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1 **Analysis of risk assessment and risk management processes in the**
2 **derivation of maximum levels for environmental contaminants in food**

3
4
5 **Abstract**

6 Environmental contaminants are substances that originate from diffuse sources
7 and may appear in foods based on their ubiquitous presence in the
8 environment. The setting of standards in food is becoming increasingly
9 important within the European Union and world-wide in order to protect
10 consumers' health and to avoid trade barriers. This paper analyses how
11 maximum levels for environmental contaminants in food were derived by the
12 *Codex Alimentarius Commission*, by the European Union and by national
13 authorities (USA, Germany). Both the risk assessment process (derivation of
14 tolerable intake values and intake assessment by scientific bodies) and the risk
15 management process (derivation of maximum levels by risk management
16 bodies) are discussed. The different organisations show similar principal
17 approaches and similar numerical values for those maximum levels that are
18 available for the same contaminants in the same food items. For the risk
19 management decision-making, a noticeable lack of transparency is observed in
20 all the investigated systems. Recommendations for harmonisation and
21 improvement are provided for the exposure assessment, for the communication
22 between risk assessment and risk management processes and for
23 improvements for better documentation and transparency of the risk
24 management decision-making processes.

Key words: Derivation of maximum levels, environmental contaminants, food, risk assessment, risk management

Introduction

Significant steps towards harmonisation have been achieved in the European Union (EU) for the regulation of environmental contaminants in food. Common maximum levels have been enacted for heavy metals (lead, cadmium, mercury), polychlorinated dibenzodioxins and furans (PCDD/F), and benzo(a)pyrene as a reference substance for polycyclic aromatic hydrocarbons. Additional maximum levels are in preparation, e.g. for non-dioxin-like polychlorinated biphenyls (PCBs). But for other contaminants, maximum levels only exist on different national scales, e.g. arsenic maximum allowable concentrations in the UK for food in general, while in Spain only for fruits, vegetables and seaweed.

At the same time, the internationally agreed upon maximum levels from the *Codex Alimentarius* (CA) are growing in their importance as a means to secure the safety of food worldwide and to avoid trade barriers for food products between countries. CA maximum levels are referred to by the World Trade Organization (WTO) as suitable hygienic standards in the context of the WTO “Agreement on Sanitary and Phytosanitary Measures” (SPS Agreement).

1

2 In recent years, it has been emphasized that food safety and transparency of
3 the food-related regulatory process is of pivotal importance to enhance
4 consumer's confidence in food in Europe (Horton, 2001). Taking into
5 consideration the above mentioned parallel existing standards for environmental
6 contaminants in food, the German Federal Ministry for the Environment, Nature
7 Conservation and Nuclear Safety initiated a research project, which was
8 overseen by the German Federal Institute for Risk Assessment. This project
9 aimed to provide an analysis of the regulatory processes leading to the
10 derivation of maximum levels for environmental contaminants in food. It focused
11 on the methods for standard-setting in the EU and at the *Codex Alimentarius*,
12 as well as on the national values existing in Germany and - for comparison - in
13 the USA and takes into account both risk assessment and risk management
14 issues.

15

16 **Methods**

17 A synoptic analysis was performed for existing maximum levels for
18 environmental contaminants in the EU Regulations 466/2001, 221/2002,
19 2375/2001, 684/2004, and the *Codex Alimentarius* Standards CAC/GL 39-2001,
20 CAC/GL 7-1991, and Codex Stan 230-2001, the German Schadstoff-
21 Höchstmengenverordnung (SHmV, "Pollutant Maximum Level Directive") and
22 the action levels and tolerances of the US Food and Drug Administration for
23 methyl mercury and polychlorinated biphenyls.

1

2 Environmental contaminants as defined herein are substances that originate
3 from diffuse sources and may appear in foods based on their ubiquitous
4 presence in the environment. Only non-carcinogenic substances or carcinogens
5 with a presumed threshold-related mode-of-action (e.g. PCDD/F) are included
6 in this synopsis. Table I gives an overview of the evaluated maximum levels
7 and the associated legal documents.

8

9 [Insert Table I about here]

10

11 The analysis of the derivation of the maximum levels in food can be
12 differentiated between the tasks of the risk management bodies and the tasks of
13 the risk assessment bodies. The latter evaluate health effects and the intake of
14 a contaminant (including derivation of values for a tolerable intake, e.g. tolerable
15 daily intakes (TDI)), whereas risk managers, by setting maximum levels,
16 consider the outcome of the risk assessment process, the concentration of the
17 contaminant in food, socio-economic arguments, the technical feasibility of
18 derived values and other arguments. As the setting of maximum levels by the
19 CAC as well as in the European Union requires an agreement of independent
20 nations it is obvious that political discussions are part of the risk management
21 process.

22

For both parts, all available documents describing both the principal approaches of each of the responsible bodies and the substance-specific lines of argumentation were evaluated. Documents included e.g. EU directives, evaluations and opinions of scientific committees like the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the EU Scientific Committee on Food (SCF), and minutes of meetings of the *Codex Alimentarius Commission* (CAC). A standardized evaluation sheet was used to gather the detailed characteristics of the values with the following main groups of information:

- general information (e.g. organisation, liability, protection goal, target population)
- underlying health effect assessment
- exposure information used (e.g. population groups considered, data quality)
- criteria used for derivation of values (e.g. health aspects, analytical limit of detection/quantification, socio-economic reasons, background contamination, barriers)
- consequences of non-compliance with maximum levels.

During the project it was noticed that documentation of the regulatory processes for all organisations is generally scarce, at least for some aspects. Consequently, the project approach was broadened. When expanding the source material to beyond the documents provided by the regulatory bodies as

the basis for the maximum levels, several key elements for deriving maximum levels were identified and compared with the actual procedures used. To this end, publications in the scientific literature were evaluated as well as background documents (e.g. CAC, 1997; CAC, 2004; WHO, 2000; WHO, 2003), research reports (e.g. EFCOSUM, 2001), and other sources related to food safety. Furthermore, food safety experts were contacted bilaterally via e-mail or face-to-face interviews for in-depth analysis of specific topics. This expanded analysis was presented to and supported by an expert panel accompanying the project during two meetings.

Results

Synopsis: Derivation of maximum levels

The evaluation showed that maximum levels or comparable limit values exist for only a few environmental contaminants (Table I). These values partially differ in their legal status. The maximum levels of the European Union are legally binding to all member states. By definition, the *Codex Alimentarius* values only represent recommendations, yet they attain a prescriptive character at the same time due to their acceptance by the World Trade Organization (WTO) as international hygienic standards. Action levels and tolerances of the US FDA (Food and Drug Administration) differ in their degree of legal responsibility and enforceability.

1 In cases where values from different procedures are available for the same
2 contaminant within the same food commodity (e.g. heavy metals in EU and CA
3 regulations) and, thus, a comparison is possible, the numeric values are
4 identical for the most part. For example, values for lead in milk, fruits and other
5 food groups are numerically identical in the respective EU Directive
6 466/2001/EEC and Codex Standard 230-2001. For cadmium the EU set
7 maximum levels for a lot of individual types of vegetables. This was done by the
8 CAC only recently in a similar way when Codex Standard 248-2005 came into
9 force.

11 The general objectives of the standards are principally the same: they aim at
12 ensuring the food to be safe for consumer's health and reducing the burden of
13 contaminants in food to a level as low as possible. In addition, the standards of
14 the *Codex Alimentarius* as well as the EU standards intend to facilitate the free
15 trade of food products.

17 With respect to the data and methods used to derive the values, distinct
18 differences could be discerned (Table II):

[Insert Table II about here]

21 Most of the values, with the exception of individual maximum levels of the
22 German SHmV, are based on toxicologically derived tolerable intake values.
23 For some of the values (Pb, Cd, Hg values of the EU, all standards of the

German SHmV) only limited or no information on the exposure data (data on food contamination as well as on food consumption) underlying the derivation of the values is available. Therefore, a satisfactory transparency is not possible here. For the remaining maximum levels, the underlying exposure data are more or less well documented.

A review and update is intended for all maximum levels, if the apparent data situation warrants it, with the exception of the German SHmV. For the US values, however, no updates have been undertaken in the last 20 years after initial amendments. In all regulations examined, the availability of suitable analytical procedures for monitoring purposes is considered important. Only for the maximum levels of the US FDA are the substance-specific derivations well documented. For the EU values, no documents are available that provide information on the rationale for the individual values. The short background information given in the German SHmV also does not provide sufficient information to understand nor to retrace the numerical derivation of the values. In spite of access to the protocols of the sessions of the *Codex Alimentarius Commission* and the Codex Committee on Food Additives and Contaminants (CCFAC), it remains unclear which considerations were finally responsible for setting the values of the Codex Alimentarius.

As a result of the incomplete documentation, it cannot be ascertained for individual values whether additional criteria (e.g. best available practice, socio-

1 economic factors) besides safety for human health were important when
2 deriving maximum levels.

3

4 In summary, the documentation of the derivation of maximum levels is
5 insufficient for a transparent standard-setting. A methodological document only
6 exists for the limit values of the Codex Alimentarius procedure.

7

8 *Synopsis: Derivation of tolerable intakes*

9 The toxicological evaluations that form the basis for the maximum levels are
10 better documented. The Joint FAO/WHO Expert Committee on Food Additives
11 (JECFA) is responsible for the evaluation and derivation of TDIs for
12 contaminants upon request of CAC. JECFA is presenting its evaluations in
13 comprehensive monographs. The JECFA evaluations regarding heavy metals
14 also formed the basis for the derivation of maximum levels in the context of
15 Directive (EC) 466/2001. The Scientific Committee for Food (SCF), which was
16 responsible for the toxicological evaluation of PCDD/F in 2001 in the EU,
17 formulated its evaluation as opinion reports. Responsibility for the evaluation of
18 contaminants in the EU has recently been reassigned to the newly formed
19 European Food Safety Authority (EFSA) and EFSA's "Panel on contaminants in
20 the food chain" (CONTAM) continued the SCF tradition to document its
21 evaluations by publishing opinion reports (e.g. EFSA, 2004). EFSA acts as an
22 independent scientific body that responds to requests by the Health and

Consumer Protection Directorate General of the European Commission on the basis of defined “Terms of Reference”.

The methodological approach used by JECFA and WHO committees has been described in two Environmental Health Criteria documents (WHO, 1987; 1994) and continuous efforts for methodological improvements and harmonisation is undertaken by WHO in the framework of its “IPCS harmonization programme” (<http://www.who.int/ipcs/methods/harmonization/en/>) and the “IPCS project to update the principles and methods for the assessment of chemicals in food” (<http://www.who.int/ipcs/food/principles/en/index.html>).

The principal approach for deriving tolerable intakes used by EU scientific committees is comparable to that of JECFA, applying safety factors to NOAELs (no-observed-adverse-effect-levels). Evaluation of polychlorinated biphenyls in the USA by FDA used both threshold and non-threshold concepts. This probably reflects the state-of-knowledge on this group of substances back in the 1980s, and should not be taken as proof of diverging methods. Only for the *Codex* and EU maximum levels could continuous follow-up activities be identified for the underlying toxicity and exposure assessments.

Proposals for improvement or harmonisation with respect to exposure assessment

Exposure assessment for environmental contaminants in food requires data for the concentration of the contaminants in various food types, as well as data on

1 the food consumption. Information on contaminant concentrations may come
2 from total diet studies (also called market basket surveys), from duplicate
3 studies or from other data on individual dietary items. To calculate contaminant
4 intake from data on occurrence of contaminants in various food items and from
5 food consumption data food categorisation systems are of special importance
6 (Ireland and Moeller, 2000). Categorisation systems allow to bring both types of
7 data together and to compare the food items investigated. These systems
8 aggregate various food items into groups, which may be hierarchically
9 structured or not, e.g. in a hierarchical system oranges may belong to the group
10 of citrus fruits, which belongs to the fruits group.

11
12 Various categorisation systems are in use, e.g. two different systems have been
13 used recently by the Codex Committee on Food Additives and Contaminants for
14 food additives and contaminants (CAC, 2001a; CAC, 1997). In EU “Scientific
15 cooperation” (SCOOP) task reports, which compile exposure data for various
16 contaminants in food, different approaches have also been used to collect data
17 from Member States. The SCOOP report on heavy metals and arsenic used the
18 Codex categorization system for food additives (SCOOP, 2003). The SCOOP
19 reports on dioxins didn’t make use of a specific categorization system. Rather,
20 member states were asked to provide consumption data for any food item for
21 which occurrence data were available (SCOOP, 2000).

Recognizing that different purposes may require different systems and no single system may serve all purposes, there is still a need and room for improvement for the harmonisation of categorisation systems. Considerable effort has already been spent in the past to harmonise categorisation systems for food or to find a common approach for the exchange of data (e.g. EU research projects DAFNE, EFCOSUM, see e.g. Ireland and Moeller, 2000; EFCOSUM, 2001). One promising approach is the Euro Food Groups Proposal, which combines food items in 33 basic groups (Table III). In a recent opinion of the EFSA Scientific Committee on exposure-related questions it was proposed to aggregate the Euro Food Groups further into only 16 groups for the development of an EU concise food consumption database (EFSA, 2005a).

[Insert Table III about here]

Additional difficulties arise when intake of contaminants is to be assessed from insufficient data on the occurrence in food. Uncertainty in the assessment refers to, among other things, insufficient or unknown analytical quality standards, availability of data for only unprocessed crops, and different ways to deal with concentrations below the limit of detection (Kroes et al., 2002). The poorer the data quality situation, the more important it is to indicate how data quality and reliability is assessed and how data gaps are dealt with. Table IV lists some important issues which should be addressed within an exposure assessment for food contaminants.

[Insert Table IV about here]

Probabilistic exposure assessment methods allow for consideration of (some of) the variability and uncertainty connected to the variables influencing the exposure assessment (Kroes et al., 2002). Probabilistic methods are especially useful to describe the variability in intake levels in the human population. Intake assessment should not only focus on the average exposure but consider also intakes for special risk groups (e.g. children) and the higher end of the distribution (population groups with higher than average intakes, e.g. populations with high fish consumption with respect to contaminants in fish). Considering the increased efforts for a probabilistic assessment, a tiered approach might be useful, starting with simple point estimates of intake. The second step is the description of intake distributions, taking into account variability in the human population. The most sophisticated step would consist in probabilistic modelling, considering major sources of uncertainty and variability (Hart et al., 2003; Leclercq et al., 2003). EFSA also recognized the significance of a clear methodological approach to exposure assessment, especially with respect to associated uncertainties (EFSA, 2005a).

The focus of maximum levels is to regulate exposure from food. But for certain substances exposure from other sources may significantly contribute to the overall body burden. E.g. infants may take up substantial amounts of lead from drinking water used for the preparation of baby formulas (Wilhelm et al., 2004). Other potential sources are inhalation or dermal/oral contact to consumer products, house dust, soil, etc. (Olin, 1998). Significant contributions from these

1 pathways to the overall intake of a contaminant should be considered in the
2 exposure assessment, taking into account the pathway-specific absorption
3 efficiency, as absorption from water, food and air may vary considerably
4 (Sunderman et al., 1989; WHO, 1994).

5 *Proposals for improvement with respect to risk management*

6 Risk management decisions make use of the outcome of the risk assessment
7 process but have to take into account additional arguments. These include the
8 considerations to avoid trade impediments, to address social and economic
9 factors, and to reduce concentrations of contaminants in food to levels as low
10 as possible, while taking into account the technical feasibility in applying best
11 practice (conformity to the values with justifiable methods, analytical
12 verifiability).

13
14 Both in the Codex system and in the EU, the risk assessment and the risk
15 management processes are separated and dealt with by different organisational
16 bodies. This guarantees that scientific opinions are not influenced by the above
17 mentioned risk management arguments. At the same time, information flow
18 must be secured (Lützow, 2003). For optimal information of risk management
19 committees, it is proposed here that the risk assessment body which carries out
20 the exposure assessment describe in detail what proportion of the tolerable
21 daily intake is consumed by different levels of the contaminant in food. This
22 information is most important for risk managers when contemplating lines of
23 argumentation for higher or lower maximum levels. After having proposed

specific maximum levels, risk managers should also inform the public about the level of contaminant intake associated with these maximum levels compared to the tolerable daily intake (Figure 1).

[Insert Figure 1 about here]

Risk management decisions require that various arguments and interests be weighed and balanced against one another, which might be difficult especially on an international scale. For reasons of transparency, major lines of argument leading to the derivation of specific maximum levels should be summarized. The outcome of the decision-making process should also be interpreted in terms of the health protection level achieved, in terms of the economic and social balances, and in terms of the technical feasibility. Publication of substance-specific reasons for a maximum level in a concise document would be an important step towards transparency and would help to increase confidence in food safety. Table V lists recommendations for improving transparency of the risk management process.

[Insert Table V about here]

Discussion

At present, only a few maximum levels for environmental contaminants are provided by the EU and the *Codex Alimentarius*. But numbers are expected to rise in the near future, substituting still existing national values, e.g. for arsenic

1 and non-dioxin-like PCB. As far as comparisons are possible, the numerical
2 values, e.g. from EU directives and from Codex standards, are in close
3 agreement. To the extent disclosed in the available documents, the principles
4 for deriving maximum levels are similar with all institutions. The prime objectives
5 are to protect human health, while avoiding trade barriers.

6
7 To provide better information concerning the risk management process, it is
8 proposed herein that for various contaminant levels in food, the degree to which
9 the tolerable daily intake values are exhausted at these levels, should be
10 described in the risk assessment reports. This exercise should be done at least
11 for those food items which contribute most to the intake of the population. This
12 would inform the risk managers directly about the health consequences of
13 various risk management options and would make time-consuming additional
14 consultations with the risk assessment bodies unnecessary.

15
16 The synopsis shows that differences exist between the risk assessment and the
17 risk management portion of the derivation of maximum levels for environmental
18 contaminants, specifically in respect to documentation and transparency.
19 Scientific bodies like JECFA and the CONTAM panel of EFSA are publishing
20 their substance-specific risk assessments in comprehensive monographs or
21 opinion reports.

1 Outcomes of the decision-making process within risk management bodies like
2 CCFAC and SCFCAH, are not documented transparently nor presented in
3 satisfactory detail. A recent example is the proposal of maximum levels for non-
4 dioxin-like PCB by the European Commission (BMU, 2006). Proposed
5 maximum levels are not accompanied by any documentation of the arguments
6 leading to specific numerical values. Recently, the EFSA CONTAM panel
7 evaluated the non-dioxin-like PCB. The panel did not derive a tolerable intake
8 because parallel exposure of non-dioxin-like and dioxin-like PCB impedes the
9 differentiation between them. The panel emphasised, however, that efforts to
10 lower the levels in food should be continued (EFSA, 2005b).

11
12 Protocols of CCFAC meetings are also not particularly helpful in this regard, as
13 the arguments leading to specific values are not documented. A reason might
14 be that socio-economic and technical arguments cannot be communicated as
15 easily as the scientific (e.g. toxicological) arguments. Ultimately, setting
16 maximum levels is a political decision, which takes into account scientific
17 arguments, but has also to achieve agreement of involved states. Nevertheless,
18 all these arguments are important for the attained numerical values. For the
19 sake of transparency of the overall process of deriving maximum levels,
20 documentation of the methodological approach as well as the substance-
21 specific discussion and results is urgently needed for all parts of the process.

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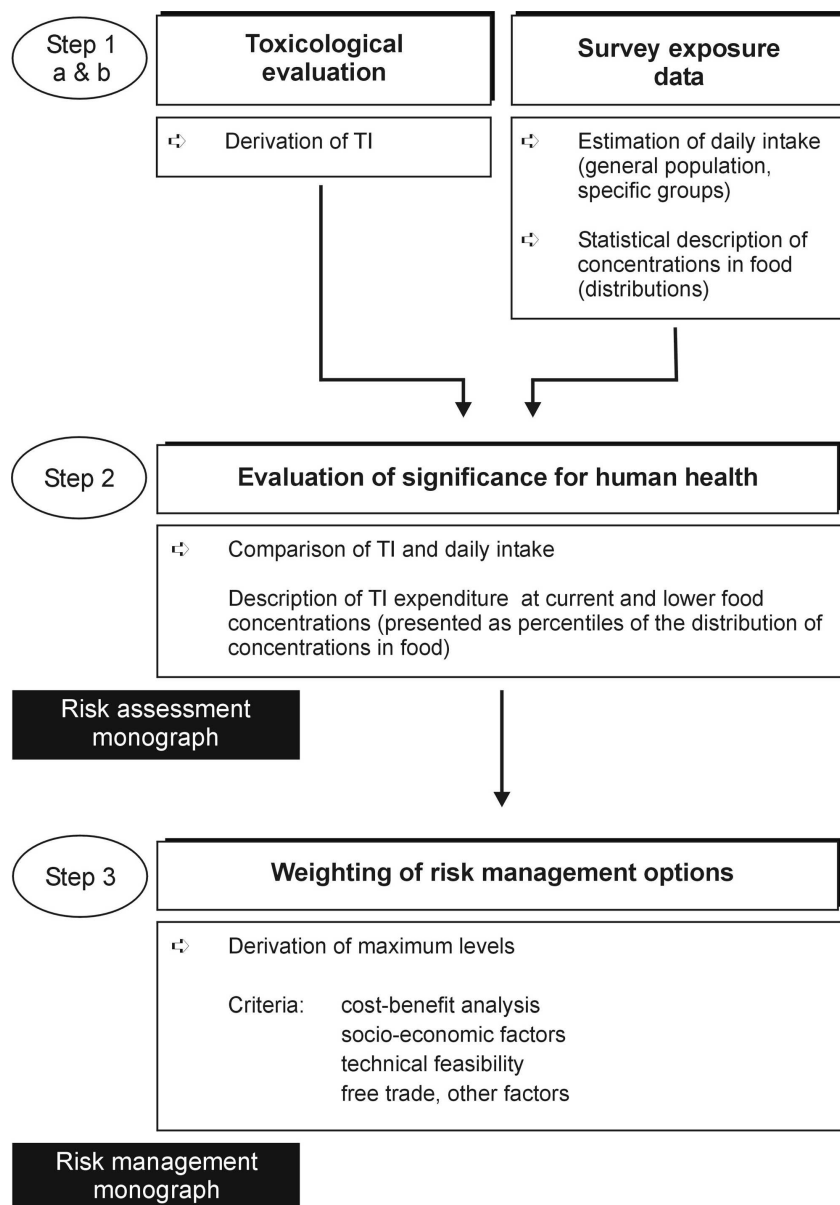
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Recommendation on the division of tasks between risk assessment (Steps 1 and 2) and risk management in the derivation of maximum levels (TI: \hat{A} tolerable intake \hat{A})
168x241mm (300 x 300 DPI)