Bundesinstitut für Risikobewertung (BfR)
(Federal Institute for Risk Assessment)

Guidance Document

The Format for Health Assessment Documents

Last updated: May 2003

Title

1. Subject of Assessment

2. Results

3. Argument

- Risk Assessment
  - *Agent*
  - *Potential hazard*
  - *Exposure*
  - *Risk characterisation*
- Other Aspects
- Discussion
- Scope for Action/Measures

References

Date of last search

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Introduction

1. BfR: Principles of approach

(1) In accordance with its terms of reference, the BfR should estimate and assess the risks posed by specific substances, products and processes for human and animal health, to recommend measures that may have to be taken and to point out areas where action is required.

Specific problems may also ask for an assessment of the benefit claimed for such substances, products and processes.

(2) The statements and assessments made by the BfR should be substantiated, taking into consideration the following:

- Existing knowledge should be presented adequately and conspicuously; and any relevant scientific viewpoints to the contrary mentioned;
- The latest state of scientific and technical knowledge should be expressed so as to be comprehensible for the respective target group and conclusions be reproducible for outsiders;
- Efforts should be made to include reference to earlier statements and the statements of other organisations;
- The comments made should be in line with internationally recognised principles of risk analysis.

(3) It is not always possible to present the comments made by the BfR in full and, for reasons of efficiency, this is *not always necessary*. However, in many cases and in spite of incomplete information, consumer protection measures may have to be taken and sometimes, they must be taken *very quickly*. This should be borne in mind when developing risk assessments, as they are meant to serve as a basis for decisions.

(4) Unless legal reasons prevent them from doing so, the BfR make health assessments of general interest available to the general public. As far as possible and appropriate, external expertise is considered by the BfR when conducting health assessments, by way of e.g. hearings or advisory committees.

2. Purpose of this guidance document

(5) To assist them in complying with the above-mentioned requirements under conditions of practice, the guidance document entitled *"The Format for Health Assessment Documents"* has been distributed among the employees of the BfR. On principle, all BfR documents commenting problems of health assessment (listed in Appendix 1) should conform to this format.

(6) The guidance document should be applied in a flexible manner and adapted to the individual case to be assessed.

(7) The guidance document is designed to facilitate implementation of the above-mentioned requirements by formatting instructions based on uniform principles, thereby contributing to an improvement in quality.

(8) The guidance document is reviewed and updated at regular intervals.

3. How to use this guidance document

(9) “Health Assessment” documents produced by the BfR should be given a title and, as a minimum, consist of the following main sections:

Subject of assessment
Results
Argument

(10) Depending on the subject, a specific, uniform format of the document should be attained by using *subsections*, which are given below for standard cases. In individual cases, the format may be adapted to the type of process involved (see list in Appendix 1).

(11) To facilitate understanding of the document, subsections not required due to the nature of the subject may be omitted.

(12) The document is transmitted as an *enclosure to a covering letter*. In the covering letter, reference may be made e.g. to the result, disclosure to third parties, confidentiality, etc.

(13) At the left-hand side of the document head, the words "Bundesinstitut für Risikobewertung (BfR)” and the BfR file reference should appear. The right-hand side of the head of the assessment should show the word "Enclosure" and the date of the document.

(14) As the document is occasionally passed on by the organisation/person to whom it is addressed, e. g. for use in administrative procedures, *legal proceedings* or for publication on the internet, the statements made therein should be clear and not require any further explanation.

(15) In the interest of a *uniform technical and legal terminology* also within the BfR, existing and documented terminology, e.g., legal definitions should be used. For reasons of uniformity, the text formatting instructions shown in Appendix 2 should be observed.

II. Structure of the document

Title

(16) Each assessment document should be given a short title. A heading with key words should make it possible to quickly allocate the assessment document and should contain e.g. information on substances, products and matrices.

1. Subject of assessment

(17) The subject of the health assessment should be described here. Where required for understanding of the problems involved, information on *cause and background* should be given.

(18) A *repetition of the question asked*, with reference to previous correspondence and the current status of the procedure will help the reader to familiarise with the subject.

(19) If relevant, the legal provisions may be cited which could be used for the assessment and, if applicable, for the minimisation of the risk involved.

(20) If a product is assessed, a brief *product characterisation* is given here, e.g. by stating the CAS number, the product name, licence number or similar data, ingredients, packaging, indications etc., if the product is not identifiable otherwise. Also, where product groups and substance groups are to be assessed, a definition and delimitation of the subject of the assessment is necessary.

2. Results

(21) If required, a very brief summary and a *conclusion* based on the information given in the Argument section may be presented here. Example: "The BfR agrees to an approval of this product / under the following conditions / for 10 years." At this point, the length of the wording will not exceed one paragraph.

3. Argument

(22) The Argument chapter (Justification chapter) which refers to *risk assessment and recommendations/options for action* is based on the knowledge available to the BfR which is presented in a conspicuous and structured manner and whose sources should be disclosed by citations or other data including such from studies conducted at the BfR. The BfR should draw their own conclusions from the available scientific knowledge.

(23) This knowledge may originate from the following *sources*:

- Approval/notification dossier submitted by the person/organisation responsible for the product;
- Scientific literature;
- Other publicly available information;
- Opinions expressed by (scientific) panels;
- Opinions expressed by external experts;
- Results of research conducted by the BfR; and
- Other information available to the BfR.

(24) In the Argument chapter, the adequacy of the available data for a *sufficiently reliable statement* on the inherent risk or the benefit to health should by established. In cases of uncertainty, lack of knowledge or controversy, the most appropriate place for doing so is in the

section in which the problem occurs, e.g., in cases of doubt concerning the validity of food consumption studies containing exposure data, in the Exposure chapter.

(25) The Argument chapter should reveal

- The extent to which the BfR can rely on information in a dossier (approval/notification dossier), e. g. that submitted by the *person / organisation responsible for the product*;
- The extent to which the dossier – due to legal provisions or for other reasons – lacks certain information necessary for a decision, and further action to be taken in this case;
- The extent of inadequacy of data submitted to the BfR by the person / organisation responsible for the product so that they have to rely solely on their own research using publicly available sources and the gaps in knowledge which may arise as a result;
- Where there is a discernible lack of knowledge and to what extent this may influence the evidence of the results;
- Where any necessary quality requirements have been ignored in studies and to what extent this influences the reliability of the results;
- Where any opposing scientific views which may be relevant have been presented; and
- Where differing interpretations in international assessment systems, e. g. of rules for classification and labelling, may influence the results.

Risk assessment

(26) In this section, the following question is commented:

Which health risks arising from a substance, product, group of substances or products, or microbial agent may be derived on the basis of contemporary scientific knowledge?

(27) In each case, it should be examined whether the following sections are actually relevant to the issue. They have been developed on the basis of comments on individual substances but remain principally valid for statements on mixtures of substances and products. The proposed structure for subdivision of a risk assessment document, i.e.

- *Agent*
- *Potential hazard*
- *Exposure*
- *Risk characterisation*

should not lead to a duplication of explanations in various places in the text but rather condense the explanations. Where justified in single cases, this structure may vary.

- *Agent*

(28) This section describes the agent (possible risk source, risk factor), e.g. a product, a substance or a microbial agent. The description includes, as a rule,

- Identification of the agent and its chemical, biological or physical characteristics, the properties of a microbial agent, including its pathogenicity, virulence factors, and the minimal infective dose;
- Knowledge of the qualitative and, where relevant, the quantitative distribution of a microbial agent in the environment, among farm animals and in food production, e.g. along the food chain;

- A description of general analytic or diagnostic data;
- Where relevant, a discussion of the methodological detection limits and possible contaminants;
- A description of the presence, production and use of the agent in accordance with its proposed purpose and under foreseeable conditions of use; and
- knowledge of agent-food combinations and the influence of food technology on the microbial agent.

- *Potential hazard*

(29) This section describes the *potential hazard* of the product, substance or micro-organism involved *(hazard identification*). It gives information on the identification of possible damage to health or other unacceptable effects, on the incidence of illnesses and possible complications caused.

(30) The potential hazard and pathogenesis are described, taking into account the intended use of the agent (e. g. of the product), especially in view of microbiological risk factors associated with the respective foods. The degree of severity, the duration and clinical manifestations of possible health hazards are commented.

(31) The effects are *related to the dose (hazard characterisation).* The characterisation should be presented in the commonly used order, e. g.:

- Toxicokinetics / pharmacokinetics (intake, distribution, metabolism, excretion)
- Infection-related effects (e.g. pathogenicity, infectivity)
- Toxic effects, e. g. acute toxicity, sub-chronic/chronic toxicity, mutagenicity, carcinogenicity, reproductive toxicity, neurotoxicity)

Regarding an assessment of the dose-effect relationship of microbial risks, the interaction of *the microbial agent* (taking into account its minimal infective dose and its virulence factors) with the *matrix* (e. g. with respect to the multiplication behaviour of the microbial agent in a defined type of food) and the *human body* (taking into account e.g. immune status and age) should be described.

(32) Toxicological or epidemiological parameters[1] should be described, e.g.:
- NOEL;
- NOAEL;
- LO(A)EL; and
- Incidence figures and other information on frequency.

(33) If applicable, health-relevant dosage limits[1] should be derived and stated, e.g.:
- ADI;
- ARfD; and
- AOEL

[1] See list, Appendix 3

- *Exposure*

(34) This section refers to exposure estimates. These may be based on the following:

- Information on exposed *population groups* and, if applicable, different exposure situations for consumers, users, sick persons, pregnant women, taking into account age and body weight;
- Information on the *distribution* of the microbial agent, e.g. on the type of products harbouring the agent;
- Information on *consumption data* and other information on the frequency of exposure; and
- Information on the qualitative and quantitative presence of a microbial agent and/or the *residue levels* in and on foods or other products.

- *Risk characterisation*

(35) In this section the risk is characterised *in summary form (risk characterisation)*. Unless considered before, the following topics should be covered:

- A comparison between the *potential damage* caused by the product, substance or microbial agent and the calculated or estimated *exposure*, taking into account the *dose-effect relationships* and the *exposure limit values* ;
- Consideration of incidence data which should be as accurate as possible (calculated or estimated by means of reports on individual cases and other information);
- Rating of the *quality* of the available data and consideration of uncertainties; and
- If relevant, mention of special *exposure scenarios* and outline of different risks together with data on frequency and incidence.

(36) The following points on risk characterisation should be covered in a summarised form:

- Characterisation of a hazard/risk for the population or individual sub-groups;
- Evaluation of the *probability* of the *occurrence* of impairment of, or damage to, health;
- Evaluation of the extent of health impairment or damage; and
- If relevant, a comment on *user and consumer safety.*

<u>Other Aspects</u>

(37) This section is optional. It contains explanations beyond the scope of the above-mentioned risk assessment if these are needed to substantiate the result. In particular, reference may be made here to *misleading information* for consumers.

(38) For example, reference may be made to health benefits, for example, in appraisals of

- Foods and food ingredients for which positive health effects are claimed; and
- Specific dietary regimens which allegedly offer health benefits.

(39) The presumed effectiveness of governmental *monitoring measures* may be discussed here if these have any influence on potential risks.

(40) Methods of detection and monitoring may also be described here.

(41) Comparative risks may be considered if being of relevance to the result. This may be necessary, e.g. where there is a threat of malnutrition or an insufficient supply of vital nutrients can occur.

Discussion

(42) This section is optional. If considered expedient, the chapters on Risk Assessment and Other Aspects may be discussed in summary form here, e.g.

- Whether the health benefits claimed for the population or individual groups if weighed against the risks are justifiable;
- Why there is reason for concern from the angle of consumer health protection on the basis of the information presented and its assessment; and
- Whether the methods recommended for official control will guarantee success at justifiable expenditure.

Any points of the information available which require clarification may be discussed here if this is necessary to substantiate the result and appropriate at this point as part of the BfR opinion.

Scope for action / measures

(43) This section discusses the extent to which the BfR regards *measures for consumer protection* (protection against potential health hazards and misleading of consumers) necessary or the possible scope of such measures, cf. § 2, para 1, Nos. 1 and 2 of the BfRG. The actors involved may be: manufacturers, commerce (downstream users), government authorities, legislative bodies, or consumers.

(44) The following measures to protect consumers may be considered

- Restrictions of distribution/sale or commercial use;
- Limit values / standards for a tolerable exposure, e.g. maximum levels in foods when being marketed, the microbial counts in foods at the time of consumption;
- Classification, labelling, warnings, recommendations and restrictions on use;
- Measures to avoid or reduce contamination with and multiplication of microbial agents, the reduction of such agents in the food chain by producers/manufacturers, wholesalers and retailers, e.g. GHP, HACCP, hygienic or control measures, and consumers;
- Action to control misleading advertising claims; and
- Increased information and education of consumers.

(45) If a BfR opinion / assessment containing recommendations or options for action as a basis for an *administrative decision* is submitted for the purposes of legal proceedings, e.g. if consent to or consultation on the approval of a product is given or refused, then *precise, clear and unambiguous* phrasing and suggested measures are important. If applicable, standardised text elements may be used for this purpose. While reference is made to the pertinent legal provisions, it should become clear that similar hazards are considered in the same way as far as possible, as required by the provisions of the relevant special legislation. Together with the administrative decision, such opinions are subject to review by administrative courts in Germany.

(46) For *other cases* where the assessment gives rise to concern, targets, strategies and options for action are proposed. Where in opinions / assessments for legislative or supervisory purposes, several measures are considered as similarly suitable and necessary for risk reduction, the BfR will only point out the *scope for action* to the responsible institutions. In such cases the BfR does not restrict the option for the responsible institutions to a single set of measures unless there is an urgent need to do so. They are given all the technical information necessary for their decisions, especially those on the application of the precautionary principle. They decide on measures of consumer protection under the aspects of their suitability and feasibility.

(47) If relevant, the respective *consequences* of the various *measures/options for the consumer* are mentioned, e.g. the avoidance of risks among the general population, attentive readers of the product declaration, etc. Additionally, *technical and scientific background* information is given if necessary for a better understanding. Predictable trends for future distribution of the products concerned are mentioned and included in the suggestions.

(48) If necessary for understanding, information is given as to whether and to what extent measures have to be taken

- according to the principles of *risk/danger avoidance,* or
- according to the *precautionary principle*;

and whether they are

- imperative; or
- not imperative.

Information is given on whether and why an onward assessment may be necessary and what information or studies may be required for this purpose.

(49) If a *need for research* is expressed because available knowledge is unsatisfactory, this does not necessarily mean that no consumer protection measures are considered necessary at the present time. If there is sufficient cause for concern the BfR will specify consumer protection measures, *even where current knowledge is insufficient.*

References

(50) If a reference to literature is made in the text of the health assessment, the citation will commonly be placed at the end of the document. Reference should be made to original literature only. Citations should be in a uniform style throughout the entire document, but should also conform to external requirements for citation. Indication of the date of the last literature search is optional but occasionally this may be useful.

(51) Examples of citation style :

Schellhorn, B., Döring, A., Stieber, J., 1998. Zufuhr an Vitaminen und Mineralstoffen aus Nahrungsergänzungspräparaten in der MONICA-Querschnittsstudie 1994/95 der Studienregion Augsburg, Z Ernährungsw. 37, 198-206.

Stahly DP, Andrews RE, & Yousten AA (1991). The genus Bacillus - insect pathogens. In: Balows A, Truper HG, Dworkin M, Harder W, & Schleiffer K-H ed. The prokaryotes, 2nd ed. New York, Basel, Springer-Verlag, vol II, pp 1697-1745.

Surprenant DC (1989). Acute toxicity of Bacillus thuringiensis var. Tenebrionis technical material to rainbow trout (Salmo gairdneri) under static renewal conditions. Wareham, Massachusetts, Springborn Life Sciences Inc., pp 1-19 (Unpublished Abbott document).

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Reference: European Commission, First Report on the Harmonisation of Risk Assessment Procedures, 26-27 October 2000

Appendix 1

This Guidance Document is based on the following BfR documents being of significance for the format for health assessments:

No.	Document addressed to	Object of assessment	Procedures, Criteria
1	BMVEL	Foods, food ingredients, additives, flavourings, feeding stuffs and feeding stuff ingredients	Opinion on proposed legislation suggesting a derivation of ADI levels in accordance with JECFA (EHC Vol. 70), 89/107/EEC and EU documents (SCF).
2	BVL	Foods, cosmetics, tobacco products, advertising claims (if relevant), applications according to § 37 of LMBG	Opinion as preliminary work for a decision by BVL.
3	BVL	Foods, cosmetics, tobacco products, , advertising claims (if relevant), applications according to § 37 of LMBG	Opinion as preliminary work for a decision by the BVL
4	(Supreme) Länder authorities	Foods, food ingredients, feeding stuffs and feeding stuff ingredients, contaminants, advertising claims (if relevant)	Opinion as consultation and as argument for monitoring measures pursuant to LMBG (copy to BMVEL)
5	BMVEL; BMU, Länder authorities	Contaminants of foods and feeding stuffs	Opinion as consultation e.g. to determine maximum residue levels, guideline values and target levels. Also for EU and Codex Alimentarius position papers . e.g. on dioxins, mycotoxins
6	BMVEL; (supreme) Länder authorities	Contamination of foods with micro-organisms, e.g. agents of food infections and intoxication	Opinion for legislative purposes, also for EU and Codex Alimentarius, as well as opinion for purposes of surveillance
7	BMVEL; (supreme)Länder authorities	Production processes of foods and other products, e.g. in respect of possible influences on pathogenic organisms	Opinion on proposed legislation, also for EU and Codex Alimentarius purposes, as well as on risks from production processes – supervisory problems; (copy to: BMVEL)
8	BMVEL	Food irradiation	Opinion as preliminary work on Regulations pursuant to § 13 LMBG
9	BVL	Novel foods, applications, cf. provisions of the NLVO (Novel Foods Regulation)	Risk assessment in the form of opinions on initial assessment reports on applications submitted to the BVL or to applications or initial assessment reports from other Member States, declaration of consultation on the "essential equivalence" of the products
10	BMVEL	Genetically modified plants etc. used in the production of foods	Opinion on risk assessment in proposed legislation

No.	Document addressed to	Object of assessment	Procedures, Criteria
11	BMVEL	Coffee, tea, alcoholic beverages, tobacco products	Opinion on proposed legislation (assessment of products and their ingredients)
12	BMVEL	Ingredients of body care products and decorative cosmetics	Opinion on proposed legislation and listing of substances in the Cosmetics Regulations and European Parliament Directive 76/768/EEC
13	BMVEL	Olfactory substances	Opinion on the assessment of these substances and their regulation pursuant to the Cosmetics Regulations and European Parliament Directive76/768/EEC
14	BMVEL	Foods and other commodities covered by the Foods Act (food contact materials)	Opinion on the assessment of materials coming in contact with foods corresponding to Commission Directive 89/109, with TDI levels (for details see SCF Note for Guidance of Applicants)
15	BMVEL, Länder authorities	Other commodities covered by the Foods Act, e.g. toys, textile clothing	Opinion on the assessment of substances contained in such commodities, if necessary, with information on maximum migration levels, as developed by CEN (pursuant to Council Directive 88/378/EEC and according to assessments by CSTEE)
16	BMVEL	Governmental supervisory systems	Opinion on proposed legislation, also those of the EU and Codex Alimentarius
17	BVL	Feeding stuff additives, applications pursuant to the Feeding Stuffs Act, and guidelines	Declaration of consultation in the registration procedure, opinion
18	BMVEL / (supreme) Länder authority	Pharmacologically active substances	Opinion with assessment of residues of veterinary medicines / maximum residue levels for legislative purposes / purposes of surveillance
19	BVL	Plant protection products, applications pursuant to §§ 11, 15, 15b, 15c, and 18 of the Plant Protection Act	Assessment and declaration of consultation in the approval process for plant protection products in which the following critical limits were derived: ADI/former DTA , acute reference dose (ArfD), AOEL
20	BMVEL	Active substances of plant protection products	Opinion on proposed legislation with determination and substantiation of maximum residue levels of plant protection products in foods

No.	Document addressed to	Object of assessment	Procedures, Criteria
21	BVL	Active substances of plant protection products	Assessment of active substances for inclusion in Appendix I of Council Directive 91/414/EEC concerning the placing on the market of plant protection products (draft monographs, peer reviews); comments in letters to the BVL
22	BVL	Plant stimulants and additives, applications pursuant to § 31a III 1 of the Plant Protection Act	Declaration of consultation regarding the listing of plant stimulants
23	BAuA	Biocidal products, applications pursuant to §§ 12b and 12j of the Chemicals Act	Declaration of agreement in the biocide approval procedure
24	BAuA	Active substances of biocides	Assessment by the EU of active substances for inclusion in Appendices I, Ia or Ib of Directive 98/8/EC on the placing on the market of biocidal products (draft monographs, peer reviews, comments) in letters to the BAuA
26	BAuA	New substances / legislation on chemicals , applications	Opinion based on §§ 4, 12 of the Chemicals Act
27	BAuA	Existing substances / legislation on chemicals	Opinion with assessment based on Regulation (EEC) 793/93 in coordination with EU Member States as stipulated in the Technical Guidance Document or in § 17 of the Chemicals Act; measures of risk reduction by e.g. classification, labelling. Responsible for the Risk Assessment Report: BAuA. Or bans, restrictions etc.
28	BMU	Hazardous substances in water	Opinion on the classification of substances harmful to water pursuant to the Regulations on the Protection against Environmental Accidents
29	BMVEL	Fertilisers	Opinion on the assessment of the risk to human health from fertilisers, Fertiliser Regulations
30	Länder authority	Fumigants, applications for approval pursuant to § 15 d of the Dangerous Substances Regulations	Opinion
31	BMU; BMVEL	Reporting of cases of poisoning with chemical products, § 16c Chemicals Act	Opinion on product risks and suggested measures, if relevant

No.	Document addressed to	Object of assessment	Procedures, Criteria
32	Federal ministries, EU bodies, international panels, the German Länder, courts, institutions Multiplier agents	All substances, products and harmful influences covered by the terms of reference of the BfR	Opinions addressed to • Federal Ministries for purposes of establishing legal and technical norms/standards, for answers to parliamentary questions and other purposes; • EU and other international standardisation bodies; • German Länder, e.g. in matters of surveillance; • Authorities, courts and in justified special cases, also non-governmental institutions; and • Multiplier agents, as press releases and other forms of public relations on

Appendix 2

Formatting instructions

General Instructions for text formatting

Margins	Standard (left, right and top 2.5 cm, bottom 2 cm) should always be used. *This also applies to tables*.
Font type/size	Arial 11
Line spacing	Single spacing (one blank line between paragraphs)
Text alignment	Text block style with automatic hyphenation (no manual hyphenation). Hyphenation, in particular that of technical terms, should be rechecked.
Indentation	Use tabulators, not spaces
Sub-headings	One 'genuine' blank line before and after each sub-heading. Do not define a diverging value using the Format menu
Tables	Should not exceed one page in size. If this cannot be avoided, divide table, repeat the heading on the following page(s) and label the latter as a continuation page
Footnotes	Include these in the text body, do not place them in the footer.

Text structure formatting

Main Title	**Arial 12, bold**
Sub-Title	Arial 11, light
1.	**Arial 11, bold**
1.1	Arial 11, light, underlined
1.1.1	*Arial 11, light italic*
1.1.1.1.1	Arial 11, no additional highlighting

Further Suggestions:

Please avoid bold type that is underlined (a graphic form of tautology) and bold type for italics (another graphic form of tautology)

Instead of using "I" or "we" or "the rapporteur", use "the BfR", "the Federal Institute for Risk Assessment ", "the Federal Institute", etc.

Use a single and uniform date format in the entire text, e.g. "02.11.2002".

Appendix 3

Abbreviations used in this document

Abbreviation	German name / translation	English name / translation
ADI	Duldbare tägliche Aufnahme	Acceptable daily intake
AOEL	Grenzwert für die Anwenderexposition	Acceptable operator exposure level
ARfD	Akute Referenzdosis	Acute reference dose
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin	Federal Institute for Occupational Safety and Health
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety
BMVEL	Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft	Federal Ministry of Consumer Protection, Food and Agriculture
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	Federal Office of Consumer Protection and Food Safety
CEN	Europäisches Komitee für Normung	European Committee for Standardization
CSTEE	Wissenschaftlicher Ausschuss für Toxikologie, Öko-Toxikologie und Umwelt	Scientific Committee for Toxicity, Ecotoxicity and the Environment
DTA	Duldbare tägliche Aufnahmemenge	Tolerable daily intake (TDI)
EU-MS	EU-Mitgliedsstaaten	EU member states
GHP	Gute Hygiene-Praxis	Good Hygienic Practice
HACCP		Hazard Analysis and Critical Control Point
JECFA		Joint FAO/WHO Expert Committee on Food Additives
LMBG	Lebensmittel- und Bedarfsgegenständegesetz	Foods and Other Commodities Act
LO(A)EL	Niedrigste geprüfte Dosis mit beobachteter nachteiliger Wirkung	Lowest observed adverse effect level
NLVO	Verordnung über neuartige Lebensmittel	Novel Foods Regulation
NOAEL	Höchste geprüfte Dosis ohne beobachtete nachteilige Wirkung	No observed adverse effect level
NOEL	Höchste geprüfte Dosis ohne beobachtete Wirkung	No observed effect level
PSM	Pflanzenschutzmittel	Plant protection product(s)
SCF		Scientific Committee on Food
TDI	Duldbare tägliche Aufnahme	Tolerable daily intake