of whether external actors can be involved in TC 229 (see Table 5.29 and Figure 5.14). Based on these data the overall rating for *external accountability* is *low* as indicated by the mean of 2.5 on a scale of 1 (very low) to 5 (very high) (see Table 5.30).

Figure 5.14: The Distribution of Stakeholders' Perceptions on *External Accountability*



As illustrated by Table 5.29, respondents from both developed countries and LDCs indicate that there are low opportunities for external parties to hold TC 229 accountable. The low level of accountability towards external actors is shown to be a problem for many other transnational private governance arrangements; a problem that is caused mainly because of the institutional structure that these institutions have, which allows the decision-making process to be opened to members only (Take, 2012; Chango, 2011; Hachez and Wouters, 2011). In this way the results in Table 5.29 are not very surprising given that the design of the ISO allows for this institution and its TCs to display a fair degree of accountability towards its members only.

The idea of opening up the process to a wide-range of actors who can present the society at large is considered by many scholars to come with a price. For instance, Beishem and Dingwerth (2010) argue that it may impact the quality of deliberation amongst experts, as well as the possibility for these actors to achieve an agreeement on particular decisions. In earlier studies of TC 229, Delemarle and Throne-Holst (2012:14) have also observed that "the fear of the white page to stay […] and the need to start working on something" pushed the Committee and its members to focus mostly on setting multiple projects, without much focus on how the selection and the voting on these projects was done. Forsberg's (2010: 47) main concern was that this idea of trying to deliver multiple projects and outcomes would led TC 229 to focus mostly on creating a "protected space" in which experts can work in peace, rather than ensuring that everyone has access to the standardization process. However, it is difficult to say whether this is still the case in TC 229 as respondents did not comment much on the issue of *external accountability*.

Looking at the evolvement of TC 229 it seems that the Committee has acknowledged the need for ensuring *external accountability* and has responded to it through the creation of the two TGs that were mentioned earlier. The main reason why these TGs were pushed forward by the former Chairman of TC 229, as Delemarle and Throne-Holst (2012) argue, was to gain the trust of the society on this emerging technology and to demonstrate the benefits and values of nanotechnology. These TGs have established clear agendas and future plans. In fact, the TG on Sustainability has also proposed to the Committee to include a new selection criteria according to which the ethical issues related to new work item proposals would also be considered. However, the Committee has not taken any steps in this regard, and it remains still an open question of how successful these TGs will be to enhance the inclusion of underrepresented groups in the standardization process.

Table 5.29: The Perceptions of Stakeholders on *External Accountability* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	2	0	1	0	2.7
Belgium	1	3	0	0	0	1.7
Canada	0	3	0	0	1	2.7
China	0	1	1	1	0	3.0
France	0	0	2	2	0	3.5
Germany	0	1	1	2	0	3.3
India	0	1	0	0	0	2.0
Iran	0	4	1	0	0	2.2
Italy	0	2	2	1	0	2.8
Japan	0	1	2	2	0	3.2
Liaison EU	1	1	0	1	0	2.3
Malaysia	0	0	0	2	0	3.0
Mexico	0	1	1	0	0	2.5
The Netherlands	2	3	0	2	0	2.3
Norway	1	0	1	0	0	2.0
South Africa	0	0	2	0	0	3.0
South Korea	0	1	2	0	0	2.7
Spain	0	0	1	0	0	3.0
Switzerland	2	0	0	0	0	1.0
UK	1	2	0	0	0	1.7
US	0	2	2	1	0	2.8

In summary, the institutional structure of ISO emphasizes that the responsibility for decision-making is shared between a large number of actors, who are generally not mandate holders and do not have clear chains of delegation. This creates many difficulties for holding them directly accountable for their decisions. For the most part, TC 229 is open to members who pay their own membership fees. At this point, low levels of transparency with the external environment are observed given that the documents produced by TC 229 are for purchase, and have never been designed to be readily and freely available to the public at large. Access to documents and voting on standardization proposals is limited to certain actors only, creating therefore unequal opportunities for affected parties to influence and control the decision-making process. This "pay-to-play" requirement ensures that the community to which TC 229 is accountable remains smaller than it would otherwise be.

TC 229 relies on informal internal accountability mechanisms in relation to its engagement with its members and delegations. While ISO has significant stakeholder diversity as a whole, evidence indicates that smaller organizations, including those from the not-for-profit arena, are often prevented from participating as the economic cost is simply too great. The establishment of the TGCSDN and TGS, appear to have been one approach to opening up the membership of TC 229, and thus making its actions accountable to a broader range of actors. However, their creation does not in itself address the "pay-to-play" hurdle, and yet there are many questions about the actual impact that these TGs have on the TC 229 standardization process. As a result, respondents appear relatively satisfied with the responsiveness of the ISO, and TC 229 in particular, to ensure that appropriate mechanisms of transparency and accountability are embedded, which provide for the democratic control of the process and ensure that actors have a realistic chance of being heard. This is indicated by the mean score of 3.3, which corresponds to medium level of *effective process control* on a scale of 1 (very low) to 5 (very high) (see Table 5.30).

Table 5.30: The Perceptions of Stakeholders on *Effective Process Control*

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Transparency	19	31	18	3	3	3.8
Domestic Accountability	14	20	23	10	2	3.5
Internal Accountability	14	30	22	8	1	3.6
External Accountability	1	13	20	28	8	2.5
Overall Rating						**3.3**

Scale: 1 (very low) to 5 (very high).

5.2.3.e. Recommendations to Improve Effective Process Control

According to respondents, an *effective process control* in TC 229 can be ensured by sharing information in a timely manner, enhancing access to ISO standardization discussions and fostering collaboration between NSBs to exchange information on nanotechnology standardization activities. Furthermore, while referring to the development of other ISO standards, in particular to ISO 26000, respondents argued that TC 229 may follow similar steps and consider to upgrade the status of *liaison* and civil society organizations to "expert status, which would allow these organizations to participate and access documents at different stages. Respondents viewed these strategies also as necessary preconditions for accountability, mainly because access to the decisions and comments of decision-makers was considered to provide better opportunities for stakeholders to trace the development of standards and hold relevant parties accountable for their actions at international level. More specifically, based on the recommendations of the respondents, TC 229 and the convenors of the working groups need to:

- provide members detailed and continuous reports on the discussions and decisions made in WG and TG meetings from the agenda-setting to the end stage;

- provide members up-to-date information on the status of the project proposals during and in-between the meetings;
- provide members detailed summaries of the discussions held in TC 229 meetings based on compiled reports of member states;
- upgrade the status of *liaison* and civil society organizations to “expert status” to allow them more access to TC 229 documents (TC 299 could learn from the work of the ISO 26000 on how to improve the culture and practices within the Committee);
- enhance coordination of work with other standard groups, TCs, international scientific unions and industry groups, by exchanging information and attending each-other meetings; and
- hold public and/or trade information, awareness seminars or briefings, to inform external actors on what the Committee has achieved so far and discuss the areas in which further work is needed.

5.2.4. Trustworthy Expertise at ISO/TC 229

To understand the performance of TC 229 on *trustworthy expertise*, the survey explored the perceptions of stakeholders on *competent expertise*, *scientific validity*, *robustness* and *objective judgments.* In the following paragraphs I first provide background information on TC 229 and afterwards analyze the perceptions of stakeholders on each performance indicator.

5.2.4.a. Competent Expertise

The organizational structure of TC 229 allows for a high degree of expertise through the national mirror committees, working groups, task groups and *liaison* organizations. In Table 5.2 it is clearly emphasized that the development of international standards involves a wide range of experts and expertise. From the analysis of the biannual plenary meetings we could observe that the majority of experts in the standardization process are chemists, physicists and engineers by background, with toxicologists, pharmacologists, industrial hygienists, occupational health practitioners, academics and other socio-environmental actors having a lower representation. As Hatto (2010) indicates, the role of knowledgeable experts is very important for the development of new work item proposals or the approval of other standardization proposals at TC 229.

To understand the perceptions of stakeholders on *competent expertise*, surveyees were asked to indicate the extent to which they feel that standardization decisions at TC 229 are based on expert knowledge. 75 respondents answered this question. The results of the survey indicate that 12 respondents believe that standardization decisions are based on a *very high level* of expert knowledge, followed by 41 respondents evaluating expert knowledge - *high* and 22 respondents - *medium*. One respondent did not reply to this question (see Table 5.31 and Figure 5.15). This data emphasize that respondents are highly satisfied with the knowledge of experts that contribute to the setting of TC 229 standards. This is supported by the mean of 3.9, which on a scale of 1(very low) to 5 (very high) is quite close to “high” level of *competent expertise* (see Table 5.43).

Figure 5.15: The Distribution of Stakeholders’ Perceptions on *Competent Expertise*

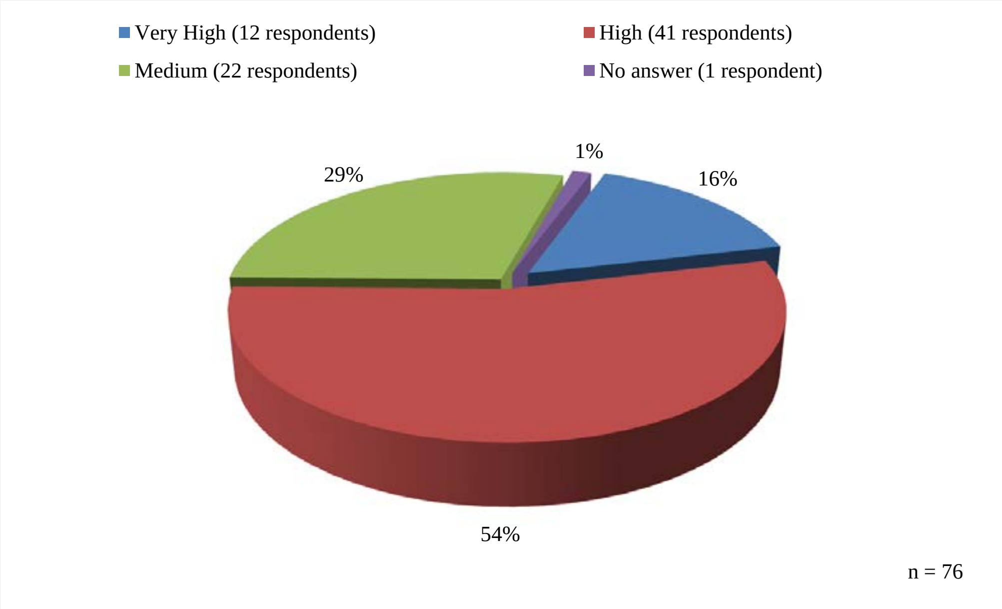


Table 5.31 presents the scores given on *competent expertise* by different stakeholders based on their *country of origin*. Looking at the scores of the respondents from LDCs and developed countries it is clear that the variation of responses is similar and ranges between “medium” and “high” level of *competent expertise*. In particular, whereas the mean scores for LDCs range between 3.8 to 4.5, the scores for developed countries range between 3.3 to 4.3, which in both cases is between “medium” and “high” level of *competent expertise*. LDCs perceive *competent expertise* higher than other performance indicators that were discussed in earlier sections.

In general, respondents stated that TC 229 is doing a great job with standardizing this novel field and that WGs consist of reputable experts. However, two respondents (coming from developed countries), were concerned with the way experts were selected to participate in TC 229. In particular, they argued that the participation of experts at the national committees, and

TC 229, was mainly based on experts’ interest to join these committees. However, they did not undergo any specific selection procedure or training program before joining NSBs or TC 229. This, as the two respondents argued, leads to many questions about the contribute that these experts provide in relevant project groups. In 2010, Forsberg observed similar issues at the Norwegian Standardization Body, indicating that in this NSB experts had the tendency to vote positively on certain standardization proposals rather than abstain or be against them, even in cases when the committee lacked the expertise to assess the proposals (Forsberg, 2012).

These issues appear to have been acknowledged by TC 229 with the former Chairman, Dr. Peter Hatto, advising NSBs to introduce additional, unwritten questions to the ballot form, which would ask delegates to indicate if they have reviewed the documents and have the appropriate expertise to comment on them (Hatto, 2010). In 2012 a supplementary clause was added to the ISO/IEC Directives (clause 2.3.5), which requires from national members to indicate the reasons why a new work item proposals is acceptable to them (ISO/TC229 Secretariat, 2012). To ensure that the principle of consensus is not distorted, Hatto suggested that members respond to project proposals from a position of knowledge, and abstain in cases when they do not have the appropriate knowledge (Hatto, 2010). However, the views of the surveyees (even though limited in numbers), seem to provide an indication that much more work needs to be done at NSBs and TC 229 on the way experts are selected to participate in the setting of nanotechnology standards.

Table 5.31: The Perceptions of Stakeholders on *Competent Expertise* and the *Country of Origin*

	Medium	High	Very High	Mean
	Number of respondents			
Australia	2	1	0	3.3
Belgium	2	2	0	3.5
Canada	1	2	1	4.0
China	1	1	1	4.0
France	0	3	1	4.3
Germany	2	2	0	3.5
India	0	1	0	4.0
Iran	1	4	0	3.8
Italy	1	3	1	4.0
Japan	3	1	1	3.6
Liaison EU	1	2	0	3.6
Malaysia	0	1	1	4.5
Mexico	0	1	1	4.5
The Netherlands	2	7	0	3.8
Norway	0	2	0	4.0
South Africa	0	1	1	4.5
South Korea	2	1	0	3.3
Spain	0	1	0	4.0
Switzerland	0	2	0	4.0
UK	2	1	3	4.2
US	2	2	1	3.8

In a similar way, the organizations with which stakeholders are associated emphasize that respondents of all stakeholder groups have a positive impression about the knowledge of experts that contribute to the setting of nanotechnology standards in TC 229. As we can observe in Table 5.32 their mean scores range between 3.3 to 4.1, that is between “medium” and “high” level of *competent expertise*. The mean scores reveal that respondents from industry, research institutes, academia, trade associations and governmental agencies, generally perceived *competent expertise* higher than respondents coming from NGOs, TUOs and regulatory agencies (see Table 5.32).

Table 5.32: The Perceptions of Stakeholders on *Competent Expertise* and the *Type of the Organization*

	Competent *Expertise*			**Mean**
	Medium	**High**	**Very High**	
	Number of respondents			
IO	5	11	1	3.8
RI	4	8	6	4.1
Acad	4	8	4	4.0
Gov.	2	8	1	3.9
NGO	4	2	0	3.3
Reg.	1	1	0	3.5
TA	0	1	0	4.0
TUO	1	1	0	3.5

Looking further at the characteristics of respondents, I was able to observe that respondents evaluating *competent expertise* higher were mainly chemists, physics, material scientists and toxicologists by background. These respondents have been actively participating in the TC 229 meetings and have advanced technical expertise on nanotechnology standardization issues. On the other hand, respondents from NGOs, TUOs and regulatory agencies that evaluate *competent expertise* lower are toxicologists and environmental scientists by background and have intermediate technical expertise on nanotechnology standardization issues. Furthermore these respondents have participated only in two to three TC 229 meetings, which as one respondent argues, makes it difficult for them to determine whether decisions in WGs are made by knowledgeable experts. The data suggest that there may be a correlation between respondents' perceptions on *competent expertise*, their own understanding of the technicalities of the field, as well as their involvement at TC 229 meetings (see Table 5.33). The results of the Kendall's tau_b test confirm that there is a positive and but not a very statistically significant relationship between respondents' perceptions on *competent expertise* and their level of technical expertise on nanotechnology standardization issues (τ = 0.11; significant level = 0.29), as well as between respondents' perceptions on *competent expertise* and their level of participation at TC 229 meetings (τ = 0.15; significant level = 0.16) (see Appendices 7 and 8).

Table 5.33: The Perceptions of Stakeholders on *Competent Expertise, the Level of Technical Expertise,* and *Participation at ISO/TC 229 meetings.*

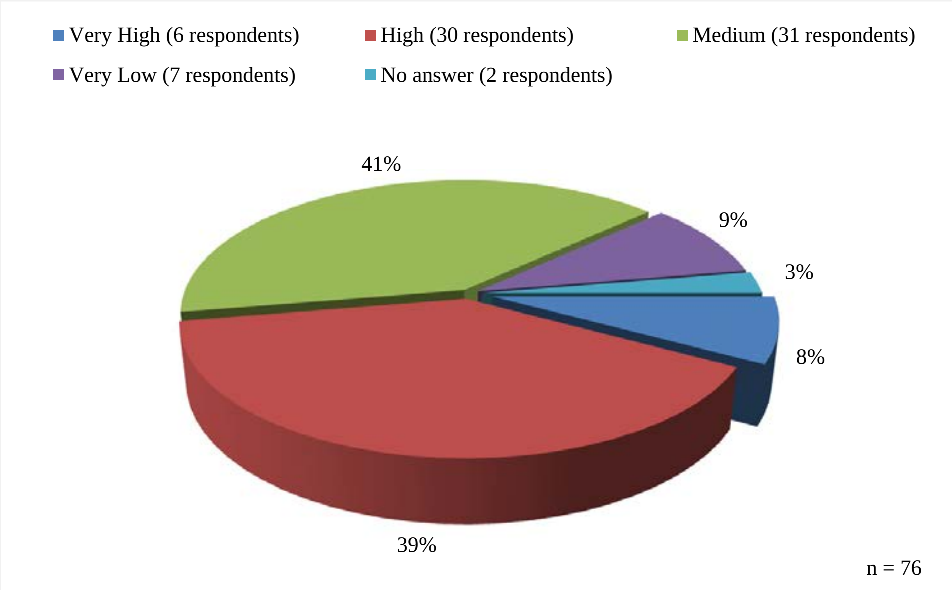
Level of Technical Expertise	Number of respondents	**Mean**	***Participation at TC 229 meetings***	Number of respondents	**Mean**
Basic	3	3.3	1- 4 meetings	28	3.7
Intermediate	18	3.7	5-8 meetings	25	3.8
Advanced	29	3.9	9-13 meetings	22	4.1
Specialist	25	3.9			

5.3.4.b. Scientific Validity

In its business plan TC 229 commits itself to developing high-quality standards that promote the best available knowledge and practices in the production, use and disposal of nanomaterials, nanotechnology products and nanotechnology enabled systems (ISO, 2012). To this aim, nanotechnology standards are developed by using a "rigorous and robust process" (Hatto, 2010:12). Such processes build on the use of peer review at different stages, so that users have confidence that the procedures to be standardized are validated and the results obtained are verified. In ISO there are several standards, which guide the personnel involved how to perform validation testing or assess the precision and trueness of measurement methods or results (e.g. ISO 5275; ISO 21748). These standards and other documents are referred when new projects are developed at TC 229 (Hatto, 2010).

To understand the value of the evidence and results that guide decision-making at TC 229, surveyees were asked to evaluate the *scientific validity* and *robustness* of the evidence provided by experts. With regards to *scientific validity*, surveyees were asked to indicate the extent to which they feel that nanotechnology standardization decisions at TC 229 are based on scientifically verified results. 74 respondents answered this question. In particular, 6 respondents perceived the *scientific validity* of the results guiding the development of nanotechnology standards at TC 229 *very high*, followed by 31 respondents perceiving *scientific validity - high*, 30 respondents - *medium* and 7 respondents - *low*. Two respondents did not reply to this question (see Table 5.34 and Figure 5.16). These data reveal that respondents are relatively satisfied with the *scientific validity* of the results guiding the development of nanotechnology standards at TC 229. This is indicated by the mean of 3.5, which corresponds to medium level of *scientific validity* on a scale of 1 (very low) to 5 (very high) (see Table 5.43).

Figure 5.16: The Distribution of Stakeholders' Perceptions on *Scientific Validity*



At the country level there are mixed perceptions amongst respondents on *scientific validity* (see Table 5.34). Respondents coming from Belgium, India, Liaison Organizations, Malaysia, Switzerland and Norway appear to be less satisfied with the *scientific validity* of the results guiding the development of nanotechnology standards. However, the mean scores of the respondents from other countries, such as Germany, Australia, Canada and France, for example, emphasize that developed countries seem also to have issues with *scientific validity*.

In comparison to *competent expertise*, respondents coming from developed countries and LDCs evaluate *scientific validity* lower. The mean scores in Table 5.34 emphasize that there is a higher variation on the perceptions of stakeholders coming from developed countries with responses ranging between 2.0 to 4.0, that is between "very low" and "high" level of *scientific validity*. The perceptions of respondents from LDCs range between 3.0 to 4.5, that is between "medium" and "high" level of *scientific validity*. An explanation for the lower variation on the perceptions of respondents from LDCs could be the relatively small number of responses received from these countries (i.e. 18 responses out of 76).

Table 5.34: The Perceptions of Stakeholders on *Scientific Validity* and the *Country of Origin*

	Low	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents				
Australia	0	2	1	0	3.3
Belgium	1	1	1	0	3.0
Canada	1	2	0	1	3.3
China	0	1	2	0	3.7
France	0	2	2	0	3.5
Germany	0	3	1	0	3.3
India	0	1	0	0	3.0
Iran	0	2	3	0	3.6
Italy	0	2	3	0	3.6
Japan	1	1	2	1	3.6
Liaison EU	1	1	1	0	3.0
Malaysia	0	2	0	0	3.0
Mexico	0	0	2	0	4.0
The Netherlands	0	5	3	1	3.6
Norway	2	0	0	0	2.0
South Africa	0	0	1	1	4.5
South Korea	0	0	3	0	4.0
Spain	0	0	1	0	4.0
Switzerland	0	2	0	0	3.0
UK	1	2	2	1	3.5
US	0	2	2	1	3.8

The views of the respondents on *scientific validity* seemed to also vary with the extent to which they were associated with industrial organizations, governmental agencies or organizations representing civil society. As shown by Table 5.35, respondents from research institutes and governmental agencies appear more satisfied with the *scientific validity* of the results guiding the development of nanotechnology standards. This is indicated by the higher mean scores that research institutes (mean = 3.7) and governmental agencies (mean = 3.7), have in comparison to other respondents. Respondents from industry appear less satisfied with *scientific validity* (mean = 3.4) (see Table 5.35). These respondents believed that TC 229 is willing to make the outmost use of science as long as it was available. In their view, the persistent lack of certainty in metrology, characterization and measurement seem to be the main challenges impacting the validity and the relevance of the scientific results.

Other complicating factors for *scientific validity* were mentioned by the respondents of regulatory agencies, which related mainly to the limited scientific knowledge and uncertainty surrounding the behaviour of nanomaterials. These issues were mentioned primarily by the respondents participating in the WG2 and WG4. Respondents from civil society organizations perceived the lack of diverse experts to be a practical problem in the WGs. These respondents have participated mostly in the WG3 and WG4 of the TC 229. In the view of these respondents, the domination of business interests (which as observed earlier are mainly chemists and physicists by background) is often a key challenge for the WGs to focus on results that are considered reliable by all participants, and reflect the opinion of a wide range of experts. This was considered to create many implications also for the production of the international nanotechnology standards.

Table 5.35: The Perceptions of Stakeholders on *Scientific Validity* and the *Type of the Organization*

	Scientific Validity				**Mean**
	Low	**Medium**	**High**	**Very High**	
	Number of respondents				
IO	1	9	6	1	3.4
RI	1	6	8	3	3.7
Acad	2	5	9	0	3.4
Gov	0	4	6	1	3.7
NGO	1	4	0	0	2.8
Reg.	0	2	0	0	3.0
TA	0	1	0	0	3.0
TUO	2	0	0	0	2.0

Similar to *competent expertise*, the perceptions of stakeholders seem to vary on the basis of the *technical expertise* that they have in the standardization work for nanotechnologies, as well as their level of participation at the TC 229 meetings. Recent interviews conducted with experts on the potential of regulatory agencies to contribute to the risk management of nanomaterials (Beaudrie et al. 2013), emphasize that the knowledge of experts on risk assessment methodologies as well as their trust in respective agencies, were the main factors impacting the positive impressions of experts on the potential of various agencies. Looking at the mean scores in Table 5.36, it is safely to assume that we might be dealing with similar issues at TC 229 and that the experts' depth understanding of the technicalities of nano standards and their involvement in the process may serve as important factors for them to determine the validity of the scientific results guiding the development of nano standards. It may be that these respondents are more keenly aware on how successful the TC 229 WGs have been in incorporating scientifically valid results in the setting of nanotechnology standards. By looking at Table 5.36 we can observe that the higher the technical expertise and participation in TC 229 meeting, the higher the scores on *scientific validity*. The results of the Kendall's tau_b test also verify that there is a strong and positive correlation between the *level of technical expertise* and *scientific validity* (τ = 0.25; significant level = 0.01), as well as between the *level of participation at TC 229* meetings and *scientific validity* (τ = 0.29; significant level = 0.01) (see Appendices 9 and 10).

Table 5.36: Stakeholder Perceptions on *Scientific Validity, the Level of Technical Expertise,* and *Participation at ISO/TC229 meetings*

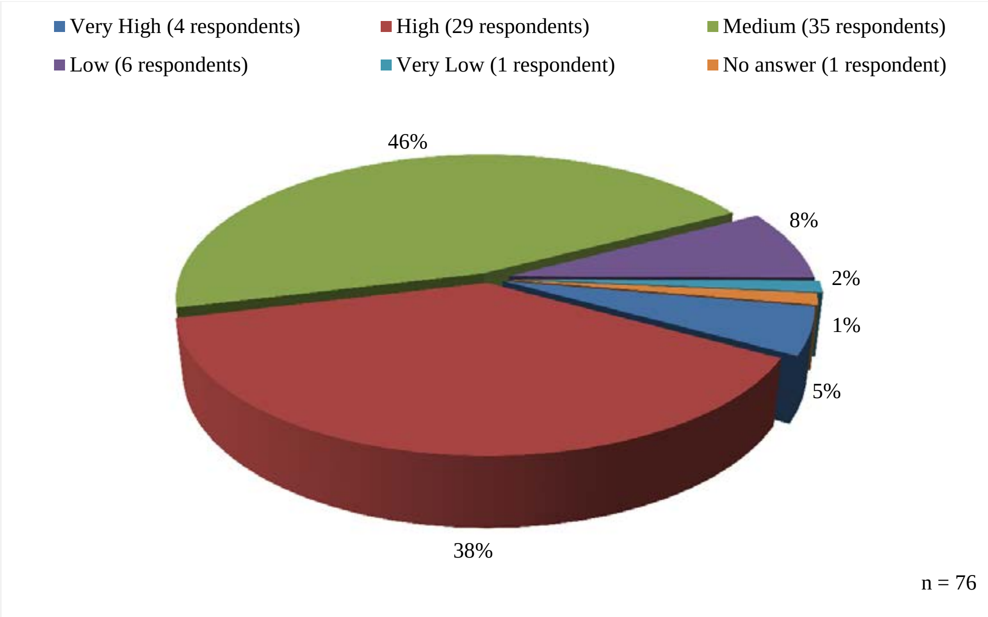
Level of Technical Expertise	Number of respondents	**Mean**	***Participation at TC 229 meetings***	Number of respondents	**Mean**
Basic	3	3.0	1- 4 meetings	27	3.1
Intermediate	18	3.2	5-8 meetings	25	3.6
Advanced	28	3.5	9-13 meetings	22	3.7
Specialist	25	3.7			

5.2.4.c. Robustness

On his "*Practical Standardisation Guide for Researchers*", Hatto (2010: 27) suggests that project leaders must resolve the disputes amongst experts during the development of standards, while maintaining the focus on the "technical accuracy and robustness of the drafts under development". A robust development of standards is highly recommended by ISO/IEC Directives as well.

To see how this works in practice, surveyees were asked to indicate whether they believe that nanotechnology standardization decisions are based on robust evidence. 75 respondents answered to this question. The results indicate that the *robustness* of evidence provided during the TC 229 process is perceived to be lower than *scientific validity*. In particular, 3 respondents perceived *robustness very high*, 27 respondents - *high*, 37 respondents - *medium*, 7 respondents - *low* and one respondent - *very low*. One respondent did not answer to this question (see Table 5.37 and Figure 5.17). The results emphasize that respondents are relatively satisfied with the *robustness* of evidence provided during the TC 229 process. This is indicated by the mean of 3.4, which corresponds to “medium” level of *robustness* on a scale of 1 (very low) to 5 (very high) (see Table 5.43).

Figure 5.17: The Distribution of Stakeholders’ Perceptions on *Robustness*



At the country level there were mixed perceptions amongst respondents on *robustness* (see Table 5.37). As Table 5.37 indicates only respondents from China, Mexico, South Africa, Spain and France appear highly satisfied with the *robustness* of evidence guiding the decisions made on international nanotechnology standards. This is indicated by the higher mean scores that respondents of these countries have. The rest of the respondents seem to be less satisfied. Though the number of responses for each individual country is small to see if the differences between counties are statistically significant, the mean scores in Table 5.37 emphasize that even respondents from bigger delegations, such as those coming from US, UK and Germany, seem to have issues with *robustness.* As we can see in Table 5.37 their mean scores range between 3.0 to 3.5, which correspond to “medium” level of *robustness.*

Table 5.37: The Perceptions of Stakeholders on *Robustness* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	2	1	0	3.3
Belgium	0	0	3	1	0	3.2
Canada	0	1	1	1	1	3.5
China	0	0	1	1	1	4.0
France	0	0	0	4	0	4.0
Germany	0	1	2	1	0	3.0
India	0	0	1	0	0	3.0
Iran	0	1	3	1	0	3.0
Italy	0	0	2	3	0	3.6
Japan	0	1	2	1	1	3.4
Liaison EU	0	1	1	1	0	3.0
Malaysia	0	0	1	1	0	3.5
Mexico	0	0	0	2	0	4.0
The Netherlands	1	0	6	2	0	3.0
Norway	0	1	1	0	0	2.5
South Africa	0	0	0	1	1	4.5
South Korea	0	0	2	1	0	3.3
Spain	0	0	0	1	0	4.0
Switzerland	0	0	1	1	0	3.5
UK	0	0	3	3	0	3.5
US	0	0	3	2	0	3.4

The views of the respondents seem to also vary with the extent to which they are associated with industrial organizations, governmental agencies, research institutes or other organizations representing civil society. By looking at Table 5.38, we can observe that respondents coming from governmental agencies and research institutes are more satisfied with *robustness*. Respondents from NGOs seem to have more issues with *robustness*. A number of respondents (i.e. 21 respondents), coming mainly from the industry and governmental agencies commented on this indicator. The arguments of the respondents on *robustness* are in many ways similar to the comments mentioned on *scientific validity*. These respondents perceived the unforeseen techno-scientific externalities, the rapidly evolving environment in which nanotechnology is developing, as well as the uncertainties related to the identification, characterization and measurement, to be the main complicating factors for *robustness*. In contrast, respondents from NGOs and academia, generally perceived the lack of expert diversity in the WGs and the lack of collaboration with other TCs, to be the main complicating factors. This has been also suggested by Forsberg (2012), who has argued that the lack of comprehensive scientific discourse creates implications for *robustness*, mainly because the standardization decisions do not incorporate the views of a larger scientific community. In the view of many survey respondents, the aforementioned factors create many challenges for the WGs to ensure that the evidence or the results remain stable for a long period. In fact, the ISO/IEC Directives acknowledge that the technical provisions of an international standard can be amended as knowledge, science or other related factors develop further (see clause 2.10.2 and 2.10.3 of the ISO/IEC Directive). With regards to nanotechnology standardization, both Forsberg (2010) and Hatto (2010) argue that the revision of nanotechnology standards may be important for incorporating the most up-to date scientific knowledge on relevant nanotechnology issues. However, as emphasized at ISO/IEC Directives, the revision of international standards may lead to many financial and business consequences for both the ISO and the users of standards (ISO/IEC Directive, 2012). Arguably, the constant revision of standards may also put into question the appropriateness of these documents to be followed in practice, as well as the preparedness of ISO to standardize in the field of nanotechnology (see also Forsberg, 2010 & 2012).

Table 5.38: The Perceptions of Stakeholders on *Robustness* and the *Type of the Organization*

	Robustness					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	1	8	7	0	3.2
RI	0	2	6	7	2	3.6
Acad	0	2	7	7	0	3.3
Gov	0	0	4	6	1	3.7
NGO	0	1	5	0	0	2.8
Reg.	0	0	2	0	0	3.0
TA	0	0	1	0	0	3.0
TUO	0	0	2	0	0	3.0

The perceptions of stakeholders seem to vary on the basis of the technical expertise that they have in the standardization work for nanotechnologies, as well as their level of participation at the TC 229 meetings. As we can see in Table 5.39, respondents that have a higher level of technical expertise and higher participation at TC 229 meetings, perceive *robustness* higher. Furthermore, the background of these respondents is most likely to be chemists, physicists, material scientists and toxicologists. This leads us to safely assume that the perceptions of the respondents on *robustness* may have been influenced by their own understanding of the technicalities of the field and of the ISO process. The results of the Kendall's tau_b test also emphasize that there is a positive and statistically significant relationship between *robustness* and technical expertise ($\tau = 0.27$; significant level = 0.01), as well as between *robustness* and their level of participation at the TC 229 meetings ($\tau = 0.31$; significant level = 0.00) (see Appendices 11 and 12). Table 5.39 provides the details of the responses.

Table 5.39: The Perceptions of Stakeholders on *Robustness, the Level of Technical Expertise,* and *Participation at TC 229 meetings*

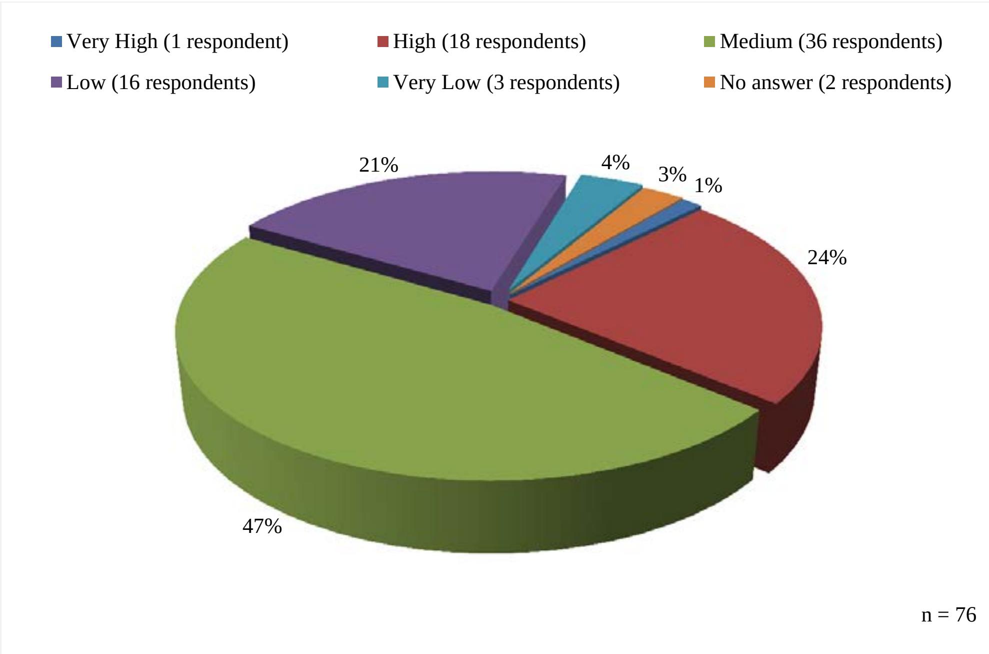
Level of Technical Expertise	Number of respondents	**Mean**	***Participation at TC 229 meetings***	Number of respondents	**Mean**
Basic	3	2.7	1- 4 meetings	28	3.0
Intermediate	18	3.0	5-8 meetings	25	3.5
Advanced	29	3.4	9-13 meetings	22	3.7
Specialist	25	3.7			

5.2.4.d. Objective Judgments

Various reports (Hatto, 2010; Widmer et al. 2010) and ISO documents (ISO, 2008 & 2012; ISO/IEC, 2012) indicate that international standards are developed primarily to support the general interests of all stakeholders, and not the commercial (or other) interests of individuals or single organizations. Although experts are nominated by their NSBs, in TC 229, they are required to serve as experts in the subject matter under discussion and not as representatives of their national bodies or employers (Hatto, 2010).

To understand the perceptions of stakeholders with regards to *objective judgments*, surveyees were asked to indicate the extent to which they feel that experts present unbiased scientifically driven views during the presentation and the appraisal of information at TC 229. 74 respondents answered this question. In particular, 1 respondent perceived the objectivity of judgments provided by experts *very high*, 18 respondents - *high*, 36 respondents - *medium*, 16 respondents - *low* and 3 respondent - *very low*. Two respondents did not reply to this question (see Table 5.40 and Figure 5.18). The results emphasize that respondents are generally not satisfied with the objectivity of the judgments guiding the development of TC 229 standards. This is indicated by the mean of 2.9, which on a scale of 1 (very low) to 5 (very high) corresponds to "low" level of *objective judgments* (see Table 5.43).

Figure 5.18: The Distribution of Stakeholders' Perceptions on *Objective Judgments*



At the country level there were mixed perceptions amongst respondents on *objective judgments* (see Table 5.40). By looking at the mean scores of respondents in Table 5.40 it is clear that respondents generally perceive this indicator lower than indicators that were discussed earlier. Only respondents from Mexico and Spain seem to be *very highly* satisfied with the objectivity of judgments in TC 229. This is indicated by the higher mean scores (i.e. mean = 4.0) that these respondents have as compared to other respondents (see Table 5.40). Respondents from Belgium, Iran, Switzerland, Malaysia, Liaison Organizations and Netherlands seem to be the least satisfied with *objective judgements*. By looking at the overall mean scores in Table 5.4, we can observe that respondents from other developed countries (such as US, UK, Germany, France, Netherlands) also are not highly satisfied with the objectivity of judgements provided by experts involved in the work of TC 229.

Table 5.40: The Perceptions of Stakeholders on *Objective Judgements* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	1	2	0	3.7
Belgium	1	1	2	0	0	2.2
Canada	0	2	1	0	1	3.0
China	0	0	2	1	0	3.3
France	0	0	3	1	0	3.2
Germany	0	0	3	1	0	3.2
India	0	0	1	0	0	3.0
Iran	1	1	3	0	0	2.4
Italy	0	1	3	1	0	3.0
Japan	0	1	2	2	0	3.2
Liaison EU	0	1	2	0	0	2.6
Malaysia	0	1	1	0	0	2.5
Mexico	0	0	0	1	0	4.0
The Netherlands	1	3	4	1	0	2.5
Norway	0	1	0	1	0	3.0
South Africa	0	0	1	1	0	3.5
South Korea	0	0	1	2	0	3.7
Spain	0	0	0	1	0	4.0
Switzerland	0	2	0	0	0	2.0
UK	0	1	4	1	0	3.0
US	0	1	2	2	0	3.2

There are two circumstances or situations that put into question the objectivity of the judgements provided by experts involved in the work of TC 229. First, the ISO/IEC Directives indicate that:

> " […] the WGs comprise of a restricted number of individually appointed experts who are brought together to deal with the specific task allocated to the WGs […] and act in a personal capacity and not as the official representative of the P-member or A-liaison organization by which they have been appointed. However, it is recommended that they keep close contact with the P-member or organization in order to inform them about the progress of the work" (ISO/IEC, 2012: 17).

In this way, this definition is somehow contradictory in itself. It states that experts need to act based on their expert knowledge, but it encourages representatives to contact their member countries as well. Second, as indicated in earlier sections (see Section 5.2.1.b and 5.2.1.c), NSBs often finance themselves through membership fees, which means that the participation of experts in TC 229 meetings is funded either by experts themselves or their respective employers.

These facts bring many questions forward, such as whether WG members support particular standardization proposals or decisions because of the technical merits that they have or because they are actually trying to push forward the interest of their employers or clients. An expert from Canada, an active participant in the WG3, touched upon this issue in his response, indicating that even though ISO/IEC Directives ask representatives to act on their expertise, in TC 229 experts often focus on prioritizing and pushing forward proposals based on country priorities, rather on what needs to be done. A representative from Italy commented that official documents at the national level indicate that experts are appointed to participate at the WGs of TC 229 and act independently based on their expertise. In practice, however, the respondent argued, a national position was established amongst members and experts were expected to align with what has been agreed at the NSB. This respondent argued that aligning with national position was important and NSB could vote against a document even in cases when the expert approved such a document. These comments show that the position of experts at the international level may be difficult sometimes, since they may be asked to represent a national point of view, while officially they are expected to act as independent experts.

The organizations with which stakeholders are associated emphasize that respondents of all stakeholder groups are generally not highly satisfied with the objectivity of the judgements provided by experts involved in the work of TC 229. As we can observe in Table 5.41, their mean scores range between 2.3 to 3.2, that is between “low” and “medium” level of *objective judgements*. Five respondents, coming mostly from NGOs, academia and TAs, commented on this indicator. These respondents argued that representatives of private companies were highly focused on defending the proposals of their employers as well as the interests of the industries from which they came. One respondent seemed highly concerned with the defensive behavior of these actors, indicating that it often led to tensions amongst experts when discussing the approval of proposals at WGs, even in cases when the scientific evidence in standardization proposals was obvious. Even though these issues were mentioned by some respondents only, it seems safe to assume that in TC 229 some members tend to be led more by the interests of their companies than by the technical merits of standardization proposals. These issues are not new in ISO.

Scholars such as Hallström (2004) and Jakobs (2010) have observed similar issues in other standardization areas as well. For instance, Hallström (2004) when discussing the development of ISO 9000 standards emphasizes that the process was mainly led by representatives who were not necessarily experts in the area and were trying to ensure that their national viewpoint was supported. Jakobs (2010) argues that company interests and the political influence have dominated many times the development of ICT standardization, overcoming therefore the technical merits of many standardization proposals. However, as Jakobs argues, this is not surprising given the active participation of these actors in standardization processes, as well as their willingness to put most efforts in the standard by investing more time and financial resources. However, even though these issues seem to be well known in such international forums they may have serious implications for the legitimacy of an institution. For example, if the nanotechnology standards are led only by some interests, this at some point will have consequences for legitmacy. Standards may not be accepted by other actors, which as Forsberg (2012) argues, will create many implications for the societal legitimacy of this organization and its outcomes. Furthermore, if the tendency to support only a set of interests goes as far as ignoring obvious scientific evidence (as one respondent argued earlier), this may also have implications for the scientific legitimacy of the institution and its outcomes. Experts may challenge the scientific quality of the TC 229 standards, and put into question the possibility for accepting these standards.

Table 5.41: The Perceptions of Stakeholders on *Objective Judgements* and the *Type of the Organization*

	Objective Judgements					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	0	3	10	4	0	3.1
RI	1	1	12	4	0	3.0
Acad	1	4	5	5	0	2.9
Gov	0	2	6	2	1	3.2
NGO	0	5	0	1	0	2.3
Reg.	0	0	2	0	0	3.0
TA	0	0	1	0	0	3.0
TUO	1	0	0	1	0	2.5

The perceptions of stakeholders seemed to vary on the basis of the technical expertise that they had in the standardization work for nanotechnologies, as well as their level of participation at the TC 229 meetings. As we can see in Table 5.42, respondents that have a higher level of technical expertise on standardization issues as well as higher participation at the TC 229 meetings, are most likely to be satisfied with the objectivity of judgements provided by experts in the Committee. The results of the Kendall's tau_b test also emphasize that there is a positive and statistically significant relationship between respondents' perceptions on *objective judgements* and their technical expertise on nanotechnology standardization issues ($\tau = 0.37$; significant level = 0.00). The relationship between respondents' perceptions on *objective judgements* and their participation at TC 229 meetings appears to be positive but less significant ($\tau = 0.23$; significant level = 0.02) (see Appendices 13 and 14).

Table 5.42: The Perceptions of Stakeholders on *Objective Judgements, the Level of Technical Expertise,* and *Participation at TC 229 meetings*

Level of Technical Expertise	Number of respondents	**Mean**	***Participation at TC 229 meetings***	Number of respondents	**Mean**
Basic	3	2.3	1- 4 meetings	28	2.7
Intermediate	18	2.4	5-8 meetings	25	2.9
Advanced	29	3.1	9-13 meetings	21	3.3
Specialist	24	3.3			

In sum, expertise and expert knowledge in TC 229 are highly evaluated by the surveyees. This leads us to safely presume that the support that TC 229 receives from respondents may be ascribed mainly to its good performance on *competent expertise*. This indicator has the highest mean score (mean = 3.9) than all indicators discussed so far. In the literature on international organizations, scholars often use expert knowledge as a key element for legitimating the activities of these organizations as well as their standards (see for example Jacobsson, 2005; Borraz, 2007). This is because standardization committees are considered to provide forums that consist of actors having considerable knowledge in the field concerned (Egan, 2001). The results of the survey emphasize that experts participating in the WGs of the TC 229 are considered highly knowledgeable and experienced by their peers on issues related to nanotechnologies. The development of nanotechnology standards, as the respondents generally argue, relies on expert knowledge, founded mainly in private companies, research institutes, governmental and regulatory agencies, as well as civil society organizations. However, in the WGs there is observed a domination of the views of the respondents coming industry, research institutes and governmental agencies, who have a background in chemistry, materials science and physics. The results of the correlation test seem to suggest that an explanation for the domination of these actors could be the powerful resources they have to afford a more active participation in the Committee and mobilize the scientific data to contribute to nanotechnology standardization.

The domination of some actors in the process raises many questions about the extent to which experts are independent in their decisions and judgements at TC 229. We have come to learn from various scholars that the main reason why private organizations, and in particular SDOs are trusted to contribute to setting various rules, is mainly because they are considered to provide the best solutions, that derive from highly qualified and independent experts (e.g. Jakobs, 2000; Hallström and Boström, 2010). However, in TC 229 the independency of experts is perceived to be low. As argued by some respondents (i.e. five respondents), some WG-members have the tendency to support proposals based on their country or employers priorities, rather on the technical merits of such proposals.

Besides objectivity, a number of respondents (i.e. 14 respondents) appear concerned with the scientific basis of the nanotechnology standards. The need for standards to be based on scientifically valid and robust results has been acknowledged in various documents and reports (e.g. Widmer et al.2010; ISO/IEC, 2012). However, the lack of diverse experts, as well as the lack of sufficient scientific knowledge and certainty on relevant nanotechnology issues, seem to be the main challenges which, as the respondents argue, put into question the validity and robustness of the results guiding the developement of nanotechnology standards. For these reasons, the overall score for *trustworthy expertise* remains *medium*, as indicated by the mean of 3.5 on a scale of 1 (very low) to 5 (very high) (see Table 5.43).

Table 5.43: The Perceptions of Stakeholders on *Trustworthy Expertise*

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Competent Expertise	12	41	22	0	0	3.9
Scientifically Verified Results	6	30	31	7	0	3.5
Robust Evidence	4	29	35	6	1	3.4
Objective Judgments	1	18	36	16	3	2.9
Overall Rating						**3.5**

Scale: 1 (very low) to 5 (very high).

5.2.4.e. Recommendations to Improve Trustworthy Expertise

According to respondents *trustworthy expertise* in TC 229 can be ensured by enhancing the quality of information in standardization documents. In the view of respondents such an enhancement could be achieved by improving the quality of consensus and ensuring that sufficient efforts are taken so that standardization issues are addressed by relevant experts. In addition, respondents argued that TC 229 needs to consider taking appropriate measures to enhance the quality of the evidence in which standardization decisions are based. Based on the recommendations of respondents, TC 229 and the convenors of the working groups need to:

- promote the participation of experts from the beginning to the end of the project, either by attending the meetings or by issuing comments (experts should not be changed continuously);
- ensure that standardization decisions are based on independent and evidence-based judgements;
- recruit independent scientific advisors to assess the scientific quality of the evidence on which standardization proposals are based;

- scrutinize work item proposals more closely to determine whether relevant expertise is found in other technical committees of ISO and be prepared to work with them;
- extend the peer review process for draft documents;
- increase reference to high quality scientific publications; and
- apply the criteria of scientific validity in new work item proposals more stringently (e.g. by requiring that pre-normative research is conducted to provide for validation).

5.2.5. Implementable Outcomes at ISO/TC229

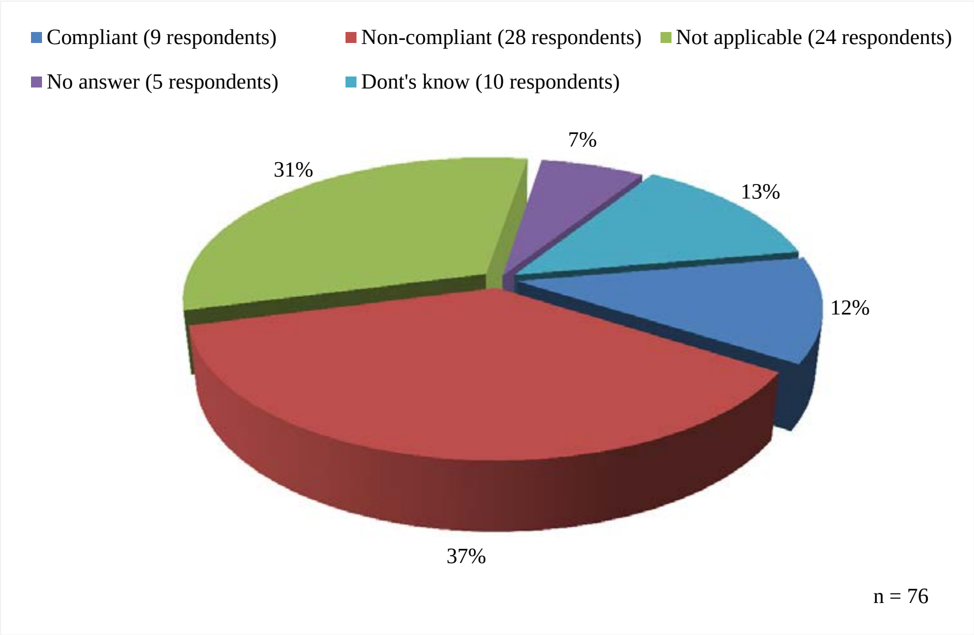
To understand the performance of TC 229 on *implementable outcomes*, the survey explored the perceptions of stakeholders on *compliance, rule clarity* (in particular *the clarity of TC 229 standards*), *problem solving capacity* and *rule benefits* (in particular *benefits of TC 229 standards* and *other deliverables*). In the following paragraphs I first provide background information on TC 229 and afterwards analyze the perceptions of stakeholders on each performance indicator.

5.2.5.a.Compliance

Nanotechnology standards are voluntary, meaning that there are no legal requirements or any other means of coercion that require compliance with these standards (Hatto, 2010). Interested parties are free to make use of standards as they see fit.

To understand the perceptions of stakeholders on *compliance*, surveyees were asked to indicate if their organizations are compliant with any TC 229 standard. 71 respondents answered this question. According to the survey results, only 9 respondents indicated compliance with nanotechnology standards. 28 respondents indicated that they do not comply with any nanotechnology standard and 10 respondents were not aware whether their organizations comply with TC 229 standards. 24 respondents indicated that compliance with international nanotechnology standards was still not applicable for their organizations. Five respondents did not respond to this question (see Table 5.44 and Figure 5.19). To measure the extent to which stakeholders comply with international nanotechnology standards, a value of 5 (very high) was added for those who answered “Yes” to compliance and a value of 1 (very low) for those who answered “No” to compliance. The majority of the respondents (54 out of 72) also indicated that they were not aware of any market-based policy that would oblige them to comply with any specific TC 229 standard. Following these data, *compliance* with nanotechnology standards is *very low*. This is indicated by the mean of 1.9, which on a scale of 1 (very low) to 5 (very high) corresponds to “low lever” of compliance (mean = 1.9) (see Table 5.58).

Figure 5.19: The Distribution of Stakeholders' Perceptions on *Compliance*



By looking at the *country of origin* (see Table 5.44), we can observe that only 9 respondents coming from Australia, China, Germany, Iran, Italy, South Korea and UK, indicate that they comply with TC 229 standards. The majority of these respondents (i.e. 7 out of 9) come from developed countries. The main standards that were mentioned by these respondents are: ISO 10801: 2010; ISO 10808: 2010; ISO 29701: 2010; ISO 27687; ISO 80004-1 and ISO 13329. Some respondents indicated compliance with other deliverables, such as: ISO/TR 13121: 2011; ISO/TS 12901-1: 2012; ISO/TR 13329: 2012; ISO/TS 80004 and ISO/TS 17200. According to respondents, there is a willingness to comply with nanotechnology standards, but the brief life span of the standardization deliverables and uncertainties characterizing the field of nanotechnologies, create many challenges for them to act in accordance with these deliverables. Furthermore, multiple respondents, from both developed countries and LDCs (i.e. 46 respondents out of 76) indicated that they do not have sufficient capacities (i.e. technical, financial and expertise) to ensure effective *compliance* with nanotechnology standards.

Table 5.44: The Perceptions of Stakeholders on *Compliance* and the *Country of Origin*

	Compliant	***Non-Compliant***
	Number of respondents	
Australia	1	2
Belgium	0	1
Canada	0	1
China	1	1
France	1	0
Germany	2	1
India	0	0
Iran	1	1
Italy	0	2
Japan	0	2
Liaison EU	0	0
Malaysia	0	0
Mexico	0	1
The Netherlands	0	8
Norway	0	2
South Africa	0	1
South Korea	1	0
Spain	0	0
Switzerland	0	0
UK	1	3
US	0	2

The organizations with which stakeholders are associated with, emphasize that only a limited number of respondents coming from industry, research institutes and governmental agencies, comply with nanotechnology standards (see Table 5.45). These respondents were mainly involved in the manufacturing of nanotechnology artifacts, in the manufacturing of products containing nanotechnology, in research directed at nanoscale products/processes, in regulatory and safety issues related to nanotechnology developments, as well as in the analysis or characterization of components at the nanoscale. A number of respondents (i.e. 24 respondents), coming mostly from academia and civil society organizations, indicated that the question on *compliance* was not applicable to their organizations. These respondents argued that working with nanotechnology standards was important for them to conduct research, provide expert advice and promote consumers' health and interests, as well as occupational and environmental safety. However, to perform these activities *compliance* with nanotechnology standards was not needed.

Table 5.45: The Perceptions of Stakeholders on *Compliance* and the *Type of the Organization*

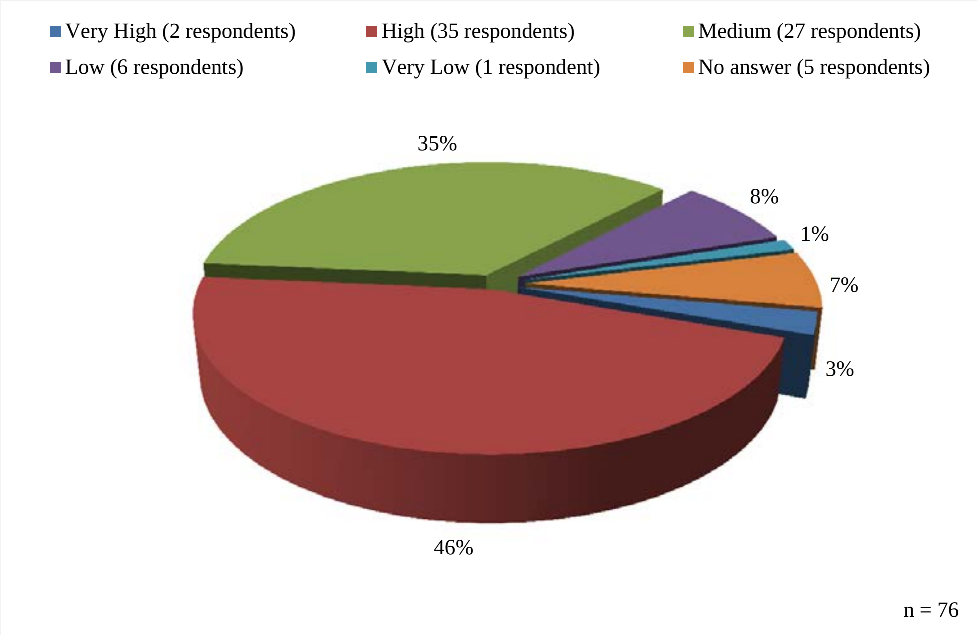
	Compliant	***Non-Compliant***
	Number of respondents	
IO	4	6
RI	3	5
Acad	0	7
Gov.	2	4
NGO	0	2
Reg.	0	1
TA	0	1
TUO	0	2

5.2.5.b. Rule Clarity

ISO/IEC Directives emphasize that a technical standard should precisely, and clearly, indicate its purpose and the technical issues that it intends to cover (ISO/IEC, 2012). These components are considered crucial to avoid overlap or duplication of efforts with other TCs working on similar subjects, and to guide effectively the behaviour of stakeholders who follow the standard. According to Hatto (2010: 13) the information in the standard "must be presented in a precise manner, making it clear to users what must be done in order to comply with the standard and what is optional".

To understand the perceptions of stakeholders on the clarity of TC 229 deliverables, surveyed were asked to indicate whether they find the current deliverables to be clearly drafted and understandable. 72 respondents answered this question. The results of the survey indicate that 2 respondents believe that the *clarity* of TC 229 deliverables is *very high*, followed by 35 respondents perceiving the clarity of TC 229 deliverables - *high*, 27 respondents - *medium*, 6 respondents - *low* and 1 respondent - *very low*. Five respondents did not answer to this question (see Figure 5.20). The results of the survey emphasize that respondents are relatively satisfied with the clarity of TC 229 deliverables. This is indicated by the mean of 3.5, which on a scale of 1 (very low) to 5 (very high) corresponds to "medium" level of *clarity*. The details of the survey responses are provided in Table 5.46.

Figure 5.20: The Distribution of Stakeholders' Perceptions on *the Clarity of TC 229 Deliverables*



At the country level there were mixed perceptions amongst respondents on the clarity of TC 229 deliverables (see Table 5.46). By looking at Table 5.46, we can observe that respondents coming from Liaison Organizations, as well as from Belgium, India, Malaysia, Mexico, Netherlands, Norway and Switzerland, generally, have lower mean scores. This suggests that they are less satisfied with the clarity of TC 229 deliverables. The variation of the responses is higher in the case of developed countries, where responses range between 2.5 to 4.3, that is between "low" and "high" level of clarity for TC 229 deliverables. The mean scores in Table 5.46 also indicate that developed countries are more likely to perceive the clarity of TC 229 deliverables high. As observed in Section 5.2.1 and 5.2.2 actors from developed countries were more included in the process and indicated that their interests were highly taken into account. It seems that there may be some connection between the input that actors have given in the setting of standards and the relative clarity of these standards. The results of the Kendall's tau_b correlation test also suggest that there is a positive and statistically significant relationship between the perceptions of respondents on the clarity of TC 229 deliverables as well as their level of participation at the TC 229 meetings (τ = 0.28; significant level = 0.00) (see Appendix 15). However, as discussed below, the expertise and organizational background of respondents also play a role on how respondents perceive the clarity of TC 229 deliverables.

Table 5.46: The Perceptions of Stakeholders on the *Clarity* of TC 229 Deliverables and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	2	1	0	3.3
Belgium	0	1	2	1	0	3.0
Canada	0	0	1	3	0	3.7
China	0	0	1	2	0	3.7
France	0	0	0	4	0	4.0
Germany	0	0	2	1	1	3.7
India	0	0	1	0	0	3.0
Iran	0	1	1	2	0	3.3
Italy	0	0	0	4	0	4.0
Japan	0	1	1	3	0	3.4
Liaison EU	0	1	1	1	0	3.0
Malaysia	0	0	2	0	0	3.0
Mexico	0	0	1	0	0	3.0
The Netherlands	1	1	4	3	0	3.0
Norway	0	0	2	0	0	3.0
South Africa	0	0	1	1	0	3.5
South Korea	0	0	0	2	1	4.3
Spain	0	0	0	1	0	4.0
Switzerland	0	1	1	0	0	2.5
UK	0	0	3	2	0	3.4
US	0	0	1	4	0	3.8

The institutional origin of respondents emphasizes that those from industry, research institutes, academic and governmental agencies, appear to be generally more satisfied with the clarity of TC 229 deliverables. Respondents from NGOs, trade unions and trade associations appear to be less satisfied. The expertise of respondents also emphasizes that respondents are highly divided as to whether or not TC 229 deliverables are clear. In particular, respondents that were most likely to perceive the clarity of TC 229 deliverables high, were chemists and material scientists by background (i.e. 40 out of 76 respondents). Toxicologists, as well as environmental, occupational and health scientists, appeared to be less satisfied with this indicator.

Table 5.47: Stakeholder Perceptions on *the Clarity of TC 229 Deliverables* and the *Type of Organization*

	Clarity of TC 229 Deliverables					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	1	5	9	1	3.5
RI	0	0	7	10	1	3.7
Acad	0	0	6	8	0	3.6
Gov.	0	1	4	4	0	3.3
NGO	0	2	3	1	0	2.8
Reg.	0	0	1	1	0	3.5
TA	0	1	0	0	0	2.0
TUO	0	1	1	0	0	2.5

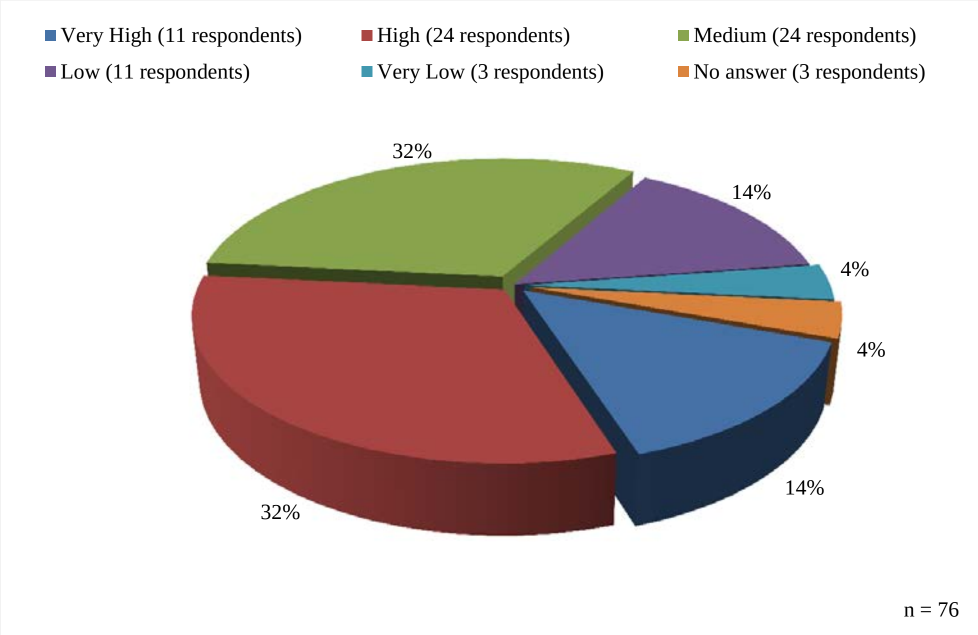
5.2.5.c. Problem Solving Capacity

The business plan of TC 229 indicates that the key objectives of this Committee are to develop (amongst others) standards that:

1) reduce scientific uncertainties and contribute to the smooth transition of the products to the marketplace;
2) support the introduction and use of nanotechnologies to new applications and markets and facilitate global trade; and
3) support regulation, develop risk assessment tools and occupational health protocols in the area of nanotechnologies (ISO, 2012).

To understand the perceptions of stakeholders on *problem solving capacity*, surveyees were asked to indicate the extent to which they perceive TC 229 standards to fulfil the global aims that are emphasized in the business plan. In particular, surveyees were asked to indicate the potential of nanotechnology standards to *facilitate global trade, enable risk and regulatory analysis*, and *reduce scientific uncertainties.* 74 respondents answered on the question related to the potential of nanotechnology standards to *facilitate global trade*. In particular, 11 respondents perceived the effectiveness of TC 229 standards to *facilitate global trade* - *very high*, followed by 24 respondents evaluating it *high*, 24 respondents - *medium*, 11 respondents - *low* and 3 respondents - *very low*. Three respondents did not reply to this question (see Table 5.48 and Figure 5.21). The results of the survey emphasize that respondents are relatively satisfied with the effectiveness of the TC 229 standards to *facilitate global trade*. This is indicated by the mean of 3.4, which on a scale of 1 (very low) to 5 (very high) corresponds to "medium" level of effectiveness for *facilitating global trade*.

Figure 5.21: The Distribution of Stakeholders' Perceptions on *Facilitating Global Trade*



At the country level there were mixed perceptions amongst respondents as to the perceived effectiveness of TC 229 standards to *facilitate global trade* (see Table 5.48). The mean scores of respondents in Table 5.48 give insight into the perceptions of respondents on this indicator. By looking at Table 5.48, we can observe that respondents from US, Malaysia, France, India, Netherlands and South Korea perceive the effectiveness of TC 229 standards to *facilitate global trade* much lower than other respondents. This is indicated by the higher mean scores that these respondents have as compared to other respondents (see Table 5.48). The respondents from Liaison Organizations, Switzerland, Belgium and Norway, which had much lower scores in other indicators, were more likely to believe that TC 229 standards *facilitate global trade*. This is quite contrary with what has been observed in other standardization areas. For example, in her research on environmental management standards (ISO 14001), Raines (2003) has observed that respondents from developed countries, who were drawn primarily from industry and had higher number of delegators in the process, were most likely to believe that standards will facilitate trade. In the case of TC 229, respondents did not comment on the problem solving capacity of TC 229 standards, but their characteristics provide several explanations about their responses. In particular, respondents that were less likely to perceive TC 229 standards as being effective to *facilitate global trade* were active participants in TC 229 meetings, indicating involvement in more than five meetings, as well as involvement in the work of other TCs in the ISO (e.g. in TC 194; TC 24; TC 45; TC 201; TC 207 etc). The activities of these respondents emphasize that they are mostly involved in using nanotechnology artifacts in the manufacturing process and/or products, as well as in the manufacturing of products containing nanotechnology (e.g. particle loaded materials or goods). A number of these respondents (in particular 30 respondents) indicated active involvement in the WG1, WG2 and WG3 of the TC 229, and as we shall in Table 5.49 they come mainly from industry and research institutes. In contrary, respondents that were most likely to perceive TC 229 standards as being effective to *facilitate global trade* have participated in 1 to 4 TC 229 meetings and have been less involved in the work of other TCs. A number of these respondents (in particular 24 respondents) indicated involvement in the WG3 of the TC 229, and come from academia and civil society organizations. They have been mostly engaged in research directed at nanoscale products or processes, as well as academic research related to nanotechnology. The results of the Kendall's tau_b correlation test also verify a negative correlation between respondents' perceptions on the effectiveness of the TC 229 standards to *facilitate global trade* and their participation at TC 229 meetings (τ = - 0.08; significant level = 0.13) (see Appendix 16).

The characteristics of respondents seem to suggest that the main reasons why some respondents were less likely to believe that TC 229 are effective in *facilitating global trade* may be due to their practical experience with TC 229 standards as users and manufacturers, as well as with the TC 229 process as active participants. These lead us to safely assume that maybe the respondents that were more likely to believe that TC 229 standards facilitate global trade, based their evaluations on the general research and investments done about the scientific and technological strength of nanotechnology, as well as its competitive advantages (e.g. public and private research investments, papers published in scientific journals)[107], but not on the actual impact that TC 229 standards have on trade. The background, as well as the institutional origin and activities of respondents seem to support these assumptions, but given the low number of responses for each individual country it is difficult to generalize and come to concrete conclusions.

[107] See for example: Sargent F.J.,2008. *Nanotechnology and U.S. Competitiveness: Issues and Opinions*. CRS Report for Congress.

Table 5.48: The Perceptions of Stakeholders on *Facilitating Global Trade* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	1	1	1	4.0
Belgium	0	1	0	1	1	3.7
Canada	0	1	0	3	0	3.5
China	1	0	1	0	1	3.0
France	0	2	1	1	0	2.7
Germany	0	0	2	2	0	3.5
India	0	1	0	0	0	2.0
Iran	1	0	1	2	1	3.4
Italy	0	0	2	3	0	3.6
Japan	0	0	4	0	1	3.4
Liaison EU	0	0	0	2	0	4.5
Malaysia	0	1	1	0	0	2.5
Mexico	0	0	1	1	0	3.5
The Netherlands	1	1	3	3	1	3.2
Norway	0	0	0	2	0	4.0
South Africa	0	0	1	1	0	3.5
South Korea	0	1	1	0	1	3.3
Spain	0	0	0	1	0	4.0
Switzerland	0	0	0	2	0	4.0
UK	0	1	2	0	3	3.8
US	0	2	3	0	0	2.6

The institutional origin of respondents emphasizes that those coming from academia, regulatory agencies, trade unions and NGOs appear to be generally more satisfied with the effectiveness of TC 229 standards to *facilitate global trade*. Respondents from industry and research institutes had lower mean scores, which suggests that they are generally less satisfied with this indicator (see Table 5.49). An explanation for these scores, as mentioned earlier, could be the activities in which these respondents are involved, but also the nature of the standards produced at the TC 229. Most of the TC 229 deliverables are process (horizontal) standards. These standards, as compared to the product standards are not focused on the product, but instead they focus on the method of production or processing, and may impose a set of techniques that can be used to minimize for instance the occurrence of hazardous activities that may lead to several problems and accidents (Knutson and Josling, 2008). For instance, the process standards may require an entire industry or a class of operation to achieve optimal levels of pollution control by installing the best available pollution control technology or to utilize a set of procedures along the supply chain to avoid the occurrence of food safety problems (Shelton and Kiss, 2005).

TC 229 standards also aim to provide resources that relevant actors can use for their own standards in terms of products and applications. For instance, the WG4 of the TC 229 has focused on setting standards that are not focused on characterizing manufactured nanomaterials (e.g. carbon nanotubes) for use in a particular application, but standards that help relevant actors to know the diameters, length and quality of the carbon nanotube through the use of various techniques. In a similar way, the WG1 of the TC229 has set standards that, so far, provide generic definitions for nanotechnology, nanoscience, nanomaterial, engineered nanomaterial and manufactured nanomaterials, to help relevant actors to make use of those definitions in terms of their standards for their own products.

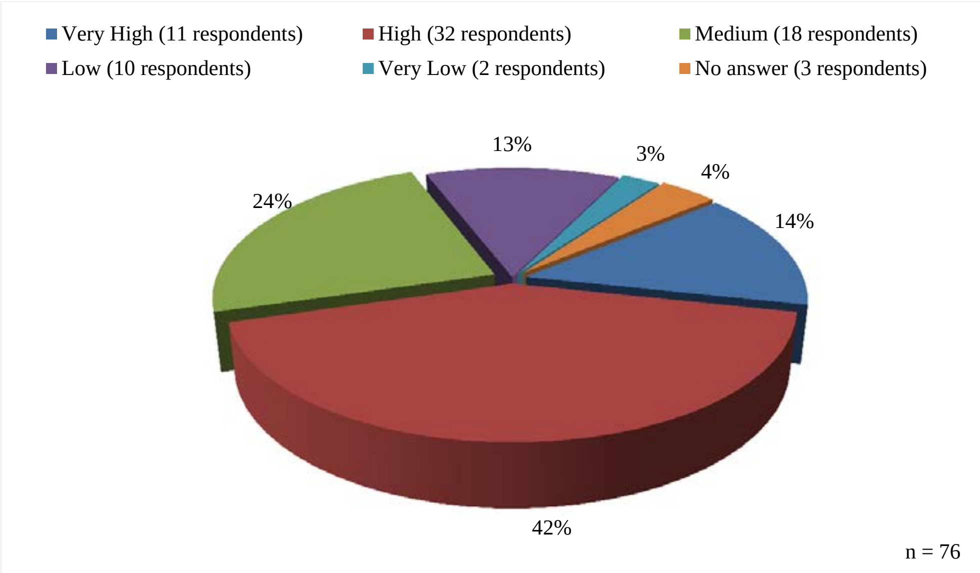
The same applies to the deliverables of the WG3 of the TC229, which has also provided risk assessment frameworks and generic methods for use by industry in handling nanomaterials in occupational settings (see also Friedrichs et al. 2013). In this way, whereas process standards may help companies across borders to be more certain that products result from qualitative and consistent manufacturing processes, these standards come with many challenges as well. Process standards often require that companies (e.g. manufacturers, suppliers) make changes in the production techniques or even implement new techniques to meet the specifications of particular standards. These can bring additional costs to companies, which may lack the financial means to afford the changes in the manufacturing processes as well as the expertise to implement new techniques (Basri and O'Connor, 2010). In fact, reflecting on the perceptions of respondents in Section 5.2.a, we can observe that financial costs and expertise were amongst the main barriers they faced to comply with TC 229 standards. Compliance is an important issue here. In particular, if standards are not used or complied in practice it may be difficult to know to what extent they can contribute to facilitating global trade. The majority of respondents (i.e. 6 out of 9) that comply with TC 229 standards appear highly satisfied with the effectiveness of nanotechnology standards to facilitate global trade. However, since the sample size is small it is difficult to generalize.

Table 5.49: The Perceptions of Stakeholders on *Facilitating Global Trade* and the *Type of the Organization*

	Facilitating Global Trade					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	2	9	4	1	3.1
RI	1	5	6	5	1	3.0
Acad	0	3	4	5	4	3.6
Gov.	1	1	2	6	1	3.4
NGO	0	0	0	3	1	4.2
Reg.	0	0	0	0	2	5.0
TA	0	0	1	0	0	3.0
TUO	0	0	0	1	1	4.5

Respondents perceived TC 229 standards to be slightly more effective in *enabling risk and regulatory analysis*. 74 respondents answered on the question related to the potential of nanotechnology standards to *enable risk and regulatory analysis*. In particular, 11 respondents perceived the effectiveness of the nanotechnology standards to *enable risk and regulatory analysis* - *very high*, 32 respondents - *high*, 18 respondents - *medium*, 10 respondents - *low* and 2 respondents - *very low*. Three respondents did not answer to the question (see Table 5.50 and Figure 5.22). The overall results emphasize that respondents are relatively satisfied with the effectiveness of the TC 229 standards to *enable risk and regulatory analysis*. This is indicated by the mean of 3.6, which on a scale of 1 (very low) to 5 (very high) corresponds to "medium" level of effectiveness for *enabling risk and regulatory analysis*.

Figure 5.22: The Distribution of Stakeholders' Perceptions on *Enabling Risk and Regulatory Analysis*



At the country level there were mixed perceptions amongst respondents on the effectiveness of TC 229 standards to *enable risk and regulatory analysis* (see Table 5.50). By looking at Table 5.50 we can observe that respondents from Belgium, India and Malaysia appear to be generally less satisfied with this indicator. The mean scores of some developed countries which were mentioned earlier, such as US, France, South Korea, are higher on this indicator. This leads us to assume that at least some of the representatives from bigger delegations, are more satisfied with the effectiveness of the TC 229 standards to *enable risk and regulatory analysis.*

Table 5.50: The Perceptions of Stakeholders on *Enabling Risk and Regulatory Analysis* and the *Country of Origin*

	Very Low	Low	Medium	High	Very High	Mean
	Number of respondents					
Australia	0	0	1	2	0	3.7
Belgium	1	0	1	1	0	2.7
Canada	0	0	1	2	1	4.0
China	0	1	0	1	1	3.7
France	0	0	1	2	1	4.0
Germany	0	0	3	0	1	3.5
India	0	1	0	0	0	2.0
Iran	0	1	1	2	1	3.6
Italy	0	0	1	3	1	4.0
Japan	0	1	0	4	0	3.6
Liaison EU	0	0	1	1	0	3.5
Malaysia	0	1	1	0	0	2.5
Mexico	0	0	0	1	1	4.5
The Netherlands	1	2	1	5	0	3.1
Norway	0	0	0	2	0	4.0
South Africa	0	1	1	0	1	4.5
South Korea	0	0	0	1	1	3.3
Spain	0	0	0	1	0	4.0
Switzerland	0	0	1	1	0	3.5
UK	0	1	2	1	2	3.7
US	0	1	2	2	0	3.2

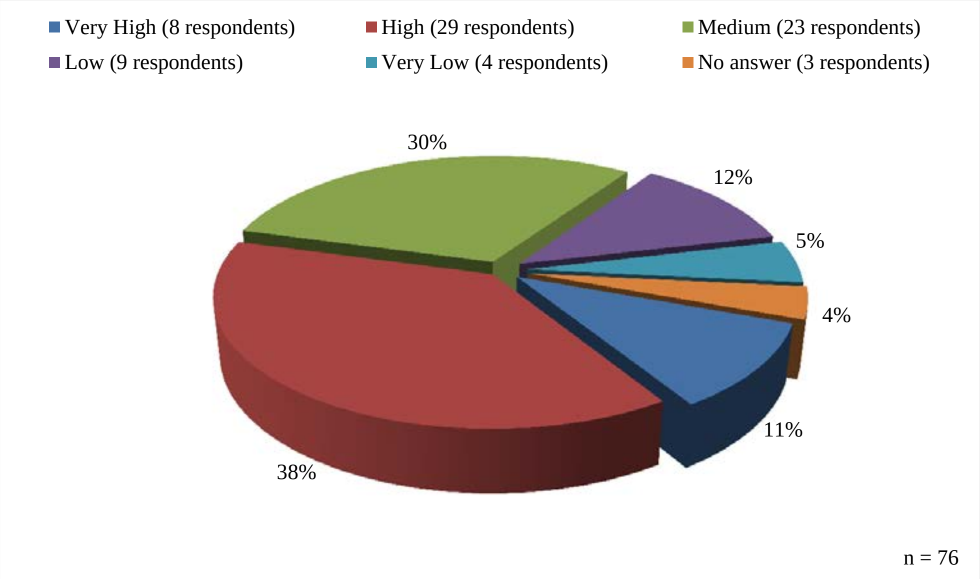
The institutional origin of respondents emphasizes that those from academia, governmental and regulatory agencies, as well as NGOs, appear to be generally more satisfied with the effectiveness of the TC 229 standards to *enable risk and regulatory analysis*. Respondents from industry also evaluate this indicator higher than the previous one (see Table 5.51).The perceptions of the respondents on this indicator, appear to be less influenced by their technical expertise on nanotechnology standardization issues as well as their participation in TC 229 meetings. The results of the Kendall's tau_b correlation test indicate also that there is a positive but not a statistically significant relationship between respondents' technical expertise and their perceptions on the effectiveness of standards to *enable risk and regulatory analysis* (τ = 0.15; significant level = 0.13), as well as between respondents' participation at TC 229 meetings and their perceptions on this indicator (τ = 0.24; significant level = 0.81) (see Appendices 17 and 18).

Table 5.51: The Perceptions of Stakeholders on *Enabling Risk and Regulatory Analysis* and the *Type of the Organization*

	Enabling Risk and Regulatory Analysis					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	0	4	10	2	3.7
RI	0	4	9	4	1	3.1
Acad	0	3	3	4	6	3.8
Gov	0	1	0	10	0	3.8
NGO	0	0	1	2	1	4.0
Reg.	0	0	1	0	1	4.0
TA	0	1	0	0	0	2.0
TUO	1	0	0	1	0	2.5

Regarding the question about the effectiveness of TC 229 to *reduce scientific uncertainties*, the scores in Figure 5.23 show that 74 respondents answered to this question. In particular, 8 respondents evaluate the effectiveness of nanotechnology standards to *reduce scientific uncertainties* - *very high*, followed by 29 respondents evaluating it *high*, 23 respondents - *medium*, 9 respondents - *low* and 4 respondents - *very low*. Three respondents did not reply to this question (see Table 5.52 and Figure 5.23). The overall mean score (mean = 3.4) reveals that respondents are relatively satisfied with the effectiveness of the ISO/TC229 standards to *reduce scientific uncertainties* (also see Table 5.54).

Figure 5.23: The Distribution of Stakeholders' Perceptions on *Reducing Scientific Uncertainties*



By looking at Table 5.52 we can observe that respondents from Belgium, India, Iran, Liaison Organizations and Netherlands, generally evaluate the effectiveness of TC229 standards lower than other respondents. Looking at the scores of the respondents from developed countries and LDCs, we can observe that the variation of the responses is similar and ranges between "low" and "high" level of effectiveness for TC 229 standards to *reduce scientific uncertainties*. In particular, whereas the mean scores for LDCs range between 2.8 to 4.5, the scores for developed countries range between 2.7 to 4.0, which in both cases is between "low" and "high" level of effectiveness.

In most LDCs (i.e. in 4 out of 6 countries) respondents appear to be highly satisfied with the effectiveness of the TC 229 standards to *reduce scientific uncertainties*. For example, looking at the scores given by respondents from China and Malaysia, we can observe that this indicator is perceived as being higher than the other two. Similar trends can be observed for some respondents coming from developed countries. For instance respondents from France and US perceive TC229 standards to be more effective in *reducing scientific uncertainties* than in *facilitating global trade* and *enabling risk and regulatory analysis*. The background of these respondents emphasizes that most of them (i.e. 6 out of 9) are physicists and chemists, followed by toxicologists and material scientists.

Table 5.52: The Perceptions of Stakeholders on *Reducing Scientific Uncertainties* and the *Country of Origin*

	Very Low	**Low**	**Medium**	**High**	**Very High**	**Mean**
	Number of respondents					
Australia	0	0	2	1	0	3.3
Belgium	1	0	1	1	0	2.7
Canada	0	0	1	3	0	3.7
China	0	0	1	1	1	4.0
France	0	0	0	3	1	4.2
Germany	0	0	3	1	0	3.2
India	0	1	0	0	0	2.0
Iran	0	2	2	1	0	2.8
Italy	0	0	2	3	0	3.6
Japan	0	0	3	1	1	3.6
Liaison EU	1	0	0	1	0	2.5
Malaysia	0	0	1	0	1	4.0
Mexico	0	0	0	2	0	4.0
The Netherlands	2	2	2	3	0	2.7
Norway	0	0	1	1	0	3.5
South Africa	0	0	0	1	1	4.5
South Korea	0	1	1	0	1	3.3
Spain	0	0	0	1	0	4.0
Switzerland	0	0	1	1	0	3.5
UK	0	2	1	1	2	3.5
US	0	1	1	3	0	3.4

The institutional origin of respondents emphasizes that those from academia, governmental agencies, industry and research institutes were generally more satisfied with the effectiveness of TC 229 standards to *reduce scientific uncertainties*. NGOs, trade unions and regulatory agencies appeared to be less satisfied (see Table 5.53). Since respondents did not comment this indicator, it is difficult to explain why some respondents tend to evaluate this indicator higher. Scholars working on international standardization have often argued that standardization reduces scientific uncertainties, because amongst others, through these documents experts are given the opportunity to share information, knowledge and best practices on how to standardize a particular fields or technology (Hallström, 2004; Brunsson and Jacobsson, 2005; Murphy and Yates, 2009; Blind and Gauch, 2009; Jacobs, 2010; Hallström and Boström, 2010). For instance TC 229 has managed, amongst other deliverables, to establish technical specifications focused on the characterization of manufactured nanomaterials (e.g. single-wall and multi-walled carbon nanotubes) by using a variety of techniques; set up technical standards related to the application of the endotoxin tests on nanomaterial samples for in vitro systems, as well as guidance documents related to the safe handling of nanomaterials in occupational settings and risk assessment frameworks for the use of nanomaterials. In this way, regardless of how deliberative the process is, still, the TC 229 horizontal standards may put the foundation for other vertical standards to be developed.

In addition, the characteristics of respondents emphasize that there may also be some correlation between the respondents' perceptions on the effectiveness of TC 229 standards to *reduce scientific uncertainties*, their own understanding of the technicalities of the field, as well as their active involvement in TC 229. Respondents that were most likely to perceive TC 229 standards as being effective in *reducing scientific uncertainties* indicated high involvement in the TC 229 meetings and high level of technical expertise on nanotechnology standardization issues. The results of the Kendall's tau_b emphasize also that there is a positive and a statistically significant relationship between respondents' technical expertise and their perceptions on the effectiveness of standards to *reduce scientific uncertainties* (τ = 0.19; significant level = 0.06), as well as between respondents' participation at TC 229 meetings and their perceptions on this indicator (τ = 0.21; significant level = 0.04) (see appendices 19 and 20). The perceptions of respondents were similar across all the WGs of the TC 229.

Table 5.53: The Perceptions of Stakeholders on *Reducing Scientific Uncertainties* and the *Type of the Organization*

	Reducing Scientific Uncertainties					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	1	6	8	1	3.4
RI	1	2	7	5	3	3.4
Acad	0	4	2	7	3	3.6
Gov	0	1	3	7	0	3.5
NGO	0	1	2	1	0	3.0
Reg.	1	0	0	0	1	3.0
TA	0	0	1	0	0	3.0
TUO	1	0	1	0	0	2.0

Overall, the scores given on the effectiveness of the TC 229 standards to *facilitate global trade*, *enable risk and regulatory analysis* and *reduce scientific uncertainties*, emphasize that respondents are relatively satisfied with the *problem solving capacity* of TC 229 standards. This is indicated by the mean of 3.5, which on a scale of 1 (very low) to 5 (very high) corresponds to a medium level of *problem solving capacity*. Table 5.54 displays the overall responses on this indicator.

Table 5.54: The Perceptions of Stakeholders on the *Problem Solving Capacity* of TC 229 Standards

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Facilitating Global Trade	11	24	24	11	3	3.4
Enabling Risk and Regulatory Analysis	11	32	18	10	2	3.6
Reducing Scientific Uncertainties	8	29	23	9	4	3.4
Problem Solving Capacity (Overall Rating)	30	85	65	30	9	**3.5**

5.2.5.d. Rule Benefits

In the business plan of TC 229 it is emphasized that nanotechnology standards are expected to benefit every industrial sector, scientists, manufacturers, governments, regulators, consumers, workers, health and environmental protection agencies, as well as users (ISO, 2012). In this way, amongst the main reasons for these actors to join standardization activities is that they want to participate in setting standards that will benefit their interests (Hatto, 2010; Forsberg, 2010).

In the survey participants were asked to prioritize the standardization areas in which they were mostly interested. In this regard, respondents indicated that they were mostly interested on issues of: *measurement* (50 respondents); *characterization* (47 respondents); *toxicity testing* (46 respondents); *safe handling of nanomaterials* (43 respondents); *risk analysis* and *evaluation* (43 respondents), and *terminology* (43 respondents). These respondents were mostly engaged in:

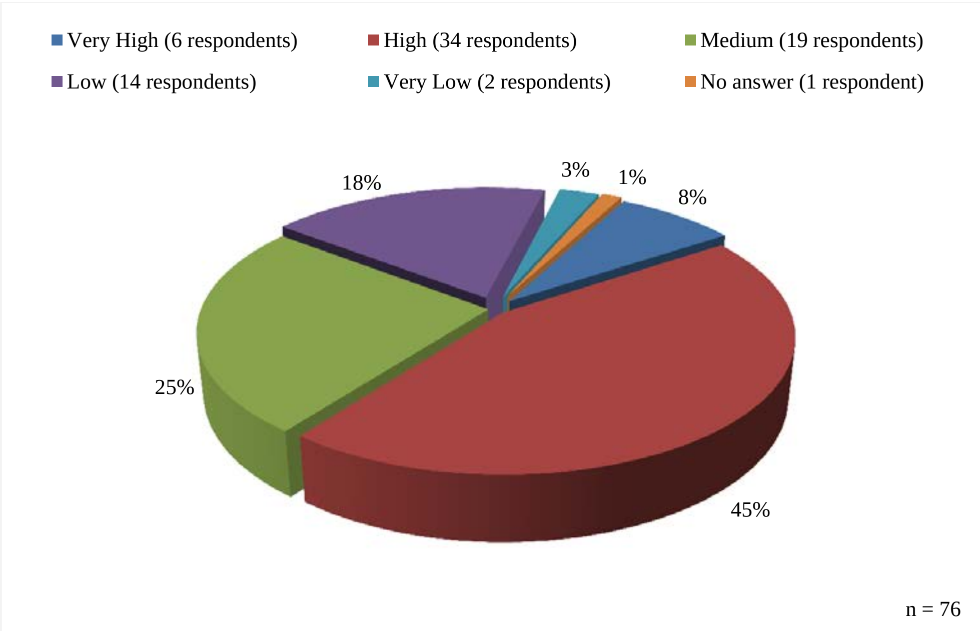
- the manufacturing of nanotechnology artifacts (e.g. nanopowders, nanotubes, nanofibers etc); research directed at nanoscale products or processes;
- regulatory issues directed at nanotechnology related products or processes;
- safety issues related to nanotechnology (e.g. in promoting consumers health interests, as well as occupational and environmental safety);

- academic research related to nanotechnology; and
- using nanotechnology artifacts in any manufacturing processes or products.

In addition, respondents engaged in the manufacturing of nanotechnology artifacts, in research directed at nanoscale products or processes, in regulatory issues directed at nanotechnology related products or processes, as well as in safety issues related to nanotechnology, were also interests on issues of : *disposal/environmental risks* (36 respondents); *materials specifications* (25 respondents) and *code of practice* (21 respondents).

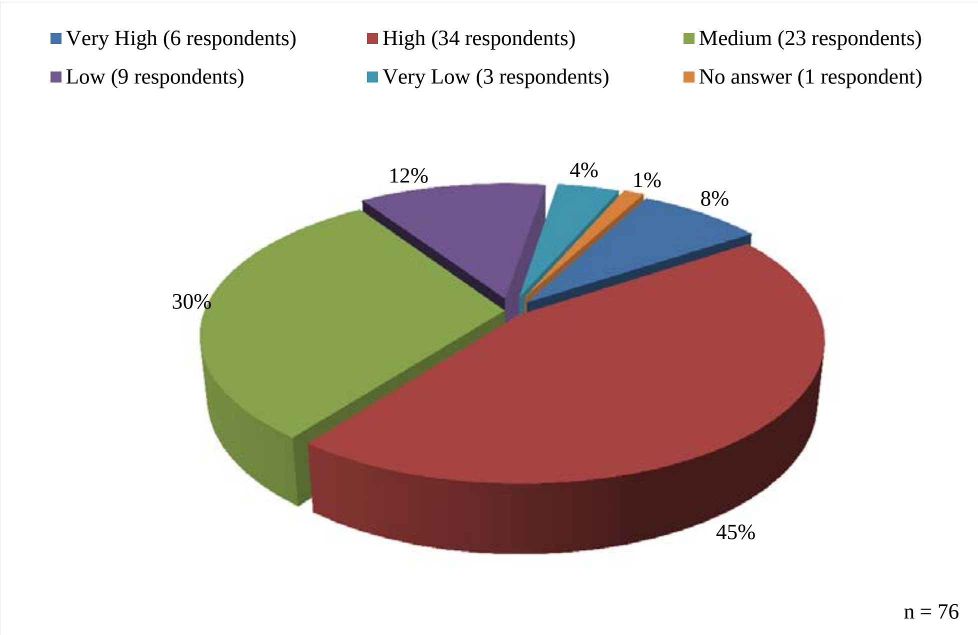
As mentioned in Chapter 2, TC 229 is working actively in all of these areas through its WGs. In the survey respondents were also asked to indicate whether they perceived TC 229 standards and other deliverables in this Committee (e.g. TSs, TRs) to be beneficial for their organizations. 75 respondents answered the question on the benefits of TC 229 standards. In particular, 6 respondents perceive TC 229 standards to be *very highly* beneficial for their organizations, followed by 34 respondents perceiving TC 229 standards *highly* beneficial, 19 respondents - *relatively* beneficial, 14 respondents *not highly* beneficial and 2 respondents - *not beneficial*. One respondent did not answer to this question (see Table 5.55 and Figure 5.24). The overall results emphasize that respondents, perceive TC 229 standards relatively beneficial for their organizations. This is indicated by the mean of 3.4, which on a scale of 1 (very low) to 5 (very high) corresponds to “medium” level of beneficial standards.

Figure 5.24: The Distribution of Stakeholders’ Perceptions on *the Benefits of TC 229 Standards*



As discussed in Chapter 2, the majority of documents published by TC 229 are in the form of technical specification and technical reports. Therefore, surveyees were also asked to indicate whether they considered these deliverables beneficial for their organizations. 75 respondents answered this question. The results of the survey show that 6 respondents perceive TC 229 deliverables to be *very highly* beneficial for their organizations, followed by 34 respondents perceiving TC 229 deliverables *highly* beneficial, 23 respondents - *relatively* beneficial, 9 respondents *not highly* beneficial and 3 respondents - *not beneficial*. One respondent did not answer to this question (see Table 5.55 and Figure 5.25). The overall results emphasize that respondents, similar to TC 229 standards, perceive other deliverables relatively beneficial for their organizations. This is indicated by the mean of 3.4, which on a scale of 1 (very low) to 5 (very high) corresponds to "medium" level of beneficial deliverables.

Figure 5.25: The Distribution of Stakeholders' Perceptions on *the Benefits of Other TC 229 Deliverables*



By looking at Table 5.55, we can see that most of the respondents from both developed and LDCs seem to be generally satisfied with the benefits that TC 229 standards and other deliverables provide for their organizations. In this way, even though LDCs indicated earlier that they were less included in the development of TC 229 standards (see Section 5.2.1.a), it appears that TC 229 has been relatively successful in meeting the needs of the stakeholders from LDCs. However, as the number of responses for each country is small more research may be needed on this. In fact, the results of the Kendall's tau_b correlation test emphasize that those that have been highly included in the development of standards are more likely to perceive TC 229 standards and other deliverables beneficial for their organizations. In particular, there is a positive and statistically significant relationship between the participants level of inclusiveness and their perceptions of the benefits of TC 229 standards (τ = 0.30; significant level = 0.00) (see Appendix 21). A less significant relationship is observed between the participants level of inclusiveness and their perceptions of the benefits of TC 229 deliverables (τ = 0.16; significant level = 0.11) (see Appendix 22).

Table 5.55: The Perceptions of Stakeholders on the *Benefits of TC 229 Standards* and *Other Deliverables*, and the *Country of Origin.*

	Benefits of TC 229 Standards	***Benefits of TC 229 Deliverables***
	Mean	**Mean**
Australia	3.7	3.7
Belgium	3.0	3.0
Canada	3.3	3.7
China	3.3	3.3
France	4.3	3.8
Germany	4.0	4.0
India	4.0	4.0
Iran	3.6	3.4
Italy	3.6	3.6
Japan	3.4	3.2
Liaison EU	3.3	3.0
Malaysia	3.0	3.5
Mexico	4.5	4.0
The Netherlands	2.7	2.9
Norway	3.0	3.5
South Africa	4.0	4.5
South Korea	3.7	3.3
Spain	4.0	4.0
Switzerland	2.5	3.0
UK	3.0	3.0
US	3.2	3.6

The views of the respondents seemed to also vary also with the extent to which they were associated with industry, research institutes, NGOs and so on. By looking at Table 5.56, we can observe that respondents coming from regulatory and governmental agencies, research institutes and industry perceive TC 229 standards and other deliverables more beneficial, than actors coming from academia, NGOs and TAs. Two respondents commented on this indicator. One respondent from academia indicated that she perceived TC 229 standards and other deliverables to be important and beneficial for her research, but not for her organization. This was because the organization was not interested nor involved on issues related to nanotechnology. Another NGO respondent indicated that he was not very much aware of the actual benefits that TC 229 standards or other deliverables have brought to the organization with which he was associated. These comments, even though very limited in numbers, are of importance because they emphasize that the type of the organizations with which respondents are involved, as well as their awareness on the benefits of TC 229 deliverables, may have impacted their perceptions on this indicator.

By looking at Table 5.56 we can observe that respondents from industry perceive TC 229 deliverables as being less beneficial than respondents from research institutes, as well as from governmental and regulatory agencies. This is interesting, amongst others, because actors from industry as observed in earlier sections (see Section 5.2.1 and 5.2.2), were those that have highly influenced the setting of nanotechnology standards in TC 229. Respondents did not comment on this, but scholars from other standardization areas relate the perceptions of respondents on standardization benefits with the nature of standards (e.g. Raines, 2002; Beisheim and Dingwerth, 2008; Basri and O'Connor, 2010). While discussing the development of software quality standards, Basri and O'Connor (2010) argue that respondents from software companies did not perceive software quality standards highly beneficial, mainly because they were not interested on generic standards that provided a broad range of technical possibilities, and were too complex and time - consuming for their purpose. Companies were mostly interested on concrete standards that focused mostly on the output and were designed to meet their business needs. The responses of the surveyees in Table 5.56, emphasize that industrial actors find TC 229 standards slightly more beneficial than other deliverables. This, as articulated above, may be because of the nature of these deliverables. In this way, while the number of responses is small to conclude that there is a statistically significant difference on the perceptions of respondents on TC 229 standards and deliverables, the results in Table 5.56 do suggest that respondents perceive the benefits of these documents differently and are worthy of further research.

Table 5.56: The Perceptions of Stakeholders on the *Benefits of TC 229 Standards* and *Other Deliverable*s, and the *Type of the Organization.*

	Rule Benefits TC 229 Standards					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	1	6	7	2	3.5
RI	0	4	5	7	2	3.4
Acad	1	4	4	6	1	3.1
Gov	0	0	2	8	1	3.9
NGO	0	3	2	1	0	2.6
Reg.	0	0	0	2	0	4.0
TA	0	1	0	0	0	2.0
TUO	0	1	0	1	0	3.0
	Rule Benefits Other TC 229 Deliverables					**Mean**
	Very Low	**Low**	**Medium**	**High**	**Very High**	
	Number of respondents					
IO	1	2	7	5	2	3.3
RI	0	1	4	10	3	3.8
Acad	1	3	5	7	0	3.1
Gov	0	0	4	7	0	3.6
NGO	1	1	2	2	0	2.8
Reg.	0	0	0	2	0	4.0
TA	0	1	0	0	0	2.0
TUO	0	1	0	0	1	3.5

Overall, the scores given on the benefits of TC 229 standards and other deliverables, emphasize that respondents perceive these deliverables relatively beneficial for their organizations. This is indicated by the mean of 3.4, which on a scale of 1 (very low) to 5 (very high) corresponds to a medium level of beneficial standards. Table 5.57 displays the overall responses on this indicator.

Table 5.57: The Perceptions of Stakeholders on the *Benefits of TC 229 Standards and Other Deliverables*

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Benefits of TC 229 Standards	6	34	19	14	2	3.4
Benefits of other TC 229 Deliverables	6	34	23	9	3	3.4
The Benefits of TC 229 Deliverables(Overall Rating)	12	68	42	23	5	**3.4**

In sum, the perceptions of the respondents emphasize that there is a considerable difference between the stated goals of the TC 229, as well as the perceived benefits and problem solving capacity of TC 229 standards. TC 229 standards are not followed in practice and they are not perceived highly effective to facilitate global trade, reduce scientific uncertainties, and enable risk and regulatory analysis. Respondents from developed countries associated mainly with industry, research institutes and governmental agencies appear to have more issues with the *problem solving capacity* and *the benefits* of TC 229 standards. This is interesting given that these actors have been active in influencing the setting of these deliverables. The weaknesses of the standards with regard to these points seem to be attributed partially to the fact that the majority of standards developed at the TC 229 are not followed in practice, but also to the nature of the deliverables produced by TC 229 and the experience of the respondents with TC 229 deliverables. Only a limited number of respondents (i.e. 9 respondents) comply with TC 229 standards. This may be, in part, due to the brief life span of these deliverables (i.e. the majority of TC 229 deliverables are set after 2009) as well as uncertainties characterizing the field of nanotechnologies. Furthermore, given that the majority of deliverables produced by TC 229 are process standards, compliance seems to be costly for most of the respondents. In view of these responses, the norm *of implementable outcomes* is perceived to be much lower than other legitimacy norms discussed in earlier sections (see Table 5.58).

Table 5. 58: Stakeholder Perceptions on *Implementable Outcomes*

Performance Indicators	**Very High**	**High**	**Medium**	**Low**	**Very Low**	**Mean**
	Number of respondents					
Compliance	9	0	0	0	28	1.9
Rule Clarity	2	35	27	6	1	3.4
Problem Solving Capacity	30	85	65	30	9	3.5
Rule Benefits	12	68	42	23	5	3.4
Overall Rating						**3**

Scale : 1 (very low) to 5 (very high)

5.2.5.e. Recommendations to Improve Implementable Outcomes

The main issue with the norm of *implementable outcomes* is that TC 229, as well as ISO in general, seems to focus mostly in setting standards and less on how these deliverables are taken up and what their impact is in practice. Therefore, respondents argue that TC 229 needs to take an active approach to facilitate compliance with its deliverables. More specifically, based on the recommendations of the respondents, TC 229 and the convenors of the working groups need to:

- look for possibilities to use the systematic review process to document not only the accuracy of TC 229 standards and deliverables, but also their acceptance and use in practice;
- collaborate with members to assess the benefits of standards and consequences of non-compliance ;
- raise awareness on how TC 229 standards benefit industry, inform research and regulation, and protect consumers;
- collaborate with members to determine their preparedness to implement TC 229 standards as well as possibilities for training; and
- reduce the costs of purchasing TC 229 deliverables;

5.3. Further Analysis and Discussion

In this section I present the total legitimacy score of TC 229 by using the individual scores given by respondents on each performance indicator. To determine the extent to which respondents perceive that the norms of legitimacy are effectively taken up in practice by TC 229 I use the evaluative matrix that was discussed in earlier chapters (see Chapter 3). By looking at Table 5.59, we can observe that TC 229 is perceived to be more successful in providing a *deliberative decision-making*, *trustworthy expertise* and *effective process control*. The Committee is perceived to be less successful in providing a *meaningful participation* and *implementable outcomes* as compared to other indicators. The individual scores of respondents on each legitimacy norm led to the final score. As we can see in Table 5.59 the final score is 63 out of 95, or 66% of the overall score. Therefore, the final score emphasizes that TC 229 is perceived to be relatively successful in taking up the legitimacy norms in practice.

Table 5.59: Overall Rating of the Legitimacy of TC 229

Norms	***Performance Indicators***	***Total Score***
Meaningful Participation	*Inclusiveness*	3.4
	Representation	3.6
	Resources	2.4
		Sub-total (out of 15) is **9.4**
Deliberative Decision-Making	*Participatory Decision Making*	3.5
	Comprehensive Agreements	3.6
	Communicative Agreements	3.7
	Effective Dispute Settlement	3.4
		Sub-total (out of 20) is **14.2**
Effective Process Control	*Transparency*	3.8
	Internal Accountability	3.6
	External Accountability	2.5
	Domestic Accountability	3.5
		Sub-total (out of 20) is **13.4**
Trustworthy Expertise	*Competent Expertise*	3.9
	Robustness	3.4
	Scientific Validity	3.5
	Objective Judgments	2.9
		Sub-total (out of 20) is **13.7**

Implementable Outcomes	*Problem Solving Capacity*	3.5
	Rule Benefits	3.4
	Rule Clarity	3.5
	Compliance	1.9
		Sub-total (out of 20) is **12.3**
		Total: Final Score (out of 95) is **63**

Considering the scores set out in Table 5.59, in this study I also used statistical analysis to understand the internal consistency and correlation of all performance indicators measuring the legitimacy norms that were discussed in earlier sections. In particular, I used the Cronbach's Alpha test, which measures the extent to which individual variables are measuring the same underlying construct and their magnitude of intercorrelation. To see whether there is a relationship or a dependency between performance indicators, I used the Kendall's tau_b correlation test (τ).

With regards to *meaningful participation*, the results of the Cronbach's Alpha test emphasize that there is an acceptable, but not a very high level, of internal consistency between the scores given on each performance indicator (Cronbach's $\alpha = 0.42$) (see Appendix 23).[108] The rationale for these results could be due to the mixed opinions of the respondents on *resources*, since they come from different NSBs, which provide different financial support for participants. In addition, the number of respondents (n-number) for each NSB is not very high. With regards to their correlation, the results of the Kendall's tau_b test emphasize that there is a higher relationship between *representation* & *inclusiveness*, and a lower relationship between these two indicators and *resources*. There is a positive and statistically significant relationship between *inclusiveness & representation* ($\tau = 0.22$; significant level = 0.02). However, there is a positive but not a significant relationship between *resources & inclusiveness* ($\tau = 0.04$; significant level = 0.62), as well as *resources & representation* ($\tau = 0.15$; significant level =.09) (see Appendix 24).

With regards to *deliberative decision-making*, the results of the Cronbach's Alpha test emphasize that there is a high level of internal consistency between the scores given on each performance indicator (Cronbach's $\alpha = 0.86$). Each of these indicators seem to contribute highly to the internal consistency of the scale (see Appendix 25). With regards to their correlation, the results of the Kendall's tau_b test emphasize that there is a high level of dependency. In

[108] According to Clark and Watson (1995) for a valid measure of a construct a mean intercorrelation as low as 0.40 - 0.50 is acceptable See: Clark, L. A., & Watson, D. (1995). Constructing validity: Basic issues in objective scale development. *Psychological Assessment, 7,* at p.316.

particular, there is a positive and statistically significant relationship between *participatory decision-making* & *comprehensive agreements* (τ = 0.71; significant level = 0.00), *participatory decision-making & communicative agreements* (τ = 0.54; significant level = 0.00), and *participatory decision-making & effective dispute settlement* (τ = 0.51; significant level = 0.00). A strong relationship is observed also between *communicative decision-making & comprehensive agreements* (τ =0.52; significant level = 0.00), *effective dispute settlement & communicative agreements* (τ = 0.54; significant level = 0.00), as well as *effective dispute settlement & comprehensive agreements* (τ = 0.49; significant level = 0.00) (see Appendix 26).

In a similar way, the results of the Cronbach's Alpha test emphasize a high internal consistency between the scores given on performance indicators related to *effective process control* (Cronbach's α = 0.75). The indicators seem to contribute highly to the internal consistency of the scale (see Appendix 27). In addition, there is a high level of dependency between performance indicators. The results of the Kendall's tau_b test emphasize that there is positive and statistically significant relationship between *transparency & internal accountability* (τ = 0.51;significant level = 0.00); *transparency & external accountability* (τ = 0.39; significant level= 0.00), as well as *transparency & domestic accountability* (τ = 0.30; significant level = 0.00). Positive and statistically significant relationship is observed also between *internal & external accountability* (τ = 0.41; significant level = 0.00) as well as *external & domestic accountability* (τ = 0.38; significant level = 0.00). However, there is a positive but not statistically significant relationship between *internal & domestic accountability* (τ = 0.18; significant level =0.08) (see Appendix 28).

With regards to *trustworthy expertise*, the results of the Cronbach's Alpha test emphasize that there is a high level of internal consistency between the scores given on each performance indicator (Cronbach's α = 0.79) (see Appendix 29). Each indicator contributes highly to the internal consistency of the scale and there is a statistically significant relationship between them. In particular, there is a positive and statistically significant relationship between the *competent expertise* & *scientific validity* (τ = 0.40; significant level = 0.00), *competent expertise & robustness* (τ = 0.54; significant level = 0.00), as well as *competent expertise & objective judgments* (τ = 0.37; significant level = 0.00). A positive and statistically significant relationship is observed also between *scientific validity & objective judgments* (τ = 0.38; significant level = 0.00), *scientific validity & robustness* (τ = 0.60; significant level = 0.00), as well as *objective judgments & robustness* (τ = 0.46; significant level = 0.00) (see Appendix 30).

The results of the Cronbach's Alpha test emphasize that there is an acceptable, but not a very high level of internal consistency between the scores given on performance indicators related to *implementable outcomes* (Cronbach's α = 0.62) (see Appendix 31). The rationale for these results could be the different measurement level used for *compliance* [such as 5 (*very high*) - for Compliance and 1 (*very low*) - for Non-compliance] as compared to other performance indicators, and the limited number of responses on this indicator. With regards to their correlation, the results of the Kendall's tau_b test emphasize a positive and statistically significant relationship between *rule benefits & problem solving capacity* (τ = 0.41; significant level = 0.00), as well as *rule clarity & rule benefits* (τ = 0.31; significant level = 0.00). However, there is a positive but not a statistically significant relationship between *rule clarity & problem solving capacity* (τ = 0.17; significant level = 0.04) (see Appendix 32).

In the previous section (see Table 5.58),we observed that the mean score for *compliance* (mean = 1.9) was much lower than the mean scores of other performance indicators. The results from the Kendall's tau_b test confirm also that there is a positive, but not a statistically significant relationship between *compliance* and other performance indicators. In particular there is a low level of relationship between *compliance & rule clarity* (τ = 0.26; significant level = 0.13), as well as *compliance & problem solving capacity* (τ = 0.03; significant level = 0.83). A higher level of relationship is observed between *compliance & rule benefits* (τ = 0.42; significant level = 0.00) (see Appendix 32).

Following this observation, I analyzed also the internal consistency and the strength of the relationship between the legitimacy norms (*meaningful participation*, *deliberative decision-making, effective process control, trustworthy expertise* and *implementable outcomes*). There is a high level of internal consistency between the scores given for each legitimacy norm (Cronbach's α = 0.84). In this way, the results of the Cronbach's Alpha test emphasize that the legitimacy norms contribute highly to the internal consistency of the scale (see Appendix 33). In addition, there is positive and statistically significant relationship between the scores given on the legitimacy norms (significant level = 0.00) (see Appendix 34). These results suggest that there is no need to add or remove any of the performance indicators used to construct the overall scores on legitimacy.

5. 4. Conclusions and Summary

The aim of this chapter was to answer the third and the fourth sub-research question. In particular to determine: *To what extent is international nanotechnology standardization perceived as legitimate by stakeholders* (sub-research question 3), and *How can international nanotechnology standardization enhance its legitimacy* (sub-research question 4). To answer these questions I applied the analytical framework and the evaluative matrix developed in

Chapter 3. Most importantly, I described and analyzed the perceptions of respondents on whether the legitimacy norms and the accompanying performance indicators are effectively taken up in practice at TC 229, as well as their recommendations for improvement.

From the results of the survey some conclusions can be drawn. Firstly, the framework and the evaluative matrix developed in Chapter 3 proved to be useful tools to explain stakeholders' perceptions on whether the legitimacy norms and the accompanying performance indicators are taken up in practice effectively. Secondly, the empirical data from the survey emphasize that respondents are relatively satisfied with the legitimacy of TC 229. However, the survey results suggest that respondents perceive that the legitimacy norms and performance are taken up in practice to a different degree. This is indicated by the various scores they have on each norm and indicator. Overall, respondents seem to be more satisfied with the norm of *deliberative decision-making* (mean = 3.6) and *trustworthy expertise* (mean = 3.5), than with *effective process control* (mean = 3.3), *meaningful participation* (mean = 3.2) and *implementable outcomes* (mean = 3). Building upon the results of the Cronbach's alpha and Kendall's tau_b tests performed in this chapter, we have also learned that there may be a statistically significant relationship and a high level of internal consistency between the legitimacy norms that were used to construct the overall score on the legitimacy of TC 229. These are important findings given that in the current stream of research there is no clear assessment of the correlation between various legitimacy norms related to the legitimacy of technology related TPGAs. Furthermore, the results of the survey emphasize that the characteristic of stakeholders, such as the country of origin, organizational background, expertise or other interests, provide interesting explanations about the individual perceptions of respondents on the legitimacy of TC 229.

Considering the explorative approach of this research, in this chapter I have searched for different explanations of the results. In the responses of the surveyees a pattern was found suggesting that respondents coming from developed countries are more concerned with the problem-solving capacity and the benefits of the TC 229 deliverables, whereas LDCs with the decision-making processes guiding the development of nanotechnology standards. This was indicated by the lower mean scores of the respondents on these issues, as well as the written comments that some respondents made while answering the survey questionnaire. In this way, in a multi-stakeholder arrangement, such as TC 229, stakeholders have mixed perceptions when it comes to assessing how various norms and indicators are taken up in practice. All of which makes the legitimation of an arrangement difficult.

The results of the survey emphasize that respondents from LDCs, as well as those associated with underrepresented groups such as NGOs, trade unions and academia, seem to be generally less satisfied with the decision-making process due to their inability to support active involvement in the standardization processes (both at the national and international level), represent their interests and influence the content of standards. The main reasons for this seem to be the insufficient financial resources and local expertise that these actors have to support their involvement in the process. In addition, the responses of the surveyees seem to suggest that other issues impacting their influence to the process relate to language barriers, as well as the technical expertise of respondents on nanotechnology standardization issues and ISO process. The way stakeholders are categorized in the ISO (i.e. full and observatory members) presents also an important challenge for the access, awareness and control that stakeholders have in the standard-setting process.

In addition to the above mentioned issues relating to the decision-making process, the results of the survey also suggest that TC 229 is facing increasing expectations to demonstrate that it provides outcomes that are accepted or followed in practice and are considered beneficial by relevant stakeholders. TC 229 has managed so far to set several deliverables in the form of standards, and mostly in the form technical reports and specifications. Compliance with TC 229 standards is very low. Some of the explanatory reasons for noncompliance with TC 229 standards are the short life span, as well as the lack of financial resources and technical understanding of these deliverables. The responses of the surveyees suggest that the production of many deliverables in the form of specifications and reports is mainly due to the lack of sufficient scientific knowledge and certainty on relevant nanotechnology issues. These issues are found to be similarly important for the scientific validity and the robustness of the evidence guiding the development of nanotechnology standards. However, even though respondents of both developed countries and LDCs indicate low compliance with TC 229 standards, an interesting finding is that actors that have been more active in participating and influencing the standard-setting process appear more concerned with the problem solving capacity and benefits of the standards. These actors come mainly from developed countries and indicate involvement in the manufacturing of products containing nanotechnology as well as in using nanotechnology artifacts in the manufacturing process. In this way, besides low compliance with nanotechnology standards, it seems that the weaknesses of TC 229 deliverables with regards to solving particular issues at global level (such as facilitate global trade, enable risk and regulatory analysis, reduce scientific uncertainties) and benefiting the interests of relevant stakeholders, can also be attributed to the nature of the deliverables produced by TC 229, the background and activities of respondents, as well as their experience with TC 229 deliverables.

In Chapter 5 of this thesis I have also reflected on the recommendations provided by stakeholders on how to enhance the legitimacy of TC 229. According to stakeholders the setting of international standards is a multilevel process, which requires both national and international bodies to join efforts and contribute to providing legitimate standardization processes and outcomes in the field of nanotechnology. Stakeholders recommend specific actions for TC 229 to enhance *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes*. In sum, the recommendations in this chapter emphasize that the legitimation of a transnational private governance arrangement cannot be viewed as a stable condition, but as something volatile and requires that effective strategies are deployed by relevant arrangements to improve not only the quality of their decision-making processes, but also the quality of standardization outcomes.

Chapter 6

6. Conclusions

6.1. Introduction

In the last decade transnational private governance arrangements (TPGAs) have increased in prominence in the field of nanotechnologies by contributing to its regulatory governance, responsible development, as well as the introduction of nanotechnology based products to the market. These arrangements have led to new relationships and partnerships, shifting the attention from traditional state regulation to polycentric regulatory structures in which the government is not the sole source of decision-making authority. With these modes of regulatory governance, the formulation and the implementation of decisions is in the hands of non-state actors, who are not directly elected by the citizens to make decisions that may become (collectively or de facto) binding and impact the interests of the public and industry. This has led to many dilemmas on whether such non-state governance arrangements can be considered legitimate and on what principles their legitimacy can be measured. As discussed in the first Chapter of this thesis, the issue of legitimacy in the context of technology related TPGAs has attracted the attention of various scholars. However, in these studies no serious efforts are made to investigate the legitimacy of technology related TPGAs empirically or assess how stakeholders perceive the legitimacy of these arrangements in practice. This thesis is an attempt to address these issues.

In this thesis legitimacy is viewed as an empirical fact and is studied through the perceptions of stakeholders. The focus is on TC 229, one of the key TPGAs in the field of nanotechnologies. This thesis argues that TC 229 provides an ideal case study for the study of legitimacy since this arrangement departs from the state-based approaches and challenge the traditional principles for evaluating legitimacy (e.g. national sovereignty, constitutionality, democracy). Furthermore, it argues that judgements about the legitimacy of a TPGA, such as TC 229, have distinctive practical implications. By providing (amongst others) standards for terminology, measurement, characterization, EHS issues, as well as test methods for use at the nano scale, nanotechnology standards are meant to serve as tools for regulating technological innovation, satisfying a particular (technical, scientific or regulatory) need and/or filling a communication gap. However, given that nanotechnology international standards are developing at a stage when the technology has not achieved it maturity yet and the potential for these standards to set the “framework in regulation and market”, the issue of legitimacy takes on an additional importance. The thesis argues that in such a controversial, competitive and challenging regulatory and scientific environment in which nanotechnologies are developing, TC 229 can only thrive if it is viewed and accepted as legitimate by relevant stakeholders.

In the remainder of this chapter, I provide a response to the main research question, and discuss the main findings and contributions that are made in this thesis by analyzing each sub-research question (Section 6.2). In addition, I emphasize how these findings contribute to answering the primary research question. Afterwards I reflect on the limitations of the study (Section 6.3) and conclude with some proposals for future research (Section 6.4).

6.2. Main Findings and Contributions

The main research question posed at the beginning of this thesis was: *How can the legitimacy of transnational private governance arrangements related to nanotechnologies be described, evaluated and enhanced in practice?* As elaborated in the body of the thesis, the legitimacy of technology related governance arrangements in practice can be understood when stakeholders come to assess different aspects of a governance arrangement that relate to its decision-making process, expertise and outcomes. In particular, when stakeholders assess the ability of a governance arrangement to provide governance “by the people”, “with the people” and “of the people”. By using a detailed framework, which comprised of various legitimacy norms and performance indicators for determining the legitimacy of technology related TPGAs, this thesis argued that a comprehensive approach to legitimacy combined with the perceptions of stakeholders, enables us to provide not only concrete analysis around the legitimacy of an arrangement, but also recommendations for its improvement.

The main research question was approached by dividing it into four sub-research questions: *What are the current transnational governance arrangements for nanotechnologies and how can we assess their role in regulating this field? How can the legitimacy of transnational private governance arrangements related to nanotechnologies be conceptualized and operationalized? To what extent is international nanotechnology standardization perceived as legitimate by stakeholders*? *How can international nanotechnology standardization enhance its legitimacy?* In the following I discuss the main findings and contributions related to each sub-research question.

6.2.1. Sub-Research Question 1

The first step towards answering the primary research question was to analyze various transnational governance arrangements that have emerged in the field of nanotechnologies. This led to the first sub-research question - *What are the current transnational governance arrangements for nanotechnologies and how can we assess their role in regulating this field?* This question was addressed in Chapter 2, where a typology for understanding the main features and the role of nanotechnology transnational governance arrangements was introduced. The typology focused on six attributes according to which the role of transnational governance arrangements in the field of nanotechnologies was assessed on the basis of the *actors involved* in governance arrangements, their *functions*, *degree of institutionalization*, the *regulatory stages* in which governance arrangements contribute, as well as *the normative scope* and *the substantive depth* of transnational outcomes. Building upon the current debates of nanotechnology transnational governance, I focused on five arrangements: ISO/TC 229, OECD/WPMN, IFCS, IRGC and ICON.

By thoroughly reviewing and comparing these transnational governance arrangements, the main conclusion in Chapter 2 was that these arrangements contribute, to a varying degree, in the regulatory governance of nanotechnologies. More specifically, I observed that whereas all transnational governance arrangement have managed to establish a network of growing stakeholders, broaden their activities to include various functions and establish non-binding outcomes, the institutional structure as well as the normative scope of their outcomes are key factors for determining their role in regulating the field of nanotechnologies. In comparison to IFCS, ICON and IRGC, other governance arrangements, such as OECD/WPMN and ISO/TC 229 appear to be the most organized working groups with clear and formalized institutional structures. They have both organized frequent meetings for their members to share information and developed concrete roadmaps that describe future actions and strategies. In this way, these arrangements have been able to promote collaboration, contribute to nanotechnology regulatory agenda at transnational level, and establish various regulatory governance mechanisms in the form of standards, guidelines, technical specifications or reports.[109] Both of these arrangements have also ensured the political support of key actors in Europe (such as for example the

[109] This is not without precedent, whereas for example it is widely acknowledged that the OECD Chemicals Committee played a leading role in promoting harmonized chemical control policies through the system of the Mutual Acceptance Data (MAD). In addition, ISO and international standards in particular, have often been referenced as the most appropriate solutions for policy and technical issues, supporting therefore different sectors, such as medical devices, road vehicles, railways, food products etc (see Visser, 2007; ISO, 2007; OECD, 2010; Bell and Marrapese, 2011).

European Commission). Furthermore the outcomes of these arrangements (e.g. some of the TC 229 deliverables and OECD/WPMN recommendations) have already started to be accepted and implemented by relevant stakeholders.

However, the analyses on the normative scope of the deliverables provided by the five arrangements mentioned above, emphasize that some deliverables have a narrower scope focusing on certain products (e.g. the deliverables of OECD/WPMN focus mainly on human health and environmental safety implications of manufactured nanomaterials limited to the chemical sector), settings (e.g. the deliverables of ICON focus mainly on workplace) or activities (e.g. the deliverables of IRGC focus on risk governance). In comparison to these arrangements, TC 229 and its deliverables provide much more concrete and practical information, and cover a broader range of products, settings and activities. The deliverables of TC 229 go beyond environmental, health and safety issues. Building upon the comparative analysis of the five governance arrangements mentioned above, the Chapter concludes that TC 229 is in a better position, than other arrangements, to take a led on the regulatory governance of nanotechnologies.[110]

6.2.2. Sub-Research Question 2

The second sub-research question of this thesis is : *How can the legitimacy of transnational private governance arrangements related to nanotechnologies be conceptualized and operationalized?* This question was addressed in Chapter 3, where an analytical framework for conceptualizing the legitimacy of technology related TPGAs and a matrix for evaluating the legitimacy of these arrangements in practice was developed. To answer this sub-research question I explored the normative and empirical perspectives of legitimacy that have been discussed by a wide range of political, legal and sociological scholars. These scholars have commented on various attributes of “good governance”, which relate mainly to the governance “by the people” (i.e. input legitimacy), “with the people” (i.e. throughput legitimacy) and “of the people” (i.e. output legitimacy). However, the current stream of research on the legitimacy of

[110] As mentioned in Chapter 1, my main focus in this thesis has been to analyze the potential of initiatives or governance arrangements at transnational, with less focus on the initiatives undertaken at the state level to contribute to the regulatory governance of nanotechnology (e.g. FDA has published guidance on how regulated entities should consider nanomaterials in cosmetic and food applications). In 2007 the Environmental Defense Fund collaborated with the US Environmental Protection Agency to create a voluntary reporting program asking companies to provide information related to the potential toxic nanomaterials in commerce. In relation to new industrial nanomaterials several tentative responses have been observed in jurisdictions such as France and Australia, as well as California. France for instance has created a registry for nanomaterials in commerce, and similar action have been taken in Belgium, Denmark and Italy as well. The European Parliament and Council have adopted more wholesale approaches with the introduction of nano-specific provisions for cosmetics as part of the recast of the Cosmetic Regulation.

technology related TPGAs lacks a consistent and comprehensive approach for measuring the legitimacy of these arrangements in practice.

To complement the existing research, in this chapter an analytical framework was developed by reconceptualizing the concept of input, throughput and output legitimacy. In particular, the concept of input legitimacy was extended to include all legitimacy norms that guide the functioning of TPGAs and the setting of transnational rules. Building upon the work of Van Kersbergen and Van Waarden (2004), I refer to these norms as the "rules of the game", which provide the basis for the legitimacy of transnational governance arrangement and assist them to justify actions at transnational level. The concept of throughput legitimacy is used to emphasizes what goes on inside the governance arrangement - whether the "rules of the game" are taken up in practice. The concept of output legitimacy refers to compliance and stakeholder beliefs on the effectiveness of transnational outcomes.

In this way, I take a more comprehensive approach in the conceptualization of legitimacy by bringing together the "rules of the game" that guide the functioning of TPGAs and stakeholders' beliefs on how these rules function in practice. In this thesis legitimacy is viewed as a relational concept between stakeholders and governance arrangements. According to this framing, the legitimacy of a technology related TPGA is an empirical fact and is determined by stakeholders on the grounds that they believe that the legitimacy norms are taken up effectively in practice, perceive transnational outcomes to provide effective solutions and comply with them. With this definition of legitimacy I respond to the primary research question as to *how the legitimacy of TPGAs in nanotechnologies can be described in practice.*

In the absence of a theory that can be employed to help explain the evaluation of the legitimacy of technology related TPGAs in practice, in Chapter 3 a significant effort was made to:

- firstly, identify and operationalize the key legitimacy norms for the construction of the analytical framework;
- secondly, for each legitimacy norm certain performance indicators were defined, which provided a detailed explanation about the content of the norms and served as parameters for measuring compliance with them; and
- thirdly, to evaluate how these norms are taken up in practice an evaluative matrix was developed.

I the matrix, a Likert scale was used in which a value from 1 to 5 was assigned to each performance indicator. In this way, the overall rating of each legitimacy norm was determined by using the mean values of performance indicators. As explained in Chapter 4, the empirical application of this evaluative is considered important to provide detailed information on each legitimacy norm and analyze the perceptions of stakeholders in a consistent way. This framework and evaluative matrix drove also the construction of the survey questionnaire. These steps were very important and provided the basis for answering the primary research question as to *how the legitimacy of TPGAs can be evaluated in practice.*

6.2.3. Sub-Research Question 3 & 4

In Chapter 5 of this thesis I addressed two sub-research questions. These questions were: *To what extent is international nanotechnology standardization perceived as legitimate by stakeholders* (sub-research question 3), and *How can international nanotechnology standardization enhance its legitimacy?* (sub-research question 4). These questions were addressed by empirically investigating, for the first time, the perceptions of stakeholders on the legitimacy of TC 229. The findings in Chapter 5 emphasize not only the responses of stakeholders on whether the norms of legitimacy and performance indicators are taken up effectively at TC 229, but also prove that the analytical framework and the evaluative matrix developed in this thesis (see Chapter 3) are useful mechanisms for evaluating the legitimacy of technology related TPGAs in practice. Furthermore, these findings are crucial for answering the primary question, because they suggest that the perceptions of stakeholders can play an important role in determining the legitimacy of TPGAs. Stakeholders bring forward practical information on how the legitimacy norms are taken up in practice and provide recommendations for improvement.

To answer the sub-research questions mentioned above, in Chapter 5 of this thesis I described and analyzed the perceptions of respondents on whether the legitimacy norms and the accompanying performance indicators are effectively taken up in practice at TC 229. To calculate the perceptions of stakeholders on legitimacy norms I used the mean values of each performance indicator. Taking into account the explorative approach of this research, in this chapter I have searched for different explanations of the results. In particular, while discussing the perceptions of respondents on the performance of TC 229, I have also explored how other factors, such as the respondents' country of origin, backgrounds, expertise and other interests, impact the individual perceptions of respondents. The chapter also reflected on the main recommendations provided by respondents to enhance the legitimacy of TC 229.

The results of the survey emphasized that respondents seemed to be relatively satisfied with the legitimacy of TC 229. However, the responses provided on each performance indicator emphasize that the perceptions of respondents on how these indicators are taken up in practice are mixed. The characteristics of the survey respondents suggest that respondents from developed countries (who have been generally more active in the decision-making process) appeared to be more concerned with the benefits and problem-solving capacity of standardization outcomes. Respondents from less developed countries (LDCs) (who have been less involved in the setting of TC 229 standards) appeared more concerned with decision-making processes guiding the development of nanotechnology standards. Evidence from the survey responses, suggests that experts participating in the WGs of the TC 229 are highly knowledgeable and experienced on issues related to nanotechnologies. Respondents indicated that the development of nanotechnology standards is open to a wide range of experts coming from the private sector (including consulting and testing companies), industrial research centers, laboratories, metrology institutes, governmental and regulatory agencies, academia and civil society organizations. However, in the WGs there was observed a domination of the respondents coming from developed countries and associated with industry, research and metrology institutes, laboratories and governmental agencies. The majority of these respondents were chemists, physicists, toxicologists and material scientists by background. Some explanations for the domination of these actors seemed to be the powerful resources they had to afford their active involvement in TC 229 and mobilize the scientific data to contribute to nanotechnology standardization.

The responses of the surveyees emphasized that not all stakeholders were well-equipped to participate in TC 229 process. Overall, respondents from LDCs were more likely to be absent in the TC 229 meetings, because of the lack of the financial resources and local expertise. The lack of inclusiveness seems also to have impacted the perceptions of respondents on the deliberativeness of the decision-making process. Respondents of underrepresented groups, such as NGOs, trade unions, academia, and LDCs appeared to be less satisfied with the influence they have made to the content of the standards. They were represented by smaller delegations and have been less successful in establishing powerful resources and networks to influence the content of standards. The institutional structure of the ISO process, which grants access and voting rights only to members who pay their own membership fees, is also another explanation of why some respondents feel less included in the process. This “pay-to-play” requirement has also ensured that the community to which TC 229 is accountable remains smaller than it would otherwise be.

The unequal input and representation of respondents has consequently generated debates about the nature of outcomes produced by the Committee. Several respondents found it difficult to work for a consensus decision in TC 229, partially because of the language barriers and the diversity of background amongst participants, but also because of the uncertainties that accompany the field of nanotechnologies. Speaking of uncertainties, many respondents perceived the evolving environment in which nanotechnology is developing, as well as the uncertainties related to the identification, characterization and measurement of nanomaterials, as the main challenging factors that impact the scientific validity and robustness of evidence guiding the development of standards. However, it should be noted that the perceptions of respondents appeared to be influenced by their own understanding and expertise on the technicalities of field as well as the ISO process itself. Respondents having an active involvement in the process and advanced technical expertise on nanotechnology standardization issues, appeared more satisfied with scientific validity and robustness.

The responses of the surveyees on standardization outcomes provided many insights on how TC 229 deliverables are accepted and perceived in practice. The results of the survey emphasized that besides the concerns that respondents form LDCs, NGOs, trade unions and regulatory agencies had on influencing the development of nanotechnology standards, they seemed more satisfied with the TC 229 deliverables as compared to other respondents. In the view of these respondents TC 229 standards are beneficial and effective in solving various issues at global level, such as facilitating trade, enabling risk and regulatory analysis, and reducing scientific uncertainties. Therefore, it seems that TC 229 has been relatively successful in meeting the needs of underrepresented stakeholders.

The survey responses seem to suggest also that the higher inclusiveness and participation in the decision-making process, did not lead respondents from developed countries to perceive TC 229 outcomes more beneficial and effective in solving various issues at global level. In fact, respondents from developed countries, associated with industry, research institutes and governmental agencies, appeared to be generally more concerned with the benefits and problem-solving capacity of TC 229 standards. The weaknesses of the TC 229 standards with regards to these points seemed to be attributed partially to the fact that the majority of these deliverables were not followed in practice (which often creates difficulties to determine the extent to which TC 229 standards are beneficial and contribute to solving various issues at global level), but also to the nature of the deliverables produced by the Committee and the experience of respondents with these deliverables.

At the practical level the responses of stakeholders seem to justify that for a governance arrangement to be perceived legitimate both its processes and outcomes are crucial. It is clear from this research that the participation gap, as well as the challenges to access, control and influence the decision-making process, and benefit from TC 229 deliverables, are likely to have important implications for the perceptions of stakeholders on the legitimacy of TC 229.

Respondents provided specific recommendations for TC 229 to enhance *meaningful participation*, *deliberative decision-making*, *effective process control*, *trustworthy expertise* and *implementable outcomes*. Whereas these recommendations are discussed in more details in Chapter 5, in general respondents recommend TC 229 to collaborate with NSBs in recruiting the participation of underrepresented stakeholder groups to ensure the engagement and representation of actors throughout the process; improve the quality of decision-making process by turning it into an open, fair and participatory process; take appropriate measures to enhance the quality of scientific evidence in which decisions are based; and facilitate compliance with its deliverables. As such these recommendations are of importance for answering the primary question *as to how the legitimacy of nanotechnology related TPGAs can be enhanced in practice.*

How these findings and recommendations will be taken up by TC 229 it depends on the Committee itself. It may be possible that TC 229 or ISO will want to make some improvements as a result. Given that this thesis provides analysis of several performance indicators responding to legitimacy norms, there may be possibilities for this Committee to take either minimal actions and improve its performance at the indicator level (e.g. on *compliance, resources*, *external accountability* where the scores are lower), or take major actions and improve its performance on a set of legitimacy norms (e.g. on *implementable outcomes*, *meaningful participation* or *effective process control* where the scores are lower). In either case, the recommendations of stakeholders are of particular interest. Their practical implication rests on the fact that they reflect the perceptions of key experts in the field and can serve as a guidance for standardization bodies and also for policy makers and other transnational governance arrangements (with similar institutional structure and functions) on how to enhance the legitimacy of their processes and outcomes.

6. 3. Limitations of the Study

As already mentioned in Chapter 5 of this thesis, there are a number of limitations in this study. First, generalizability is limited in this study because of the size of the survey sample. For this study I contacted stakeholders from 28 (out of 35) ISO member countries. However, I received responses from representatives of 20 member countries.[111] Nine member countries did not reply and for the rest of the member countries (i.e. 6 members) key actors could not be identified. Initially I sent 136 invitations and received 76 complete responses. In this way, the response rate (56%) is relatively high and sufficient for the empirical validation of the legitimacy framework

[111] In particular responses were received from representatives of 14 developed countries and of 6 less developed countries. A limited number of responses (n = 3) was also received from respondents of Liaison Organizations.

that I have developed and for supporting the conclusions of this study. However, these responses cannot be easily generalized for the whole population of the ISO members.

Second, in this study the data were collected mainly through the use of a self-administered survey. The online survey method in the present study was chosen for practical reasons. Since my main objective was to examine the extent to which the legitimacy norms and performance indicators are taken up at TC 229, I concluded that surveys offered more precise answers on this front. They are cost-effective, convenient for respondents and provide an opportunity for measuring the perceptions of stakeholders empirically. However, the disadvantage here is that it is difficult to see what may have been the reasons that have influenced respondents to evaluate certain norms or indicators lower or higher than the others. In this study, I have already made some attempts to provide answers on this front by analyzing the written comments provided by the surveyed respondents, and by exploring the extent to which the characteristics of respondents, such as their country of origin, organizational association, expertise and other interests, influenced their perceptions of legitimacy. However, further research could also address this issue by supplementing the survey results of this study with in-depth interviews with various members of TC 229.

6.4. Ideas for Future Research

This section reflects on some ideas that are interesting for future research. To begin with, a potential arena for further research would be to apply the analytical framework and the evaluative matrix developed in this study to other standard development organizations. Prior to establishing TC 229, nanotechnology standardization has attracted the attention of other standardization bodies operating at national and European level. For example, in early 2000s China made the first standardization efforts at national level by establishing the United Working Group for Nanomaterials Standardization. Similar efforts were taken in UK (i.e. through the establishment of the British Standards Institute Committee for Nanotechnologies (BSI - NTI/1)), US (i.e. through the establishment of the American National Standards Institute's - Nanotechnology Standards Panel (ANSI-NSP)) and Japan (i.e. through the establishment of the study group for nanotechnology standardization (see also Murashov and Howard, 2012; Forsberg, 2010). The first nanotechnology standardization efforts at the European level were made in 2005 with the establishment of the European Committee for Standardization Nanotechnologies (CEN/ TC 352). Therefore, future research could conduct comparative analysis on these standardization activities and explore how stakeholders perceive the legitimacy of these arrangements in practice. Such analysis could also provide useful information on whether standardization bodies at the national or European level are perceived by stakeholders more or less legitimate than ISO.

A potential future work could also be to see whether the support that other nanotechnology transnational governance arrangements enjoy from stakeholders can be ascribed to similar attributes (i.e. legitimacy norms and performance indicators) as those identified in the case of TC 229. An example that could be included here is the case of OECD/WPMN. Similar to TC 229, OECD/WPMN has also an important role in the transnational debates of nanotechnology governance - it is highly institutionalized and is engaged in various nanotechnology activities. However, as an intergovernmental forum OECD/WPMN is different from TC 229 in terms of its membership, organizational structure and decision-making processes. In this way, the case of OECD/WPMN could provide valuable insights on how the characteristics of a governance arrangement impact its legitimacy. More specifically, this case could provide insights on the legitimacy norms and/or performance indicators that contribute mostly to the legitimacy of this intergovernmental forum. These findings could also contribute to the refinement of the legitimacy framework developed in this thesis, by adding or removing attributes that may impact the overall score of legitimacy.

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Appendices

Appendix 1.

SURVEY QUESTIONNAIRE

ISO/TC229 and Key Stakeholder Survey Questionnaire

Letter of Invitation

Dear

I hope that this email finds you well. I am writing to you in the context of my PhD research. In my research I analyze the role of transnational private governance arrangements in the field of nanotechnology. ISO/TC229 is my case study.

Given your experience with nanotechnology standardisation, I want to invite you to participate in an online survey. The aim of this survey is to examine how different actors (e.g. participants/members of TC229) are engaged in the development of nanotechnology standards and what are their perceptions/impressions in regards to the process of developing these standards.

The survey should not take more than 15 -20 minutes to complete and most of the questions are multiple-choice. Your answers to this survey will be treated as confidential and no access will be granted to individual answers. The collected data will be de-identified and only aggregate data will be published.

I would really appreciate if you could spend just a few minutes filling out the survey.

The link to the survey is:
https://surveys-igs.utwente.nl/index.php?r=survey/index/sid/82139/token/dx375qvd7e3qna2/lang/en

Thank you in advance for your interest in this study,

Best Regards,
Evisa Kica

University of Twente
Faculty of Management and Governance
Building Ravelijn : RA 4266
PO Box 217, NL -7500 AE Enschede

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

Thank you for your interest to participate in this anonymous online survey!
The survey should not take more than 15-20 minutes to complete and most of the questions are multiple-choice.

The aim of this study is to provide a broader understanding of the development of international standards in the field of nanotechnologies and to examine how the members of the TC229 are engaged in these standardisation processes.

The results of this survey are intended to provide recommendations to help ISO TC229 provide for effective standardisation outcomes that result from the inclusion of various stakeholders, as well as from qualitative decision-making processes and scientifically robust evidence.

The study is being conducted by Evisa Kica (PhD Candidate) and supervised by Dr. Bärbel Dorbeck-Jung (Professor of Regulation and Technology) and Dr. Ramses A. Wessel (Professor of the Law of the European Union and other International Organizations) at the University of Twente.

The survey is comprised of 6 sections, these are:

- General Information about your background;
- Information about the participation in the standardisation process;
- Information about the decision-making processes over the ISO TC229 standards;
- Information about the transparency and accountability within the standardisation processes;
- Information about scientific robustness and expertise;
- Information about the standardisation outcomes of the ISO TC229.

Your answers to this survey will be treated as confidential. Answers will be used exclusively for this study. The collected data will be de-identified and only aggregate data will be published. No access will be granted to individual answers. Only researchers involved in this study will have access to the data.

To thank you for your participation, we would be happy to send you a summary of the key findings of this study once it is completed. Please check "Yes" on the last question and the summary of the key findings will be sent to you.

Please direct any questions or complaints arising from completing this survey to :

Evisa Kica
University of Twente
Faculty of Management and Governance
Building Ravelijn : RA 4266
PO Box 217, NL -7500 AE Enschede
Email: e.kica@utwente.nl
Telephone: + 31 53 489 5482.

Thank you again for your interest in this study and for taking the time to complete the survey.

Please click on the "Next" button to enter the online questionnaire.

Exit and clear survey | Load unfinished survey | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0%
100%

General Information

* Please indicate your country:

* Please choose your area of expertise:

- Pharmacology
- Materials science
- Biology
- Physics
- Chemistry
- Medicine
- Toxicology
- Occupational safety and health
- Environmental safety
- Consumer and societal dimensions
- Other:

Please indicate your level of technical expertise in the international standardisation work for nanotechnologies?

- Awareness
- Basic
- Intermediate
- Advanced
- Specialist

* Type of the organisation you are associated with?

- Industrial Organization
- Research Institute
- Academia/University
- Government
- NGO
- Regulator
- Trade Association
- Trade Union Organisation
- Other:

* How many employees work in your organisation?

- < 100
- 100 - 999
- 1000 - 2500
- 2501 - 5000
- 5001 - 10,000
- > 10,000

Which of the following options describes best the activities of your organization related to nanotechnology (NT)?

- A manufacturer of NT artifacts (e.g. nanopowders, nanotubes, nanofibres, thin films, etc).
- A distributor or supplier of NT artifacts manufactured by others.
- A manufacturer of products containing NT artifacts (e.g. particle loaded materials or goods).
- A user of NT artifacts in any manufacturing process or product (e.g. catalysts).
- Engaged in research directed at NT or nanoscale products/processes.
- Engaged in regulatory issues directed at NT related products or processes.
- Engaged in the analysis or characterisation of components or products at the nanoscale either for yourself or as a service to others.
- Engaged in safety issues related to NT developments (e.g. engaged to promote consumers' health and interests, occupational and environmental safety).
- Engaged in academic research related to NT.
- Other:

Exit and clear survey | Resume later | Previous | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0% 100%

Participation in ISO TC229

Have you previously participated in any ISO Technical Committee other than TC229?

- Yes
- No

How many ISO TC229 meetings have you attended?

- 1 - 4 meetings
- 5 - 8 meetings
- 9 - 13 meetings

In which ISO TC229 Working Group(s) and Task Group(s) have you participated?

- ISO TC229 JWG1 on Terminology and Nomenclature
- ISO TC229 JWG2 on Measurement and Characterization
- ISO TC229 WG3 on Health, Safety and Environmental Aspects
- ISO TC229 WG4 on Material Specifications
- ISO TC229 TG2 on Consumer and Societal Dimensions
- ISO TC229 TG3 on Nanotechnologies and Sustainability

To what extent do you feel that you have been able to actively participate in the nanotechnology standardisation activities of your National Standardisation Body?

- Very Low
- Low
- Medium
- High
- Very High

To what extent you think that ISO TC229 is committed to ensure the representation of a wide range of stakeholders in the standardisation processes?

- Very Low
- Low
- Medium
- High
- Very High

What level of resources (i.e. financial support to cover specific costs; technical assistance and other) does your National Standardisation Body provide for you to participate in the ISO TC229 activities?

- Very Low
- Low
- Medium
- High
- Very High

What do you consider to be a barrier (if any) for your organisation to participate actively in the National Standardisation Body?

	No Barrier	A minor Barrier	A moderate Barrier	A major Barrier
Lack of financial resources	○	○	○	○
Lack of awareness and availability of information about standardisation	○	○	○	○
Lack of technical understanding of nanotechnologies	○	○	○	○
Lack of human resources	○	○	○	○
Lack of time	○	○	○	○

Please provide any recommendation that you feel would enhance the inclusion of a wide range of stakeholders in the international standardisation activities?

Exit and clear survey | Resume later | Previous | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0% 100%

Decision making over ISO TC229 standards

To what extent do you consider ISO TC229 decision-making processes to provide fair opportunities for all participants to influence the contents of the standards?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you consider the making of the standardisation agreements in ISO TC229 to be considerative and respectful of the participants' perspectives and interests?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you consider the making of the standardisation agreements in ISO TC229 to be based on careful analytical evaluations?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that agreements on ISO TC229 standards are based on effective exchange of arguments amongst participants?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that ISO TC229 successfully manages to settle disputes amongst participants?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

Please provide any recommendation that you feel will help ISO TC229 to make its decision-making processes more deliberative?

Exit and clear survey | Resume later | ‹ Previous | Next ›

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0%
100%

Transparency and Accountability

To what extent have you been able to access and obtain information about the technical discussions and decisions of the ISO TC229?

- Very Low
- Low
- Medium
- High
- Very High

To what extent do you consider ISO TC229 to be accountable to all interested parties about its performance and decision-making processes?

- Very Low
- Low
- Medium
- High
- Very High
- Other:

To what extent do you think that parties who are not formally involved in the decision-making processes have appropriate opportunities to hold ISO TC229 accountable for the decisions made?

- Very Low
- Low
- Medium
- High
- Very High
- Other:

To what extent do you think that your National Standardisation Body successfully manages to hold its delegates accountable for their actions at the ISO TC229 standardisation processes?

- Very Low
- Low
- Medium
- High
- Very High
- Other:

Do you engage in 'peer' accountability with other negotiation partners about your actions at standardisation processes?

- Yes, at the domestic level
- Yes, at the international level
- No engagement in 'peer' accountability

Can you specify to whom you are accountable for your actions at the ISO TC229?

- To my Organisation
- To the National Standardisation Body
- To ISO TC229
- To other peers
- None of the aforementioned
- Other:

Can you identify any accountability mechanism that your National Standardisation Body uses to hold its delegates accountable?

Please provide any recommendations that you feel will assist ISO TC229 in enhancing its transparency and accountability to its members and/or other external stakeholders?

Exit and clear survey | Resume later | Previous | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0%
100%

Scientific Robustness and Expertise

To what extent do you think that nanotechnology standardisation decisions in the ISO TC229 are based on expert knowledge?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that nanotechnology standardisation decisions in the ISO TC229 are based on robust evidence?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that nanotechnology standardisation decisions in the ISO TC229 are based on scientifically verified results?

○ Very low ○ Low ○ Medium ○ High ○ Very High

To what extent do you believe that the presentation and the appraisal of scientific information in the ISO TC229 are independent from the individual /business /or political interests of the participants?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that ISO TC229 is equipped to ensure that experts present unbiased scientifically driven views?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

Please provide any recommendation that you feel will enhance the ability of ISO TC229 to provide for scientifically robust outcomes?

Exit and clear survey | Resume later | Previous | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0%
100%

ISO TC229 Outcomes

Can you specify what standards your organisation needs in its current nanotechnology sector?

	Not needed	Somehow needed	Most needed
Terminology/Definition	○	○	○
Classification/Characterization	○	○	○
Toxicity testing	○	○	○
Measurement/Calibration	○	○	○
Code of practice	○	○	○
Safe handling of nanomaterials	○	○	○
Disposal/Environmental risks	○	○	○
Materials specification	○	○	○
Risk analysis/Evaluation	○	○	○

To what extent do you think that ISO TC229 standards are beneficial for your organisation?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you think that other ISO TC229 deliverables (such as technical reports, technical recommendations) are beneficial for your organisation?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

To what extent do you find the current ISO TC229 standards to be clearly drafted and understandable?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

Is your organisation compliant with any ISO TC229 nanotechnology standard?

○ Yes ○ No ○ Not Applicable ○ Don't know

To what extent do you think that the technical, financial and human resources of your organisation are sufficient to ensure compliance with ISO TC229 standards?

○ Very Low ○ Low ○ Medium ○ High ○ Very High

Are you aware of any regulatory or market-based policies that require the implementation and/or certification of any specific ISO TC229 standard?

○ Yes ○ No

What is your general assessment regarding the global impact of the ISO TC229 standards or other deliverables in relation to:

	Very Low	Low	Medium	High	Very High
Reducing scientific uncertainties with regards to nanoproducts and processes	○	○	○	○	○
Facilitating global trade	○	○	○	○	○
Enabling risk analysis and regulatory decision-making with regards to nanoproducts	○	○	○	○	○

Please rate the following criteria according to their level of importance for the ISO TC229 standardisation processes?

	Not important	Somehow important	Very important
Participation	○	○	○
Transparency	○	○	○
Accountability	○	○	○
Deliberative Decision-Making	○	○	○
Impartiality and Consensus	○	○	○
Scientific Knowledge and Expertise	○	○	○
Implementable Standardisation Outcomes	○	○	○
Other	○	○	○

Please specify if 'Other':

Would you like a one-page summary of the survey results?

○ Yes ○ No

Exit and clear survey | Resume later | Previous | Next

LimeSurvey

ISO TC229 and Key Stakeholder Survey Questionnaire

0% 100%

Evaluation of the survey questionnaire

Do you want to provide feedback about the survey questionnaire?

● Yes ○ No

Was each question in the survey clear and understandable?

○ Yes ○ No

Did the cover letter motivate you to participate in the survey?

○ Yes ○ No

What is your general impression about the survey?

How long did it take you to complete the survey?

Please provide any recommendation that you feel will help us to improve this survey questionnaire?

Exit and clear survey | Resume later | Previous | Submit

Appendix 2.

INTERVIEW QUESTIONNAIRE

Genesis of ISO/TC 229, the role of international nanotechnology standards in the governance of nanotechnology and principles of "good governance".

	Questions	Response
Part 1 - Historical background: Standardization and its role to nanotechnology governance		
1.	What was the genesis of ISO/TC229 and its driving forces?	
2.	What would you consider were the main factors behind the creation of this committee?	
3.	Were there any particular parties who were key to its creation?	
4.	What would you consider today as the main changes AND achievements within ISO/ TC229 standardization committee and its procedures?	
5.	Based on your experience with ISO/TC229, what is the role of the current standards in the governance and regulation of nanotechnology?	
6.	Which issues do you think are of the greatest priority for international nanotechnology standardization ?	
7.	In your view, how important is the establishment of health and safety nanotechnology standards and which issues are of priority?	
8.	Can you identify some (key) actors within ISO/TC229 standardization process and/or working groups?	
Part 2 - Nanotechnology standardization process		
9.	What would you consider as the main challenges/difficulties in the development of international nanotechnology standards?	
10.	Do you consider nanotechnology standardization to be different as compared to other fields?	
11.	What mechanisms ISO/TC229 have or should undertake to respond to health, environmental and safety issues?	

12.	To what extent the development of international nanotechnology standards (e.g. health & safety standards) has created the need for amending the standardization policies and procedures (both at the national and international level)?	
Part 3 - Principles of "Good Governance" and nanotechnology standardization		
13.	To what extent do you think that the legitimacy of international nanotechnology standardization is important?	
14.	Can you identify some (key) strategies that ISO/TC229 takes to comply with the principles of good governance (e.g. inclusiveness, openness, participation, accountability, etc)?	
15.	What would you consider the main principles that impact the meaningful participation of various actors in the work of SDOs (in particular of ISO/TC229)? • Participation • Resources • Expertise • Awareness • Other?	
16.	To what extent should the responsibility for ensuring adequate participation in the standardization process be shifted at the national level?	
17.	Have you observed a different level of influence in the initiation, development and adoption of standards between the public and private actors?	
18.	In your view is there something missing within ISO standardization policy to help create wide industry consensus on nanotechnology standards?	
19.	How the outcomes of ISO/TC229 (e.g. ISO/TR 12885) are taken up in practice by relevant actors (e.g. regulatory authorities, industry, manufacturers, etc)?	
20.	What would be your recommendation(s) for further improvement of the international standardization policies and processes?	

Part 4 - ISO and other organizations operating at the transnational level		
21.	In your opinion, on which standardization issues and with which organizations ISO/TC 229 should foster its collaboration?	
22.	What is your opinion in relation to the role of the OECD on health and safety issues? Do you see an overlap between the OECD/WPMN operations and ISO/TC229 WG3?	
23.	How is OECD/WPMN is contributing to the governance of nanotechnology?	
24.	Can you recommend us other documents and contact persons that might be useful for our research?	

Appendix 3

Level of Expertise and Inclusiveness - Kendall tau_b Correlations

		Level of Expertise	Participate actively in the NSBs
Level of Expertise	Correlation Coefficient	1,000	**,478****
	Sig. (2-tailed)	.	**,000**
	N	76	75
Participate actively in the NSBs	Correlation Coefficient	**,478****	1,000
	Sig. (2-tailed)	**,000**	.
	N	75	75

Appendix 4

Size of the Company and Inclusiveness - Kendall tau_b Correlations

		Participate actively in the NSBs	Size of the company
Participate actively in the NSBs	Correlation Coefficient	1,000	**,245***
	Sig. (2-tailed)	.	**,001**
	N	75	75
Size of the company	Correlation Coefficient	**,245***	1,000
	Sig. (2-tailed)	**,001**	.
	N	75	76

Appendix 5

Communicative Agreements and Attending TC 229 meetings - Kendall tau_b Correlations

		Communicative agreements	Attending ISO/TC229 meetings
Communicative agreements	Correlation Coefficient	1,000	**,378****
	Sig. (2-tailed)	.	**,000**
	N	74	74
Attending ISO/TC229 meetings	Correlation Coefficient	**,378****	1,000
	Sig. (2-tailed)	**,000**	.
	N	74	76

Appendix 6

Communicative Agreements and Level of Expertise - Kendall tau_b Correlations

		Communicative agreements	Level of Expertise
Communicative agreements	Correlation Coefficient	1,000	**,166**
	Sig. (2-tailed)	.	**,107**
	N	74	74
Level of Expertise	Correlation Coefficient	**,166**	1,000
	Sig. (2-tailed)	**,107**	.
	N	74	76

Appendix 7

Competent Expertise and Level of Expertise - Kendall tau_b Correlations

		Level of Expertise	Competent expertise
Level of Expertise	Correlation Coefficient	1,000	**,108**
	Sig. (2-tailed)	.	**,299**
	N	76	75
Competent expertise	Correlation Coefficient	**,108**	1,000
	Sig. (2-tailed)	**,299**	.
	N	75	75

Appendix 8

Competent Expertise and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Competent expertise	Attending ISOTC229 meetings
Competent expertise	Correlation Coefficient	1,000	**,147**
	Sig. (2-tailed)	.	**,162**
	N	75	75
Attending ISOTC229 meetings	Correlation Coefficient	**,147**	1,000
	Sig. (2-tailed)	**,162**	.
	N	75	76

Appendix 9

Scientific Validity and the Level of Technical Expertise - Kendall tau_b Correlations

		Level of Expertise	Scientific validity
Level of Expertise	Correlation Coefficient	1,000	**,247***
	Sig. (2-tailed)	.	**,006**
	N	76	74
Scientific validity	Correlation Coefficient	**,247***	1,000
	Sig. (2-tailed)	**,006**	.
	N	74	74

Appendix 10

Scientific Validity and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Scientific validity	Attending ISOTC229 meetings
Scientific validity	Correlation Coefficient	1,000	**,285****
	Sig. (2-tailed)	.	**,006**
	N	74	74
Attending ISOTC229 meetings	Correlation Coefficient	**,285****	1,000
	Sig. (2-tailed)	**,006**	.
	N	74	76

Appendix 11

Robustness and Level of Expertise - Kendall tau_b Correlations

		Robustness	Level of Expertise
Robustness	Correlation Coefficient	1,000	**,272****
	Sig. (2-tailed)	.	**,008**
	N	75	75
Level of Expertise	Correlation Coefficient	**,272****	1,000
	Sig. (2-tailed)	**,008**	.
	N	75	76

Appendix 12

Robustness and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Robustness	Attending ISOTC229 meetings
Robustness	Correlation Coefficient	1,000	**,304****
	Sig. (2-tailed)	.	**,004**
	N	75	75
Attending ISOTC229 meetings	Correlation Coefficient	**,304****	1,000
	Sig. (2-tailed)	**,004**	.
	N	75	76

Appendix 13

Objective Judgements and Level of Expertise - Kendall tau_b Correlations

		Objective judgements	Level of Expertise
Objective judgements	Correlation Coefficient	1,000	**,370****
	Sig. (2-tailed)	.	**,000**
	N	74	74
Level of Expertise	Correlation Coefficient	**,370****	1,000
	Sig. (2-tailed)	**,000**	.
	N	74	76

Appendix 14

Objective Judgements and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Attending ISOTC229 meetings	Objective judgements
Attending ISOTC229 meetings	Correlation Coefficient	1,000	,231*
	Sig. (2-tailed)	.	,025
	N	76	74
Objective judgements	Correlation Coefficient	,231*	1,000
	Sig. (2-tailed)	,025	.
	N	74	74

Appendix 15

Ruleclarity and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Ruleclarity	Attending ISOTC229 meetings
Ruleclarity	Correlation Coefficient	1,000	**,279****
	Sig. (2-tailed)	.	**,000**
	N	71	71
Attending ISOTC229 meetings	Correlation Coefficient	**,279****	1,000
	Sig. (2-tailed)	**,000**	.
	N	71	76

Appendix 16

Facilitate Global Trade and Attending ISO/TC 229 meetings - Kendall tau_b Correlations

		Attending ISOTC229 meetings	Facilitating global trade
Attending ISOTC229 meetings	Correlation Coefficient	1,000	**-,008**
	Sig. (2-tailed)	.	**,134**
	N	76	73
Facilitating global trade	Correlation Coefficient	**-,008**	1,000
	Sig. (2-tailed)	**,134**	**.**
	N	73	73

Appendix 17

Enable Risk Analysis and Level of Expertise - Kendall tau_b Correlations

		Enabling risk analysis	Level of Expertise
Enabling risk analysis	Correlation Coefficient	1,000	,153
	Sig. (2-tailed)	.	**,131**
	N	73	**73**
Level of Expertise	Correlation Coefficient	**,153**	1,000
	Sig. (2-tailed)	**,131**	.
	N	73	76

Appendix 18

Enable Risk Analysis and Attending TC 229 meetings- Kendall tau_b Correlations

		Attending ISOTC229 meetings	Enabling risk analysis
Attending ISOTC229 meetings	Correlation Coefficient	1,000	**,024**
	Sig. (2-tailed)	.	**,814**
	N	76	73
Enabling risk analysis	Correlation Coefficient	**,024**	1,000
	Sig. (2-tailed)	**,814**	.
	N	73	73

Appendix 19

Reduce Scientific Uncertainties and Level of Expertise - Kendall tau_b Correlations

		Reduce scientific uncertainties	Level of Expertise
Reduce scientific uncertainties	Correlation Coefficient	1,000	**,189**
	Sig. (2-tailed)	.	**,062**
	N	73	73
Level of Expertise	Correlation Coefficient	**,189**	1,000
	Sig. (2-tailed)	**,062**	.
	N	73	76

Appendix 20

Reduce Scientific Uncertainties and Attending ISO/TC229 meetings- Kendall tau_b Correlations

		Attending ISOTC229 meetings	Reducing scientific uncertainties
Attending ISOTC229 meetings	Correlation Coefficient	1,000	,209*
	Sig. (2-tailed)	.	,040
	N	76	73
Reducing scientific uncertainties	Correlation Coefficient	,209*	1,000
	Sig. (2-tailed)	,040	.
	N	73	73

Appendix 21

Rule Benefits Standards and Inclusiveness - Kendall tau_b Correlations

		Rule benefits Standards	Participate actively in the NSBs
Rule benefits Standards	Correlation Coefficient	1,000	**,291****
	Sig. (2-tailed)	.	**,004**
	N	75	74
Participate actively in the NSBs	Correlation Coefficient	**,291****	1,000
	Sig. (2-tailed)	**,004**	.
	N	74	75

Appendix 22

Rule Benefits Standards and Inclusiveness - Kendall tau_b Correlations

		Participate actively in the NSBs	Rule benefits other deliverables
Participate actively in the NSBs	Correlation Coefficient	1,000	**,159**
	Sig. (2-tailed)	.	**,113**
	N	75	74
Rule benefits other deliverables	Correlation Coefficient	**,159**	1,000
	Sig. (2-tailed)	**,113**	.
	N	74	75

Appendix 23

Meaningful Participation - Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,420	,437	3

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Inclusiveness	6,08	3,231	,297	,108	,306
Representation	6,19	3,471	,317	,114	,287
Resources	7,35	3,006	,220	,049	,469

Appendix 24

***Meaningful Participation* - Kendall tau_b Correlations**

		Inclusiveness	Representation	Resources
Inclusiveness	Correlation Coefficient	**1,000**	**,223***	**,047**
	Sig. (2-tailed)	.	,026	,627
	N	75	73	75
Representation	Correlation Coefficient	**,223***	**1,000**	**,148**
	Sig. (2-tailed)	,026	.	,092
	N	73	75	73
Resources	Correlation Coefficient	**,047**	**,148**	**1,000**
	Sig. (2-tailed)	,627	,092	.
	N	75	73	75

Appendix 25

***Deliberative Decision Making*- Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,862	,863	4

Deliberative Decision Making- Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Participatory decision-making	10,96	3,985	,767	,657	**,808**
Comprehensive agreements	10,81	4,484	,777	,652	**,812**
Communicative agreements	10,70	4,473	,716	,549	**,824**
Effective dispute settlement	11,03	4,684	,657	,477	**,849**

Appendix 26

***Deliberative Decision making*- Kendall tau_b Correlations**

	Participatory decision making	Comprehensive agreements	Communicative agreements	Effective dispute settlement
Participatory decision making Correlation Coefficient	**1,000**	**,759******	**,539******	**,542******
Sig. (2-tailed)	.	,000	,000	,000
N	74	74	74	74
Comprehensive agreements Correlation Coefficient	**,759******	**1,000**	**,571******	**,507******
Sig. (2-tailed)	,000	.	,000	,000
N	74	74	74	74
Communicative agreements Correlation Coefficient	**,539******	**,571******	**1,000**	**,542******
Sig. (2-tailed)	,000	,000	.	,000
N	74	74	74	74
Effective dispute settlement Correlation Coefficient	**,542******	**,507******	**,542******	**1,000**
Sig. (2-tailed)	,000	,000	,000	.
N	74	74	74	74

Appendix 27

***Effective Process Control* - Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,752	,756	4

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Transparency	9,81	5,425	,610	,354	**,665**
Internal accountability	10,02	5,639	,554	,369	**,714**
External accountability	11,06	5,171	,604	,390	**,683**
Domestic accountability	10,17	5,129	,525	,319	**,718**

Appendix 28

***Effective Process Control* – Kendall tau_b Correlations**

	Transparency	*Internal accountability*	*External accountability*	*Domestic accountability*
Transparency Correlation Coefficient	**1,000**	**,506****	**,391****	**,299****
Sig. (2-tailed)	.	,000	,000	,004
N	74	74	69	68
Internal accountability Correlation Coefficient	**,506****	**1,000**	**,403****	**,180**
Sig. (2-tailed)	,000	.	,000	,080
N	74	75	70	69
External accountability Correlation Coefficient	**,391****	**,403****	**1,000**	**,378****
Sig. (2-tailed)	,000	,000	.	,000
N	69	70	70	65
Domestic accountability Correlation Coefficient	**,299****	**,180**	**,378****	**1,000**
Sig. (2-tailed)	,004	,080	,000	.
N	68	69	65	69

Appendix 29

***Trustworthy expertise* - Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,794	,805	4

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Competent expertise	9,85	4,385	,570	,349	**,762**
Robustness	10,33	3,168	,713	,553	**,686**
Scientific validity	10,25	3,376	,606	,451	**,742**
Objective judgments	10,73	3,396	,546	,321	**,775**

Appendix 30

***Trustworthy Expertise* - Kendall tau_b Correlations**

	Competent expertise	*Robustness*	*Scientific validity*	*Objective judgements*
Competent expertise Correlation Coefficient	**1,000**	**,538****	**,401****	**,372****
Sig. (2-tailed)	.	,000	,000	,000
N	75	75	74	74
Robustness Correlation Coefficient	**,538****	**1,000**	**,594****	**,462****
Sig. (2-tailed)	,000	.	,000	,000
N	75	75	74	74
Scientific validity Correlation Coefficient	**,401****	**,594****	**1,000**	**,383****
Sig. (2-tailed)	,000	,000	.	,000
N	74	74	74	73
Objective judgements Correlation Coefficient	**,372****	**,462****	**,383****	**1,000**
Sig. (2-tailed)	,000	,000	,000	.
N	74	74	73	74

Appendix 31

***Implementable Outcomes* - Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,618	,668	4

Item-Item Correlation Matrix

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Compliance	10,05	4,750	,376	,265	**,660**
Ruleclarity	8,71	7,963	,412	,175	**,558**
Rule benefits Standards	8,66	6,136	,641	,471	**,379**
Problem Solving Capacity	8,72	8,321	,325	,324	**,601**

Appendix 32

***Implementable Outcomes* - Kendall tau_b Correlations**

	Ruleclarity	*Compliance*	*Problem Solving capacity*	*Rule benefits Standards*
Rule Clarity Correlation Coefficient	**1,000**	**,261**	**,173***	**,307****
Sig. (2-tailed)	.	,136	,036	,001
N	71	35	71	71
Compliance Correlation Coefficient	**,261**	**1,000**	**,031**	**,421****
Sig. (2-tailed)	,136	.	,876	,007
N	35	37	37	37
Problem Solving Capacity Correlation Coefficient	**,173***	**,031**	**1,000**	**,408****
Sig. (2-tailed)	,036	,830	.	,000
N	71	37	76	75
Rule benefits standards Correlation Coefficient	**,307****	**,421***	**,408****	**1,000**
Sig. (2-tailed)	,004	,007	,000	.
N	71	37	75	75

Appendix 33

***Legitimacy Norms* - Reliability Statistics**

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
,844	,849	5

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Meaningful participation	13,79	5,433	,588	,370	**,839**
Deliberative Decision making	13,46	5,178	,772	,689	**,785**
Effective process control	13,69	4,923	,706	,589	**,796**
Trustworthy Expertise	13,67	5,359	,795	,697	**,784**
Implementable Outcomes	13,62	5,666	,504	,420	**,851**

Appendix 34

***Legitimacy Norms* - Kendall tau_b Correlations**

	Meaningful Participation	*Deliberative decision making*	*Effective process control*	*Trustworthy Expertise*	*Implementable Outcomes*
Meaningful Participation Correlation Coefficient	**1,000**	**,346****	**,385****	**,370****	**,242****
Sig. (2-tailed)	.	,000	,000	,000	,002
N	76	76	76	76	76
Deliberative decision making Correlation Coefficient	**,346****	**1,000**	**,532****	**,689****	**,333****
Sig. (2-tailed)	,000	.	,000	,000	,000
N	76	76	76	76	76
Effective process control Correlation Coefficient	**,385****	**,532****	**1,000**	**,433****	**,277****
Sig. (2-tailed)	,000	,000	.	,000	,000
N	76	76	76	76	76
Trustworthy Expertise Correlation Coefficient	**,370****	**,689****	**,433****	**1,000**	**,446****
Sig. (2-tailed)	,000	,000	,000	.	,000
N	76	76	76	76	76
Implementable Outcomes Correlation Coefficient	**,242****	**,333****	**,277****	**,446****	**1,000**
Sig. (2-tailed)	,002	,000	,000	,000	.
N	76	76	76	76	76

ISBN: 978-90-365-3818-3