J Food Sci Technol (July–August 2010) 47(4):465–467
DOI: 10.1007/s13197-010-0079-0

BOOK REVIEW

Evaluation of certain food additives. Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series No. 952. 2009. World Health Organization. Geneva, pages 208

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This technical publication covers information on 1. Food additives – analysis, 2. Food additives – toxicity, 3. Flavoring agents- toxicity, 4. Flow curing agents –analysis, 5. Food contamination - analysis and 6. Risk assessment. As is customary, a list of committee members and declaration of interests along with a brief introduction are provided at the beginning in chapter 1. The subsequent five chapters are on general considerations, specific food additives, flavoring agents, future work and recommendations.

Chapter 2, on General consideration of the committee lists the tasks and agenda of the meeting. Notable are the deliberations under safety evaluation of flavoring agents, namely, incorporation of single portion exposure technique (SPET) in dietary exposure assessment, investigation to develop criteria for the identification of flavoring agents requiring additional consideration, analysis of a larger data set of flavoring agents, consideration of the incorporation of SPET estimate into the procedure and combined dietary exposure. To deliberate more on the use of SPET, for measuring the dietary exposure of flavouring agents, JECFA employs the maximized survey-derived intake (MSDI) method for use in the procedure for safety evaluation. The MSDI provides a per capita estimate of dietary exposure to a flavouring agent that is compared with the relevant threshold of toxicological concerns for each structural class in a decision tree approach according to the procedure. The MSDI is based on the reported amount of the flavouring agent introduced into the food supply per year corrected for under reporting, and assuming that 10% of relevant population would consume foods containing the flavouring agent. The committee considered issues related to dietary exposure to flavouring agents at many of its previous meetings and was of the opinion that MSDI may significantly underestimate exposure. The SPET was developed by the committee for presumed patterns of consumer behavior with respect to food consumption and possible uneven dietary exposure. At its previous and present meetings, the committee performed a number of SPET and MSDI calculations to determine whether a set of criteria could be indentified for future selection of flavouring agents for which MSDI could underestimate dietary exposure, and to evaluate the possible impact of using both MSDI and SPET estimates of dietary exposure in procedure for different flavour groups. In addition, thresholds of toxicological concern used in the procedure was also used.

The third chapter on specific food additives includes information on safety evaluation of asparaginase from *Aspergillus niger*, calcium lignosulfonate, ethyl lauroyl arginate, paprika extract, phospholipase C expressed in P*ichia pastoris*, phytosterols, phytostanols and their esters, polydimethylsiloxane, steviol glycosides and sulfites: assessment of dietary exposure. The technical data for the above additives discussed included the necessary aspects of the nature of compound, chemical and technical considerations, toxicological data, assessment of dietary exposure and evaluation. Human studies, if available, are also discussed. A section on revision of some additives is also included which mentions the following – canthaxanthine, carob bean gum and carob bean gum (clarified), chlorophyllin copper complexes, sodium and potassium salts, fast green FCF, gaur gum and guar gum (clarified), iron oxides, isomalt, monomagnesium phosphate, patent Blue V, Sunset Yellow FCF and trisodium diphosphate.

Chapter 4 is on flavouring agents. These were evaluated by the Procedure for the safety evaluation of flavouring

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agents, which has been very clearly outlined in the form of a flow chart and is very easy to comprehend. Ten groups of flavouring agents were evaluated using the procedure. During application of procedure, the chemical is first assigned to a structural class. Class I includes the flavouring agents that have simple chemical structures and efficient modes of metabolism with possibly a low order of toxicity by oral route. Class II are compounds with structural features less innocuous than those of substances in class I but may not be toxic. They may contain a reactive functional group. Class III agents may suggest significant toxicity. The inherent principles for ascertaining the safety of an additive, in this case flavouring agents are well outlined. An important consideration while determining the safety of a flavouring agent is whether the agent or its metabolic products are innocuous and /or endogenous substances. The definitions used by the committee for these have been included in the report. The innocuous metabolic products are defined as products that are known or readily predicted to be harmless to humans at the estimated intake of flavoring agent. Endogenous substances are intermediary metabolites normally present in human tissues and fluids. The estimated intake of flavoring agent, which may be metabolized to an endogenous substance should not give rise to perturbations outside the physiological range. These are the prime considerations for determining risk assessments.

Estimates of the intake of flavouring agents by populations typically involve the acquisition of data on the amounts used in food. These data were derived from surveys in Europe, Japan and USA. The use of survey data for deriving the use-level estimates are detailed. The different classes of additives for which the committee has provided data for safety evaluation are as under.

- Aliphatic branched chain saturated and unsaturated alcohols, aldehydes, acids and related esters: additional compounds
- Aliphatic linear – unsaturated aldehydes, acids and related alcohols, acetals and esters: additional compounds
- Aliphatic secondary alcohols, ketones and related esters: additional compounds (annual volume of production in Europe, the USA and Japan provided)
- Alkoxy-substituted allylbenzenes present in foods and essential oils and used as flavouring agents
- Esters of aliphatic acyclic primary alcohols with aliphatic linear saturated carboxylic acids: additional compounds (annual volume of production in Europe, USA and Japan).
- Furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers
- Hydroxy- and alkoxy-substituted benzyl derivatives: additional compounds
- Miscellaneous nitrogen –containing substances: additional compounds
- Monocyclic and bicyclic secondary alcohols, ketones and related esters: additional compounds
- Substances structurally related to menthol: additional compounds

Each of the above class of compounds has been discussed under the sub-headings of (i) Assessment of dietary exposure, (ii) Absorption, distribution, metabolism and elimination, (iii) Application for the procedure for the safety evaluation of flavouring agent, (iv) Consideration of combined intake from use of flavouring agent, (v) Consideration for secondary components and (vi) Conclusion. Additional information, if any by way of explanation is also included under some flavouring agent and a summary of safety evaluation is provided in the form of a table for easy reference.

Some of the flavouring agents were also re-evaluated for which the estimated intake was based on anticipated poundage data earlier. Summary data on 143 compounds which were reconsidered are presented in the form of a table for easy reference.

Chapter V is a brief note on future work, which will help in determining the task and agenda for further deliberations on these issues. Four issues which are mentioned are (i) Considerations on the thresholds of toxicological concerns used in the procedure for the safety evaluation of flavouring agents, (ii) Incorporation of the SPET estimate into the procedure for the safety evaluation of flavouring agents, (iii) Mineral oils (low and medium viscosity), classes II and III and (iv)Paprika extract.

The recommendation of the committee is included as 6th chapter which states the following:

(i) Incorporation of the SPET estimate into the procedure for the safety evaluation of flavouring agents – to enable a safety evaluation using the procedure to be undertaken, the committee requested that added use level data be provided for each flavouring agent in a timely fashion before the meeting, in addition to up-to-date data on production volumes, as part of data package for safety evaluation. The committee states its inability to perform a safety evaluation in the absence of such data.

(ii) Relationship between the ADI and specifications – The committee recommends that when proposals are made to include or revise limits for impurities or when compositional changes occur that lead to a need for revision of specifications, the consequences for the safety assessment of the substance need to be considered.

(iii) Sulfites: dietary exposure assessment and maximum level in foods. Since there are new safety concerns for use of sulfites in foods, the committee recommended that all countries should consider collecting data on the current use of sulfites in food and beverages made available on their markets and investigating whether dietary exposure in some sub-populations exceeds

the ADI. On the basis of this investigation, individual countries and the food industry could consider the possibility of taking one or more of the following measures to reduce dietary exposure to sulfites so that ADI is not exceeded in the population.

- Align national legislation with Codex Alimentarius Commission maximum levels where these are lower and take action to effectively enforce national maximum levels.
- Encourage research on alternative methods of preservation, particularly on applications in which the use of sulfites is responsible for a significant contribution.
- Take action so that the use of sulfites is reduced in foods where safe alternative solutions are available.

Codex Alimentarius Commission codes of practices for certain groups of food commodities, such as fruit juice, dried fruit and processed meat, could be amended to include suggestions to help countries and the food industry in the implementation of a reduction of the use of sulfites in food.

A list of references referred and used in the book is provided at the end. This is followed by Annexures. Annex 1 is an exhaustive list of reports and other documents resulting from previous meetings of JECFA. Annex 2 is on acceptable daily intakes, other toxicological information and information on specifications. This gives data on (i) Food additives and ingredients evaluated toxicologically or assessed for dietary exposure, (ii) Food additives including flavouring agents considered for specifications only, (iii) flavouring agents (this includes two sub sections on flavourings evaluated by the procedure for the safety evaluation of flavouring agents and re-evaluation of safety of certain flavourings). Annex 3 incorporated further information required or desired for some of the flavouring agents. Annex 4 is the summary of safety evaluation of secondary components for flavouring agents with minimum assay values of less than 95%.

An overall evaluation of the book indicates that it is a very useful technical publication on certain food additives with very relevant technical data put in and also introducing new criteria for evaluation of risk assessment of flavouring agents. This book is a must for scientists, policy makers and food industry personnel to get information on toxicology and use levels of certain food additives and their specifications. This also server as a source book for regulatory bodies.