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Food legislation and the protection of allergic and hypersensitive persons: an overview

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Abstract

So far there are worldwide no legal instruments in protecting people against adverse allergic reactions to the consumption of foods. Instruments, which generally were developed for health protection in food legislation, are not suitable to regulate the protection of allergic persons because they automatically would exclude all protein-containing foods from commercial market. The only approach to an effective protection is to indicate the presence of adverse effect causing agents or ingredients on the label. This preventive instrument was developed by the Codex Alimentarius and led to an open ''hit list'' of ten Major Serious Allergens, which have to be labeled. The hit list principle was adopted by the EU-Commission as a draft for an EC-Directive. Unsolved problems are exeptions from the labeling requirement for refined oils and a minimum limit of adverse effect causing agents which do not require labeling.

Keywords: Review; Food allergy; Food legislation

Contents

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1. Constitutional law aspects

The highest object worth legal protection in the constitutions of all modern democracies is the physical intactness of man. This also includes people who have an adverse allergic reaction to the consumption of specific foods. It is remarkable that, in spite of existing constitutional commands, practically no effective protection for persons who react with incompatibilities or allergies to foods or food ingredients were so far codified in the food legislation worldwide. For some time, efforts in order to close this legislative gap have been made on various levels. Peculiarities of allergies and incompatibility reactions, however, have come to light, which make it more difficult to apply the existing legal instruments to the protection of allergic persons and which are the reason that so far no really effective regulations exist.

2. Legal instruments for consumer health protection

General instruments which were developed for the protection of consumers against hazards and damages induced by foods are:

- Civil law regulations in product liability law
- Prohibitions for the protection against acute food poisoning
- The prohibition principle[1], e.g. for food additives and food irradiation, in combination with a reservation clause for the permission of their use in a defined and limited way
- The prohibition principle combined with a notification or approval procedure and the reservation to permit specific dietary foods or Novel Foods
- Prohibitions for the use of specific components or for the application of specific manufacturing processes for foods
- Definition of maximum limits within the governmental ''risk management'', e.g. for residues and contaminants which are not to be exceeded in foods
- Selective exclusion or substitution of such food ingredients which are harmful for persons with specific illnesses (in the form of dietary foods)
- Preventive consumer guidance by means of labeling or specific label warnings.

[1]The prohibition principle in combination with a reservation clause for possible dispensations from the general prohibition in especially defined cases is a characteristic legal instrument for the protection of human health in the German and European food legislation.

3. Suitability of health related legal instruments for the protection against adverse reactions to foods

An assessment whether the above mentioned legal instruments, which were developed for health protection, can be applied as instruments for the protection of persons suffering from allergies, immediately shows fundamental difficulties. All protein-containing foods have a potential to *cause* allergies in the human organism. Therefore, the application of the general prohibition principles, which were developed for the protection of human health in various forms, would legally result in a trade prohibition for all these foods. This absurd conclusion leads to the following statements:

- the prohibition to market acute health damaging foods can only refer to a normal, healthy and not hypersensitive consumer,
- allergenic foods may not legally be classified as health damaging and
- therefore may not be excluded from the commercial food market.

3.1. Prohibitions, prohibition principle

The reversal of this conclusion means that the above mentioned legal instruments, which were developed against food induced health damage, can not be applied to individuals who react adverse to original agricultural products and foods which are produced from these. For food additives, however,

which are subject to a controlled legal approval procedure and which have turned out to induce allergies or incompatibilities, an application of the prohibition principle would be possible. In a specific case, however, the Commission of the European Union has decided against a national prohibition of food additives with allergenic or incompatibilities inducing potential for the protection of individuals suffering from allergies [1] (please refer to Section 5.2).

3.2. Product liability law

European and US product liability legislation potentially makes claims under civil law worth considering for persons suffering from allergies, at least in the case of foods which have proven to frequently cause allergies and which possess a high allergenic potential with life-threatening effects, e.g. peanuts or peanut-containing ingredients. It is not known whether, in the case of a life-threatening or fatal illness induced by the consumption of such food, a claim under civil law based on product liability law was ever made and eventually could be won in court. As an instrument for the protection of allergic persons the legal regulations of the product liability law as part of the public legislation are not an option. In addition, the product liability law in principle is a retrospective legal instrument, designed for the legal protection of consumers after suffering from any health impairment. As an instrument for the preventive consumer protection the product liability law is therefore not suitable.

3.3. Conclusion

For a closer assessment of their suitability as instruments for consumer protection in food legislation only two principles remain:

- selective exclusion or substitution of allergenic or incompatibilities inducing foods by means of a legal dietary foods regulation and
- labeling of the allergenic or incompatibilities inducing potential of foods or food additives.

4. Attempt of a protection of allergic persons by means of regulations for dietary foods

Dietary foods, which guarantee that substances with allergenic or incompatibilities inducing potential for specific persons are not present in the product, can serve to exclude possible dangers for the health of allergic persons. The food industry, however, can not be forced to produce a special dietary product for each group of people affected by a specific incompatibility. From the economical standpoint it will not be worthwhile for the food manufacturers to produce the necessary variety of dietary products in large scale in order to satisfy the needs of persons with various allergies. At the most, a demand for gluten-free products, which justify their high price, would be thinkable by individuals suffering from Celiac Disease. The approach via regulations for dietary products is therefore not an option for a satisfactory solution for the general legal protection of allergic persons.

Nevertheless, the US Food and Drug Administration (FDA) has developed regulations for the labeling of such dietary foods which are manufactured and offered by the food industry especially for allergic persons [2].

4.1. Sec. 105.62 Hypoallergenic foods

If a food purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by food having an allergenic property, the label shall bear:

(a) The common or usual name and the quantity proportion of each ingredient (including spices, flavoring, and coloring) in case the food is fabricated from two or more ingredients.

(b) A qualification of the name of the food, or the name of each ingredient thereof in case the food is fabricated from two or more ingredients, to reveal clearly the specific plant or animal that is the source of such ingredient, if such food or such ingredient consists in whole or in part of plant or animal matter and such name does not reveal clearly the specific plant or animal that is such a source.

(c) An informative statement of the nature and effect of any treatment or processing of the food or

any ingredient thereof, if the changed allergenic property results form such treatment or processing.

5. Attempt of a regulation by means of labeling of allergenic ingredients or additives

5.1. General considerations

The only, both possible and promising, approach for a regulation in food legislation for the protection against adverse allergic reactions is to indicate the presence of allergenic or incompatibilities inducing ingredients on the label. This approach, however, can not be comprehensive and can not be valid for each case of a possible food-induced allergy. Regulations for the preventive health protection in food legislation always require to balance the options within the governmental ''risk management''.

Here, the legitimate interests of two sides are to be considered which will not be compatible with each other in each case. The interests of the food industry's side will be a subject in the following sections. The other side is represented by the consumers of food products, who demand a high level of protection. For this reason, a worldwide accepted system for the ''risk assessment'' of food additives, residues and contaminants was introduced. It is based upon extensive toxicological studies on individual substances in order to assess their risk for human health. In the course, a substance level is determined which did not show any health damaging effects in animal studies (**N**o **O**bservable **A**dverse **E**ffect **L**evel). On the basis of this NOAEL-value and with a security factor normally of 100, the quantity of a substance is defined, which is assumed to be safe for the human health when consumed for life on a daily basis (**A**cceptable **D**aily **I**ntake, ADI-value). For carcinogenic, mutagenic or teratogenic food contaminants a lower, not health damaging dose, i.e. an ADI-value, can not be determined. For these substances an absolutely effective protection of human health would only be achieved by a legally set zero-tolerance level. This, however, would automatically lead to the exclusion of nutritionally essential and economically important agricultural products. In such cases the responsible legislator can only manage by defining a specific maximum tolerance of a toxic contaminant while accepting a remaining health risk. The same basic idea of a health political risk assessment in the form of a governmental ''risk management'', which was acknowledged worldwide in the Codex Alimentarius and the SPS-Agreement (**A**greement on **S**anitary and **P**hyto**S**anitary Measures within the World Trade Organization Agreement, WTO), can be used as legal instrument in the labeling of substances with allergenic properties in foods for the protection of allergic persons.

5.2. ''Risk management'' by means of required labeling as a legal instrument for the protection of allergic persons

The legal instrument of labeling in order to protect allergic persons against allergenic foods is being developed in the Codex Alimentarius [3] for some time. It was taken up by the Commission of the European Union in a legally binding decision of the Commission regarding the protection of consumers against colorings with allergenic or incompatibilities inducing properties in foods [1] and was made public in a draft proposal for guidelines on the labeling of food ingredients, which can cause allergies or incompatibilities [4].

In the case of the above mentioned decision of the Commission the subject was the endeavor of Sweden to retain the more rigid national regulation when compared to the harmonized European Community law. This national restriction of the Community law was justified with the protection of the Swedish food consumers against allergies and incompatibility reactions induced by azo dye-stuffs. In the decision 1999/5/EG [1] the Commission refused the Swedish application. It was acknowledged though that persons with a manifested allergy need to be protected and have the right to consume food products which do not contain the respective additives. At the same time, however, the declaration of azo dye-stuffs in the list of ingredients as regulated by law was regarded as sufficient in order to be able to select safe food products.

6. The labeling of foods inducing adverse reactions

The procedure of food labeling as an instrument for the preventive protection of allergic persons was

developed by the Codex Alimentarius but is not yet completed. The EU-Commission has adopted the regulation approach as a draft proposal for a legal regulation for the labeling of such foods or ingredients which have proven to

- either frequently induce adverse reactions or
- have shown a high health damaging potential.

In the enclosure to the draft a so-called hit-list [4] of Major Serious Allergens (MSAs), containing ten foods, ingredients or substances, which have to be indicated as allergenic or incompatibility inducing, is given. This list is generally limited, since it is not possible to take all potentially allergenic foods into account. It can be created as an open end list though, and completed according to new knowledge.

So-called hit-list from the draft for an EC-Directive:

Foods and ingredients, which are recognized as reason for an increased allergenic sensitivity and which have to be declared in the ingredients list:

- Cereals containing gluten and products of these
- Crustacea and products of these
- Eggs and egg products
- Fish and fish products
- Peanuts and products of these
- Soybeans and products of these
- Milk and milk products (including lactose)
- Tree nuts and nut products
- Sesame seed
- Sulfite in a concentration of 10 mg/kg or more.

7. Unsolved problems with the labeling of allergenic substances for the protection of persons who react allergic to foods

The food labeling as a legal instrument for the protection of the health of allergic persons still requires the discussion of unsolved problems: exceptions from the labeling requirement for refined oils, e.g. peanut oil

- minimum limit for minor ingredients consisting of different components, which does not require labeling
- definition of a threshold value which is not subject to the labeling requirement or
- analytical proof that a food is free of allergenic potential

The question has risen whether refined oils derived from allergenic foods, like peanut oil, would need to be subject to the labeling requirement as well. If the processing parameters guarantee that the peanut proteins were denatured completely or up to an insignificant level or until ineffectiveness, e.g. with the result that they will not cause allergies in human organisms any more, there is no reason not to make an exemption from the labeling requirement. The marketer of such products, however, has an increased duty to exercise due care, which could be supported by an obligatory analysis regarding remaining allergenic properties or an equivalent certificate.

Food processing businesses will hardly be able to guarantee that their purchased compound ingredients will be free from remaining allergenic potential. Within the Codex Alimentarius it was therefore suggested to define a threshold value. Compound ingredients in a quantity lower than this value would not have to be declared. The originally discussed threshold value of 25% was too high in order to sufficiently protect persons suffering from allergies. As a result a lower value of 5% was discussed. It is questionable whether this amount, which would not require labeling, can offer a sufficient protection in the case of such compound ingredients which contain highly potent allergenic properties, like peanuts or other MSAs. Here, an exemption from the labeling requirement would simulate a false safety.

Instead of defining a threshold value under which a labeling of ingredients with allergenic properties is dispensable, it would also be possible to define an analytical criterion. An example for this can be the regulation of the European Union for the labeling of genetically engineered foods or food ingredients. Genetically engineered products have to be labeled as such if a modified genome or an expressed protein is present [5]. Technically inevitable contents of up to 1% are not required to be labeled. This legal criterion could also be applied to the labeling of foods with allergenic properties. For each allergenic food product or each substance which induces an

adverse reaction, an analytically measurable threshold value could be defined, which is subject to the labeling requirement whenever the content exceeds this value. These analytical criteria *would* offer a more reliable protection to allergic persons than an arbitrary threshold value. A disadvantage, however, are the higher costs for the development of precise analytical methods and for the analyses themselves, eventually leading to an increase of the prices for these products.

8. Outlook

So far, there are no satisfactory regulations on adverse allergic reactions in food legislation worldwide. At best, there are first approaches being discussed, in order to ensure a sufficient protection of consumers of food products from allergies and incompatibility reactions on one hand, which can be applied in a practicable manner by the food industry on the other hand. A hit-list of so-called Major Serious Allergens (MSAs) was developed by the Committee on Food Labeling of the Codex Alimentarius and accordingly by the EU-Commission. Whether it is sufficient to declare these potent allergens in the ingredients list or to emphasize their presence in a more prominent way is still subject of discussions. The responsible food manufacturer might even consider voluntarily given labeling as an effective instrument for the protection of allergic persons from food borne risks in addition to a legally required declaration in the list of ingredients.

References

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