chapter nineteen

Setting toxicological standards for food safety

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19.1 Introduction

Toxicological standard setting is a process carried out by legally qualified national authorities to protect the public health or the quality of the environment. A toxicological standard for a substance can be defined as a limit value for its content in food, (drinking) water, soil, or air. These toxicological standards are not only based on toxicological knowledge, but are also the result of a thorough risk–benefit analysis. In the process of standard setting, toxicological guide values or health-based recommendations are weighed against technical feasibility and check possibilities, and socio-economical and political interests (Figure 19.1). Thus, standards are based on scientific as well as practical considerations. It should be noted that standards are only of value if they can be implemented and enforced.

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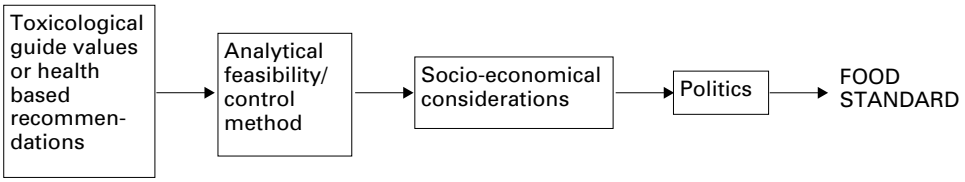

Figure 19.1 Process of standard setting.

A guide value can be defined as a limit value with the aim to maintain or protect the quality of human life and ecosystems, and to minimize risks. A guide value is an estimate of the highest acceptable or tolerable exposure level. It is based on an objective evaluation of all available toxicological information, reflecting the state of the art, including application of appropriate safety (or uncertainty) factors. In practice, guide values are maximum daily (or weekly) doses or maximum concentrations in food, drinking water, or environmental compartments.

This chapter will answer such questions as: what is a standard with regard to food safety? How are standards set? Who is responsible for the setting of standards? The general principles of recommendations for the protection of human health are discussed and the role of international bodies, such as the World Health Organization and the European Union in setting harmonized standards and the effects of these standards on national regulatory measures will be elucidated.

19.2 General principles

Usually, health-based recommendations or guide values are based on data obtained from toxicological studies in experimental animals, and only sometimes on observations in man.

It is the aim of safety evaluation to identify the type of adverse effect and to establish and quantify the dose–response relationships over certain periods of time. Therefore, adequate toxicological data are essential to determine the level at which human exposure to a substance can be considered as safe. For food additives, it was decided a long time ago by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) that an acceptable daily intake (ADI) should be established that would provide "an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers." Thus, the ADI was defined as an estimate of the amount of a substance in food, expressed on the basis of body weight, that can be ingested daily over a lifetime without an appreciable health risk. Guide values or standards based on this ADI should minimize the probability of the occurrence of adverse effects in man, if exposed to a particular substance. Crucial in this approach is the establishment of a threshold dose above which any functional or structural disturbance shows itself as a pathological effect of which the intensity increases with increasing exposure (due to both dose and duration). In evaluating the toxicological potential of substances (present in food), it is essential to distinguish between genotoxic substances, for which it is assumed that no thresholds exist, and non-genotoxic substances, which can be evaluated according to the threshold approach.

19.2.1 Determination of a threshold

For non-genotoxic substances, a deviation from the statistical mean of a normally distributed value must be reached before a particular effect in an organism can be observed. The threshold dose for the most critical effect in a test is the highest exposure level without adverse, i.e., toxicologically relevant, effects. It is called the no-observed-adverse-effect

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level (NOAEL). In practice often more than one method will be available for the toxicological evaluation. In general, the critical test is the most sensitive one, carried out in the most sensitive animal species, assuming that man is at least as sensitive as this particular animal species. The results of the various methods are compared. In a toxicological evaluation, the following points are examined: the relevance of the effect as well as the animal model, both in view of the extrapolation to man; the validity of the tests, and the quality of the report.

19.2.2 Determination of the NOAEL

For the determination of the NOAEL, a series of doses is used. In order to establish the dose–effect relationship, the dose levels are chosen in such a way that the highest dose causes an adverse effect that is not observed after the lowest dose.

Ideally, in a long-term toxicity study, the highest dose should evoke symptoms of toxicity without causing excessive mortality, and the lowest dose should not interfere with development, normal growth, and longevity. In between, doses should be selected sufficiently high to induce minimal toxic effects. The determination of an adverse effect in a particular study depends not only on the doses tested, but also on the types of parameters measured and the ability to distinguish between a real adverse effect and a false positive finding. In long-term toxicity tests, the average value of a specific parameter at a particular dose level is compared with the average value of the parameter in control animals. An effect can then be defined in purely statistical terms as a significant deviation of a control value. However, in determining an adverse effect, the biological relevance of this deviation should be taken into consideration. If, for example, a slight but significant alteration is only observed at the highest dose level, it is difficult to define it as a real adverse effect. More weight should be given to a particular change in a parameter, if a dose–response relationship can be established, or if the observed change is related to changes in other functional or morphological parameters. If an effect is irreversible, the relevance of the effect is unquestionable. In some cases, however, the biological relevance of an effect must be interpreted in relation to historical control values. This is often the case when the value of the particular parameter is highly variable among the control animals used in a number of different toxicological studies. The historical control data should originate from the same species, strain, age, sex, supplier, and laboratory to enable proper comparison.

There are many sources of uncertainty in toxicity testing. For example, effects may not show themselves if the number of animals is too small (to discriminate between various test groups), the time of observation is too short for the manifestation of a particular effect, or the experimental design is too limited to obtain conclusive evidence. In addition, the differences in sensitivity to a particular substance between man and experimental animals may not be known. Therefore, safety factors are applied in the setting of guide values for man based on animal data to compensate for these uncertainties.

19.2.3 Application of safety factors

In the extrapolation of animal data to the human situation, safety factors are applied to provide an adequate safety margin for the consumer. Usually, most national as well as international regulatory bodies traditionally apply a safety factor of 10 for interspecies variation and 10 for intraspecies variation, resulting in an overall safety factor of 100. If toxicity data in human beings are available, such data take precedence over animal data, and, generally, in such cases a safety factor of 10 is appropriate. A lower safety factor may suffice if the substance under investigation is identical to traditional food components, e.g., nutrients such as vitamins and amino acids, if the substance is metabolized into

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Table 19.1 Organizational differences between WHO standards and EU standards

	WHO standard	EU standard
Impact	Worldwide	European Union
Status	Advisory	Imperative

endogenous compounds, or if it lacks overt signs of toxicity. For substances serving as essential sources of energy in the human diet, the safety factor 100 is not applied either.

Although safety factors are employed to protect the health of the consumer, they reflect all the uncertainties in the process of extrapolating animal data to health-based recommendations for man. Therefore, the term "uncertainty factor" may be more appropriate.

19.2.4 High-risk groups

As mentioned in the previous section, when establishing guide values an uncertainty factor of 10 is applied to account for interindividual variations in the sensitivity to a particular substance. In some cases, however, specific human subpopulations can be identified as being particularly at risk. These groups may consist of young children, pregnant women, elderly persons, or specific groups of patients, for example those suffering from chronic non-specific lung disease, cardiovascular diseases, or renal deficiencies. If such a group can be clearly identified, the guide value for the general population may be based on this group.

19.3 Who is responsible for standard setting?

Within the framework of public health legislation, national regulatory authorities are responsible for standard setting with regard to food safety. The authorities can carry out the process of standard setting as a separate national affair, or adopt standards set by international bodies such as the World Health Organization and the European Union. To achieve harmonization in food standards, many countries adopt standards set by the WHO. However, since 1992 the member countries of the EU are required to accept the decisions taken by the European Commission and enforce Union standards into their own national legislation. The difference between WHO standards and EC standards are summarized in Table 19.1.

19.3.1 Role of the World Health Organization

The World Health Organization is an international advisory body with the overall aim of protecting human health. As far as toxicological risk assessment is concerned, it is not a legislative body. It backs national authorities in setting standards for the protection of human health. The International Program on Chemical Safety (IPCS) plays a guiding role in the international procedure of evaluating risks from chemicals and setting tolerances for residues of chemicals in food. Through the IPCS, the WHO participates in two joint committees of the WHO and the Food and Agricultural Organization (FAO). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint Meeting on Pesticide Residues (JMPR) serve as scientific advisory bodies of the Codex Alimentarius Commission, a joint FAO/WHO commission that sets standards for chemicals in food. The Codex Alimentarius Commission is responsible for the implementation of the Joint FAO/WHO Food Standards Program, that is intended to:

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(a) protect the health of the consumer and ensure fair practice in food trade;
(b) promote coordination of all food regulatory activities carried out by international governmental and non-governmental organizations;
(c) establish priorities, and initiate and give guidance to the preparation of provisional standards by and with the aid of appropriate organizations;
(d) finalize provisional standards and, after acceptance by governments, publish them in a Codex Alimentarius;
(e) amend published standards, after appropriate survey, in view of certain developments.

Although the Codex Alimentarius and FAO/WHO do not have any legal authority and the standards they propose are not standards as defined above, the Codex standards have been shown to be of great value in the harmonization of food standards.

It is the aim of Codex to offer proposals for Maximum Residue Limits (MRLs) to national governments for acceptance into the prevailing national registration or standardization system. There are Codex Committees on food additives and contaminants, on pesticide residues and on veterinary drug residues. The membership of the Codex Committees is open to all nations, and their meetings are attended by formal national delegations. While the considerations of JECFA and JMPR are purely scientific (as these bodies consist of experts or advisory members speaking as private persons), the proposals of the Codex Committees are partly based on national politics.

Regional differences in the use of additives, pesticides, or veterinary drugs are a problem in the harmonization of (worldwide) MRLs. Officially recommended use rates for pesticides are usually higher in those countries where extreme climatic conditions favor the development of pests or diseases than in more temperate climates. Further, countries which are important exporters of foods such as grains and meat, tend to favor relatively high MRLs, while countries that are importers tend to favor low MRL values.

In tackling these differences, the Codex Commission follows a thorough stepwise procedure, leading to the acceptance of a formal Codex Standard (see Figure 19.2).

The above procedure gives members an opportunity to participate in the decision process and to use the final result for their own national standard setting. However, national or regional policy sometimes disturbs this ideal in standard setting, for example, when the European Union uses other MRLs, based on the recommendations of one of its own Scientific Committees.

19.3.1.1 Role of the Joint FAO/WHO Expert Committee on Food Additives

The Joint FAO/WHO Expert Committee on Food Additives evaluates food additives, food contaminants and residues of veterinary drugs. JECFA first convened in 1956 with the mandate to:

- formulate general principles governing the use of food additives, with special reference to their legal authorization, on the basis of considerations such as innocuousness, purity, limits of tolerance, and the social, economic, physiological, and technical reasons for their use, taking into account work already done on the subject by national and other international bodies;
- recommend, as far as practicable, suitable uniform methods for the physical, chemical, biochemical, pharmacological, toxicological, and biological examination of food additives and of any degradation products formed during the processing, for the pathological examination of experimental animals and for the assessment and interpretation of the results.

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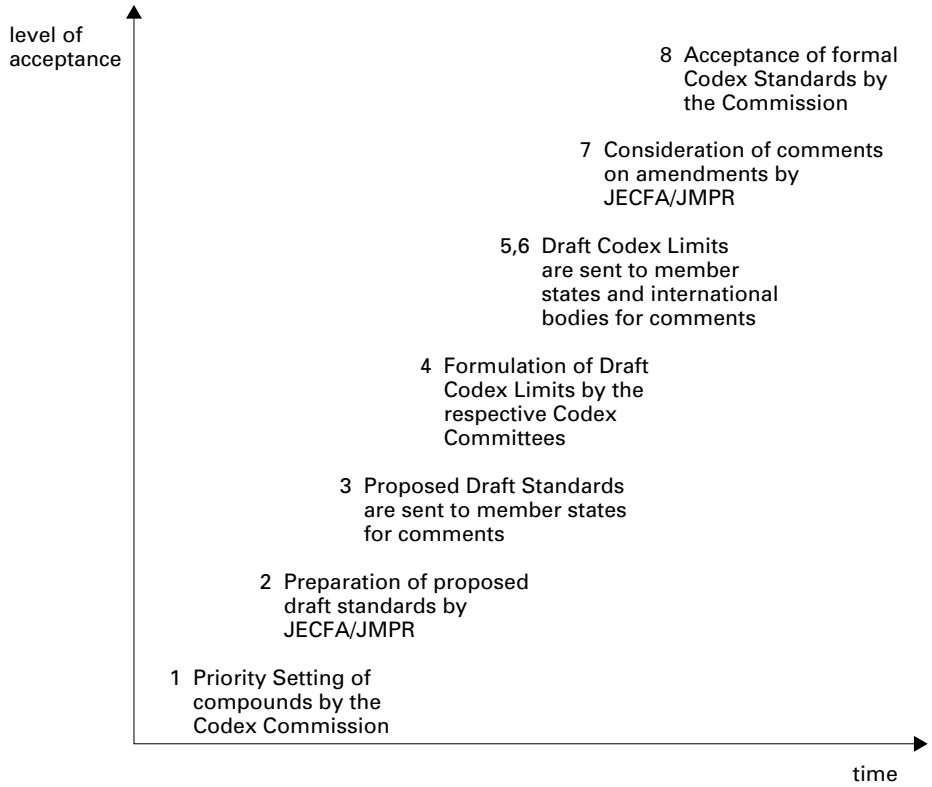

Figure 19.2 Procedure, leading to the acceptance of a formal Codex Standard.

This mandate was later (1987) expanded to include food contaminants and veterinary drugs.

For food additives, ADIs or provisional ADIs (when the available information does not warrant a final conclusion) are calculated. This parameter indicates the safe daily dietary intake of a substance. The actual daily dietary intake should not exceed the ADI. Therefore, information on dietary intake is necessary. This can be obtained from market-basket or total diet studies. In the case of major food components and some novel foods (modified starches, polyols, modified celluloses), it is often not necessary to calculate an ADI, since the effects observed in toxicity experiments concern the nutritional value. In such cases, no numerical value for the ADI is given (ADI not specified). These products are believed to be acceptable.

For residues of veterinary drugs, the WHO panel of the Joint Expert Committee evaluates the toxicological information and establishes, if possible, ADIs (or provisional ADIs). The FAO panel proposes limits (MRLs or provisional MRLs) for residues of veterinary drugs in products of animal origin, based on the WHO ADIs and on information about the distribution of the residues in tissues of the target animal. In setting the MRLs, the maximum theoretical intake should not exceed the ADI. This maximum theoretical intake is estimated using the (exaggerated) consumption package for products of animal origin as compiled in Table 19.2.

Veterinary drug residues include parent drugs as well as their metabolites. The metabolites are taken into account if they are toxicologically relevant, i.e., present in a considerable quantity or having a toxicological or pharmacological potential. The MRL is

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Table 19.2 Average daily consumption of animal products

Cattle/swine		Poultry		Fish	
Muscle	300 g	Muscle	300 g	Muscle	300 g
Liver	100 g	Liver	100 g	Liver	100 g
Kidney	50 g	Kidney	40 g		
Fat	50 g	Skin	60 g		
Milk	1.5 l	Eggs	100 g		

expressed in terms of parent drug levels or in terms of levels of a marker metabolite, if the percentage of the marker metabolite formed from the parent drug is known.

Intermezzo

Example. In 1990 JECFA evaluated the antibiotic oxytetracyclin and calculated an ADI of 0 to 0.003 mg/kg body weight (0.2 mg per person) based on the results of a study on the antimicrobial activity of tetracyclin in human volunteers. JECFA established the following MRLs: 0.6 mg/kg for kidney, 0.3 mg/kg for liver, 0.2 mg/kg for eggs, 0.1 mg/kg for milk and muscle, and 0.01 mg/kg for fat.

However, using the data presented in Table 19.2, the estimated maximum theoretical daily intake for oxytetracyclin residues in beef, eggs, and milk is: 150 µg in milk, 30 µg in muscle, liver and kidney, 20 µg in eggs, and only 0.5 µg in fat. In total, this is approximately 260 µg. This exceeds the ADI of 200 µg per person.

However, JECFA concluded that application of these recommended MRLs does not pose a risk to the consumer, since the NOAEL used for the calculation of the ADI was very conservative, and the consumption data used in Table 19.2 are at the upper limit of the range for the individual intake of animal products. Thus, in practice, the safety rules are interpreted with a certain flexibility though strict rules are applied for the derivation of health-based recommendations.

19.3.1.2 Role of the Joint Meeting on Pesticide Residues

In 1963 The Joint Meeting on Pesticide Residues convened for the first time. The WHO panel of the JMPR evaluates pesticide residues on the basis of toxicological and biochemical data. If the data are inadequate, the JMPR allocates an ADI for each individual pesticide under investigation. The FAO panel of the JMPR evaluates disposition of residues and resulting residue levels under conditions of Good Agricultural Practice, on the basis of data on patterns of use.

In order to evaluate the acceptability of a proposed MRL, it is necessary to compare the dietary intake of pesticide residues calculated on the basis of the MRL with the ADI. The dietary intake is calculated by multiplying each MRL with the quantity of the corresponding diet component, followed by summation of the residue quantities obtained. It should be noted that the use of the MRL in the calculation of total intake may lead to a higher value than the actual intake, since the actual residue levels will often be lower than the recommended MRLs.

Food consumption patterns vary considerably from one country to another, and from one culture to another. At the international level, the total intake is calculated on the basis of a hypothetical average global food consumption package, composed according to the recommendations in the FAO Food Balance Sheets, i.e., consisting of components of each

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cultural diet. At the national level, the total intake is calculated on the basis of actual consumption data. In practice, these are cultural diet data.

These three ways of calculating the daily intake of pesticide residues are summarized below.

1. Theoretical maximum daily intake (TMDI):
   TMDI = $\Sigma Fi \times MRLi$
   Fi = the hypothetical average intake of a diet compoent
   MRLi = …

2. Estimated maximum daily intake (EMDI):
   EMDI = $\Sigma Fi \times Ri \times Pi \times Ci$
   Ri = the actual residue level in the diet component
   Pi = adjustment factor taking into account reduction (or increase) in residue quantity due to industrial processing
   Ci = adjustment factor taking into account reduction (or increase) in residue quantity due to preparation of the food (boiling, frying etc.).

3. Estimated daily intake (EDI), which is a refinement of the EMDI at national level, based on adequate actual data.

The procedure in which the dietary intake of pesticide residues is compared with the ADI starts with the intake parameter that can be the highest, TMDI. If TMDI does not exceed ADI, it is highly unlikely that the ADI will be exceeded in practice, and therefore the MRL proposals can be considered to be acceptable. If TMDI is higher than ADI, a parameter concerning the *actual* situation (EMDI) should be used in order to eliminate the pesticide from further consideration.

For veterinary drugs, another procedure is applied. MRLs for veterinary drugs are based on theoretical maximum consumption data. Furthermore, veterinary-drug-residue limits are set for the fresh animal product, and effects of industrial or in-house processing on the residue content are not taken into account.

19.3.1.3 International Program on Chemical Safety

Within the framework of the International Program on Chemical Safety (IPCS), WHO has drawn guidelines for the protection of drinking water quality. Recently, a revision of these guidelines was carried out for a large number of organic and inorganic substances, including disinfectants and pesticides. It is the WHO's intention that these guidelines should be applied in setting national standards, not only for community piped-water supplies but for all sorts of drinking water except for bottled mineral waters. Adoption of these worldwide guidelines is dependent on national priorities and socio-economic factors. Since water is one of the primary needs for life maintenace, it must be available even if the quality is not entirely satisfactory. This implies that setting standards that are too stringent could limit the availability of water. This is considered unacceptable, in particular in regions with water shortage. On the contrary, it is WHO's opinion that this consideration is never allowed to lead to guide values posing health risks.

The WHO states that the established guide values protect health for lifelong consumption. The quality of drinking water should always be maintained at the highest level. On the other hand, short-time exposure above the guide value does not necessarily imply a health risk, but it should be a signal to competent authorities to consider certain measures. The information used for drawing guidelines for drinking water does not only include toxicological data but also data on the occurrence of contaminants in drinking water, physical properties like solubility, and aesthetic and organoleptic aspects. In cases where threshold

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doses were exceeded, ADIs were calculated, or adopted if they were available from other international bodies. For genotoxic carcinogens, which may be present as contaminants in drinking water, the risks were assessed on the basis of an acceptable risk of one additional case of tumorigenesis per population of one million lifelong exposed persons.
Since exposure to the substances of which the guidelines are under revision not only occurs via drinking water but also via other routes (food, air), the ADI may be partly ingested. In general, intake via drinking water amounts to 10% of the ADI. Since for most pesticides exposure via other routes is extensive, an intake value of 1% of the ADI is employed. For disinfectants used for the purification of drinking water, exposure via other routes is negligible. Therefore, higher intake values (up to 50%) are applied. The toxicological guide values calculated according to the above procedure were compared with taste and odor thresholds. If the latter values were lower, the standards were based on organoleptic quality.

Intermezzo

Example. Drinking water may be contaminated by monochlorobenzene as an indirect result of its use as an organic solvent in pesticide formulations, or as a degreasing agent in industry. Based on chronic toxicity data, WHO established a tolerable daily intake (TDI) of 0.09 mg/kg body weight (see also Sections 16.3.2.1, 17.4, 17.4.1, and 21.4.4.3). For calculation of the guide value, a body weight of 60 kg and a consumption of 2 l of drinking water per person per day are used. If the intake via drinking water amounts to 10% of the TDI, the total acceptable intake is 0.54 mg and the guide value 0.27 mg/l.

It should be emphasized that this toxicological guide value far exceeds the lowest reported taste and odor threshold for monochlorobenzene, being about 10 µg/l. Therefore, the latter value will probably be used by national authorities as standard for monochlorobenzene in drinking water.

19.3.2 Role of the European Union

The European Community was founded as a free-trade association for its member countries. One of the objectives was to achieve harmonization in setting food standards. Since January 1992, however, all member countries have to accept the products produced in other member countries without any restriction, and have to apply identical criteria for quality and safety. In practice, this means that member countries cannot approve a marketing authorization for substances used in the production of foods without the agreement of the European Community. The safety evaluation of food additives or substances present in a food as a result of their use in its production process, is formally carried out by the Commission of the European Communities.

Within the Commission, several scientific working groups are involved in food safety evaluation (see Figure 19.3). Proposals made by these working groups for the safe use of food additives and for maximum residue limits are, if adopted by Regulatory Committees, enforced by the Council of Ministers. Enforced proposals are published in the Official Journal of the European Union and are, from that time on, imperative for the regulatory authorities in the member countries.

19.3.2.1 Activities of the European Scientific Committee for Food

The Scientific Committee for Food (SCF) advises the Commission with regard to directives for food additives, flavoring substances, solvents, materials in contact with food, contami-

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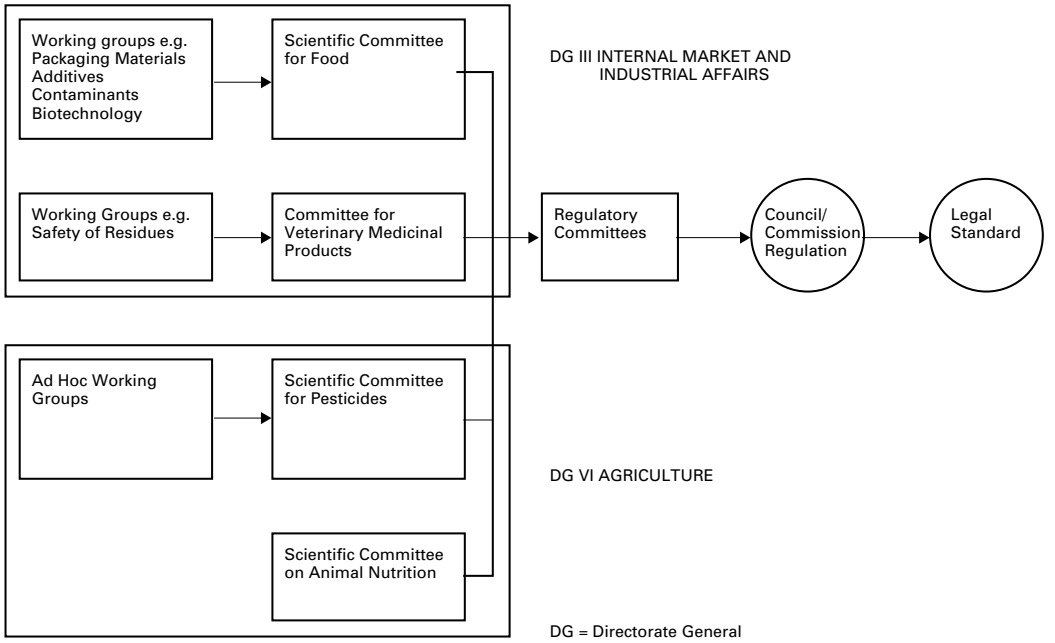

Figure 19.3 Scientific working groups involved in food safety evaluation.

nants, novel foods, and foods for particular nutritional use. Consultation of the SCF is obligatory in all cases concerning public health.

The SCF evaluates the available toxicological and analytical information in order to estimate the maximum limits for the safe ingestion of the substances under investigation, and designates these guide values using the following classification:

- Acceptable Daily Intake (or provisional ADI if more data are required) for lifetime exposure, to be used to set standards for the use of particular food components;
- ADI not specified, if the technological limits are believed to provide a sufficiently large safety margin;
- Acceptable, limited and well-defined use;
- Not Acceptable: the intentional use is considered unsafe. Particularly in the case of carcinogenic substances, no acceptable values can be given;
- Tolerable Daily Intake, for lifetime unintentional exposure (e.g., environmental pollutants and contaminants originating from packaging materials).

According to the present EU regulation, any new request for the admission of a new substance that is covered by the Food Directive should no longer be addressed to the member state concerned, but directly to the Commission.

19.3.2.2 Activities of the European Committee for Veterinary Medicinal Products

On behalf of the Committee for Veterinary Medicinal Products (CVMP), the Scientific Working Group Safety of Residues evaluates the food safety aspects of veterinary drugs used in animal production. Since January 1992, the decisions made by this Working Group and authorized by the CVMP, overrule the national safety evaluation of veterinary drug residues. At this moment, no admission of a new veterinary drug in a member country is possible if a Union Standard has not been set. In contrast to the members of the other scientific committees, the members of the CVMP and of the Working Group are national

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representatives. This means that not only scientific judgments contribute to decisions, but also national policy arguments. In order to establish ADIs and MRLs, the Working Group follows a procedure as used by JECFA. If possible, the Working Group adopts ADIs and MRLs already established by the Codex Commission on Veterinary Drugs, but sometimes the scientific judgment of the Working Group differs from those of JECFA and Codex, resulting in a different conclusion. In JECFA, the uncertainty with respect to the toxicological evaluation and the lack of sufficient data often lead to a number of questions to be answered by industry, and no ADI or MRL is established in such a case. The EU, however, is entitled to set residue levels for all veterinary drugs. Before 1997, about 400 biologically active substances present in veterinary drugs have to be evaluated and MRLs have to be established. This means that if there are not sufficient data available for an appropriate safety evaluation, a pragmatic approach has to be chosen which enables the establishment of provisional ADIs by applying larger uncertainty factors, resulting in the establishment of provisional MRLs. If the use of a particular component is a serious reason for concern, the MRL is also based on the detection limit.

Recently, the Codex Commission on Veterinary Drugs published the first regulation on MRLs for residues of veterinary drugs in foodstuffs of animal origin. In this regulation, for each biologically active substance the animal species for which the MRL is applicable, the marker residue on which the MRL is based, and the target tissue for which the MRL should be used, are listed.

19.3.2.3 Activities of the European Scientific Committee for Pesticides

For safety evaluation, the Scientific Committee for Pesticides (SCP) follows a procedure similar to that of JMPR. In general, this means that carcinogens are not acceptable as pesticides, and for other substances ADIs have to be established. The ADIs are compared with the estimated intakes of the residues through the consumption of various agricultural products. Based on this comparison, residue standards are set.

19.3.2.4 Activities of the European Scientific Committee on Animal Nutrition

Additives used in cattle, swine, and poultry feed to prevent the outbreak of diseases have already been evaluated in the past by the Scientific Committee on Animal Nutrition (SCAN) as an accepted Union procedure. Following the evaluation of all available toxicological data, conditions of use were described, which were safe for the consumer, and these conditions were included as an annex to the veterinary drug acts in several countries. However, SCAN is now in the process of developing procedures for standard setting of feed additives, a process that, in the light of the ongoing harmonization, needs to be comparable to the procedures used by the CVMP and by JECFA.

19.3.3 National regulations

Nowadays national standards appear to be of minor importance in relation to EU regulation. In the past, the responsible national regulatory authorities were obliged to evaluate substances with regard to consumer safety, and to set residue standards in foodstuffs within the framework of the local Food Acts, the Pesticide Acts, or the Veterinary Drug Acts. As was mentioned before, this responsibility is now taken over by the respective scientific and regulatory committees of the European Union. The decisions reached in the EU with respect to food standards should now be implemented in the national legislations, and standards should be adopted in the national Residue Regulations. This implies, as mentioned before, that no new marketing authorization can be granted in a member country without a Union Standard.

However, this process does not necessarily mean that all EC member states have exactly identical standards. If a member state, for whatever reason, sets a different

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standard, it has to accept that if this standard is higher than the Union Standard it can not sell the particular product in other member countries, and consumer organizations certainly will question this decision. If a country sets a standard that is lower than the Union Standard, it has to accept food products from other member countries coming up to the Union Standard. If such a lower standard will lead to additional restrictions in the use of the particular substance, one can expect the industry to complain, and to seek its rights via the European Court.

19.3.4 Role of industry

Although industry in general has no formal responsibility in the process of standard setting, it still plays an important role. First, industry provides the necessary information about the identity and purity of the substance, conditions of use, analytical methods for detection of residues, efficacy, and toxicological data that are essential for the safety evaluation. During evaluation in JECFA, JMPR, or EU Committees, hearings take place at which the industry is offered the opportunity to clarify existing problems or to comment on decisions taken by these bodies.

The Codex system, as described before, is unique in its possibility for industries to participate in pre-Codex meetings and to be members of the national delegations. In these delegations the industry representatives, however, have no voting status. Further, the International Group of National Associations of Manufacturers of Agrochemical Products and the International Animal Health Industry participate as observers in the Codex meetings without voting rights but with a limited opportunity to join in the debate. During the process of drafting a new EU regulation, the Commission or the respective Working Groups inform the industries about new proposals and offer them the opportunity to respond.

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