Health risks of excessive energy intake

Drinking energy drinks are a new kind of energy drinks that contain caffeine and sugar. In 2010, the German Federal Institute for Risk Assessment (BfR) published a guidance document on health assessments for energy drinks.

The document presents energy drinks that contain the declared dose of caffeine in either pure form or mixed with other substances. The drink is intended to be consumed as an alternative to other energy drinks, such as sports drinks.

According to BfR, if the energy drink is not used in accordance with the manufacturer's advice, health risks may arise. The study showed that energy drinks are sometimes used at higher concentrations than intended.

The document further states that excessive energy intake can lead to a range of health problems, including increased heart rate, increased blood pressure, and adverse effects on the nervous system.

At the time of the assessment, seven energy drinks were known to BfR. Five of these products were tested in detail. One product was tested as a dietary supplement for children and adolescents, especially for athletes. One product was also tested for athletes.

The document also notes that the caffeine content in these products is 1.3-5.8 mg per 100 mL. The highest concentration is found in one of the products, which contains 6 mg of caffeine per 100 mL. These products are often consumed at high concentrations, especially by young people.

The study concluded that the energy drink industry should ensure that consumers are informed about the potential risks of consuming energy drinks and that they are used correctly. The guidance document also recommends that consumers limit their energy drink consumption to one or two drinks per day and to monitor their health during consumption.
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I Principles

1 Aim of the guidance document

(1) The Federal Institute for Risk Assessment (BfR) is responsible for evaluating, assessing and, if necessary and possible, recommending measures for minimising and avoiding risks for human health of substances, microorganisms, products and processes and to provide possible options for action. In some instances it is also necessary to assess the benefit of substances, products or processes that is claimed (e.g. “health claims”, efficacy of biocides).

(2) The Opinions especially serve as scientific basis for:
- Decisions regarding the authorisation of products based on the product dossier and BfR’s own information,
- Decisions regarding action of those authorities that control food, chemical or product legislation,
- Court decisions regarding food, chemical or product safety and
- Actions by the national or EU legislative body or other political authority.

(3) BfR statements are to be in line with internationally recognised principles and are to include reasoning that is transparent for third parties. This is to incorporate and depict existing knowledge adequately and clearly. Relevant opposing scientific positions are to be included as well. References to previous BfR statements pertinent to the issue should be established.

(4) It may be the case that the data used to draw up an Opinion is scientifically insufficient. Yet even in cases where the state of scientific knowledge is incomplete, measures regarding consumer health protection are often valid or even mandatory. This must be taken into account when risk assessments are drawn up because they are meant to serve as a basis for decisions.

(5) Wherever it is possible and appropriate, BfR incorporates external expert knowledge in the process of drawing up an Opinion, e.g. by consulting with BfR Committees.

(6) BfR is required to publically communicate assessments that are of public interest, as long as confidentiality issues are not compromised.

(7) This “Guidance Document for Health Assessments” serves to implement the above stated principles into practice in order to assure the quality of BfR assessments. Members of BfR staff are instructed to use the guidance document as a standard for scientific Opinions published by BfR as far as possible.

(8) The guidance document constitutes a standard for the depiction of BfR health assessments, yet it is to be utilised flexibly. Deviations are possible, especially in cases where legal requirements apply or other forms of expression are more suited to a subject-specific issue. The legal scope of the guidance document is explained in Chapter III, p. 19 et seqq.
The guidance document is reviewed and edited on a regular basis.

2 Fundamentals of BfR health assessments

A risk assessment is the analysis of a risk by means of scientific methods. This includes:

- **Identification of a possible risk source** ("hazard identification"), i.e. the biological, chemical or physical agent which could have adverse health effects must be identified;
- **Characterisation of the hazard potential** ("hazard characterisation"), i.e. the qualitative and/or quantitative evaluation of adverse health effects that could arise from the risk source, if necessary under consideration of a dose-response relationship;
- Depending on the request, an **assessment of human exposure** ("exposure assessment"), i.e. the qualitative and/or quantitative evaluation of the intake of an agent with regard to the relevant routes of exposure in individual cases (intake through food intake, breathing or skin contact);
- Finally, a **characterisation of the actual risk** ("risk characterisation"), i.e. the qualitative and/or quantitative evaluation of the frequency and severity of adverse health effects in a certain segment of the population under consideration of uncertainties related to the assessment.

In qualitative risk assessments, risks are described verbally. The description follows the structure outlined in (10) as conceptual model. In contrast, quantitative risk assessments are at least partially based on calculations or mathematical models, and risks are described in mathematical or statistical terms based on these methods. In case a mathematical model is used, this should be selected for the specific risk question and depicted in a transparent manner. The numerical results of the model should be described verbally and incorporated in the answer to the request.

The following criteria are a selection of those to be taken into account for the risk assessment:

- The **affected population** or segment of the population (e.g. pregnant women, the elderly, sick people, children);
- The **probability** and, if it applies, the frequency of an adverse effect;
- The **nature and severity** of a possible adverse effect;
- The **reversibility** of a possible adverse effect;
- The **empirical evidence** for a causal relationship and **weight of evidence**;
- The **nature and quality** of available data including variability and uncertainty;
- The **controllability** of the risk. Whether or not consumers are able to minimise the risk is taken into account, e.g. heeding product information.

Transparency is essential on all levels of the risk assessment process. The assessment is to be comprehensible and reproducible from the initial objective to the scope of an opinion as well as source, nature and evidence of the underlying data, the methods, assumptions, uncertainty and variability all the way to the result and conclusion.

BfR risk assessments are also subject to the Institute’s risk communication as risk communication refers to the
purpose-specific exchange of risk information and opinions between stakeholders. Stakeholders include members of politics, science, public bodies, associations, non-governmental organisations and the mass media as well as individual citizens. Risk communication with all stakeholders – including knowledgeable target audiences – should follow the key basic rules of transparent, comprehensible and useful risk communication.

(15) If there are different scientific views on a point critical to the result of an Opinion, these are to be indicated transparently. If such a divergence of opinions of different national authorities or EU authorities exists, these differences are to be depicted especially precisely. Other scientists are then able to form their own opinion on the issue based on the explication.

3 Language use and terminology

(16) BfR Opinions are to use recipient-specific wording and reflect the current state of science with transparent reasoning. The Opinions are especially addressed to national and Länder authorities, which base their statutory authorisation and other executive decisions on BfR Opinions, as well as Federal Ministries that require basic scientific information for their political work. It is to be expected that recipients of BfR Opinions will pass these on to third parties.

(17) BfR Opinions should use target group-specific wording as much as possible. The target audience is broader than the original group of recipients. The target audience in particular includes members of politics, industry and consumer associations as well as individual citizens, e.g. applicants for national authorisation procedures. The Opinions can be used in scientific debates as well as in a judicial or political setting. Statements are to be well suited for use by the recipients and target groups without the need for further explanation. They are therefore to be worded in generally understandable terms, i.e. in lay terms.

(18) The wording is to be unambiguous and coherent within the context of other BfR Opinions.

(19) As far as possible, the assessment terminology used should be harmonised, e.g. in regard to assessment criteria, preferably based on an internationally recognised nomenclature. Terms should be consistent, clear and appropriate.

(20) In order to avoid linguistic diversity which could lead to misunderstandings, synonyms should be avoided, especially for the characterisation of health risks.

(21) Abbreviations and technical terms should be written out completely when first introduced and explained in generally understandable terms.

(22) BfR Opinions are to include enough information necessary for understanding, but not more. Unnecessary reiteration is to be avoided. When an Opinion is published, an abstract is added.
(23) If information regarding risk is communicated, the reference should be explained as clearly as possible and varied as rarely as possible within one text or section of a text. Examples: “not more than 100g per day”; “carcinogenic in animal tests”; “carcinogenic for humans”. It should also be noted that concentration data and units of measure are used consistently throughout the entire text in order to ensure comparability of data for laypersons as well (e.g. mg/kg body weight).

(24) Primarily numerical descriptions are to be used as far as they are available in regard to the frequency of adverse events, the extent of an adverse health effect, the probability of an occurrence of a risk etc. Thus, instead of a descriptive specification (e.g. an adverse event occurs “often”) numerical descriptions should be used (e.g. “the event occurred in x out of y cases”; or “no cases are known to have occurred”). The phrase “health risks cannot be excluded” should be avoided as especially in a court of law it has no merit. Numerical descriptions in the form of absolute frequencies (10 out of 1000 cases) are more easily understood by the target audience than percentages, especially if the percentages are small with decimal places.

(25) The frequency of adverse events can be indicated with keywords such as:
- Often,
- Occasionally,
- Rarely,
- Unknown to have occurred.

(26) The severity of an adverse health effect may be indicated with keywords such as:
- Serious,
- Moderate,
- Slight,
- Mild.

In addition, whether the adverse effect is chronic or acute, reversible or irreversible is taken into account.

(27) The probability of the occurrence of an event is characterised as:
- Certain,
- Probable,
- Possible,
- Improbable,
- Practically impossible.

Reference values for the interpretation of the terms (e.g. “certain: in more than 99 out of 100 cases” or by a comparison with known probabilities) should be provided. If quantitative assessments are available, these should be provided.

(28) Evidence of a causal relationship between possible risk source and the adverse health effect is characterised as:
- Generally accepted proof (= causality has been verified and accepted by the scientific community),
- Fact-supported reasons to suspect this (= facts make causality plausible),
- A concern (= relatively vague indications of a risk),
- No indications of risk.
It should be noted that statistical significance is not to be equated with biological significance. A statistically "significant" risk factor can be biologically irrelevant.

(29) The origin of data upon which the risk assessment is based must be indicated. This can include:
- The authorisation dossier of a company according to a legal provision,
- Scientific publications,
- Other publicly accessible information,
- Opinions of scientific committees or experts,
- Results from monitoring programmes, data from food consumption surveys,
- Other notifications received by BfR,
- Other BfR findings, e.g. from experimental BfR studies.

(30) The quality and validity of available data, the degree of uncertainty, the variability of results and unanswered questions during risk assessments should be clearly addressed and described with particular regard for comprehensibility. If recognised guidelines – as listed in Chapter IV, p. 21 et seqq. – are available for an assessment of the empirical evidence, these should be applied. The results of the assessment should be documented. If the information regarding an important aspect of the assessment is scientifically controversial and the scientific findings in this regard have not been compiled systematically, a systematic overview (systematic review) should be prepared and, if applicable, evaluated statistically (meta analysis).

(31) Certain terms are based on preformed notions because they are defined in legal provisions or introduced as legal terms in industry, law or the public. The concordant use of legal terms in BfR Opinions supports the coherence of risk assessments and aids risk management bodies in carrying out their tasks. For legal terms relevant to risk assessment and risk management see Chapter IV, p. 21 et seqq.
II  Content and structure of BfR Opinions

(32) The scientific assessment and other BfR Opinions should contain a title and the following main chapters:

- Subject of the assessment
- Results
- Rationale

(33) The structure of the document can be customised to suit the request by adjusting the subchapters. The structure can be adjusted individually to suit the subject of the Opinion. Which topics are subject to BfR Opinions are listed in Chapter III, p. 19 et seqq.

(34) An Opinion is usually sent out as an annex to a cover letter. The cover letter may contain information concerning the results, the dissemination to third parties or confidentiality.

(35) BfR Opinions do not contain the pronouns “I”, “we” or “the authors”, but rather “the Federal Institute for Risk Assessment”.

Image of structure
1 Title

Each document contains a short, informative title. A heading with **key terms** can allow fast classification of the document and contain information regarding e.g. substance, product and matrix.

2 Subject of the assessment

This chapter serves to introduce the subject of the health assessment. As far as this is necessary for a better understanding, information regarding the **grounds for and background of** the request should be included. If the scope of the question is unclear, it is imperative that this is clarified with the mandating authority as soon as possible.

Repeating the **request** in regard to prior communication and the status of the procedure facilitates the introduction of the issue. The request should be stated in a manner that allows the proceedings to be logically deduced.

The **legal provisions** which are the basis for the assessment of the risk and for risk minimisation should be included.

If a product is assessed, this chapter also includes a summarised **product characterisation**, e.g. by including designation (CAS number, product name, authorisation number or similar), ingredients, format, indications, microorganism, food or the food category etc. Defining and classifying the subject of the assessment is usually necessary.

3 Results

This chapter should include a short summary and the **conclusions** drawn from scientific research. The depiction typically does not exceed one paragraph. Examples:

- “BfR agrees to approval of this product/ under the following preconditions”
- “As a result of the quantitative exposure assessment, BfR deems it practically impossible that the TDI for X will be exceeded even when high portions of Y (95th percentile) are consumed”
- “The health claim made for the food has not been substantiated scientifically”

The main statement of the assessment (“take home message”) should be unambiguous and depicted in generally understandable terms.

4 Rationale

This section contains the reasoning that has lead to the assessment result. This includes a discussion on whether or not the data used to come to this result are sufficient, e.g. to what extent BfR can follow the claims and conclusions reached by the manufacturer’s authorisation dossier. The typical key aspects of risk assessments (frequency, data basis, etc.) listed in numbers (25) - (29) can be used as a “checklist”. Uncertainties, lack of information and matters of dispute are regularly discussed at the point in the rationale where the issue arises (e.g. doubts concerning the validity of food consumption surveys in the “Exposure” chapter).
4.1 Risk assessment

(44) This subchapter serves to explicate the extent to which health risks arising from a biological, chemical or physical source can be deduced from the state of scientific knowledge and how these should be assessed. It is often sensible to subcategorise the response to the request into the following points:

- Hazard identification,
- Hazard characterisation,
- Exposure assessment,
- Risk characterisation.

However, this should not result in multiple explanations in different sections and can be varied in individual cases if this is justified.

4.1.1 Hazard identification

(45) In this section, the possible risk source (agent) such as a product, a chemical substance (mixture) or a microorganism is characterised. This typically includes:

- The identification as well as the chemical, biological or physical characterisation of the agent; in the case of microorganisms, the characterisation of the pathogen including pathogenicity, virulence factor, minimal infectious dose, tenacity, etc.;
- Knowledge concerning the qualitative and quantitative prevalence of the agent in the environment, in the animal population and/or in the food chain;
- In the case of microorganisms, pathogen-food combinations and the influence of food technology on the pathogen;
- A depiction of the occurrence, production and application in accordance with intended and foreseeable use of the agent.

4.1.2 Hazard characterisation

(46) In this section, the hazard potential of the risk source and the pathogenesis with consideration for the agent’s intended application (e.g. of the product) are characterised. This includes information regarding possible adverse health effects or other adverse effects, the incidence of disease cases and, if applicable, complications. Opinions on severity, duration and clinical symptoms of possible adverse health effects are provided.

(47) Effects/responses are provided relative to the dose. This characterisation should reflect the prevailing order such as:

- Toxicokinetics/pharmacokinetics: absorption, distribution, metabolism, excretion;
- Toxic effects: acute toxicity, repeated dose toxicity, genotoxicity, carcinogenicity, reproductive toxicity;
- Infectious effects: pathogenicity, infectivity.

For the dose-response assessment of microbial risks, pathogen interaction (under consideration of its minimal infectious dose and its virulence factors) must be described. This includes matrix interaction (e.g. in regard to the growth of the pathogen in a certain food) and human interaction (e.g. in regard to immune status and age).

(48) Toxicological and epidemiological parameters should be explained (e.g. NOAEL), and if necessary limits relevant to human health should be derived (e.g. ADI, see Chapter IV, p. 21 et seqq).
If in addition to toxicological data, epidemiological or even clinical findings are available, these can be especially relevant for the assessment of risks to human health. The conclusions are to be drawn in regard to all existing sources of information and depend on the quality and methodology in individual cases.

4.1.3 Exposure assessment

(49) In this section, the exposure of a certain population is estimated. This is based upon:
- Information on exposed populations as well as different exposure situations for consumers, users, sick people, pregnant women under consideration of age and body weight;
- Information on the prevalence of the agent, e.g. which kinds of products release the agent;
- Information on food consumption data and other information on exposure frequency;
- Information on eating habits;
- Information on qualitative and quantitative occurrence of an agent and/or the residue concentration in and on foods or other products.

4.1.4 Risk characterisation

(50) Risk characterisation encompasses summarised information regarding the following dimensions:
- Description of the affected population or segment of the population;
- The probability and if applicable the frequency and duration of adverse events;
- The assessment of type and severity of adverse health effects;
- The reversibility of possible adverse health effects;
- The empirical evidence of a causal relationship;
- The type and quality of available data as well as variability and uncertainties;
- The controllability of the risk.

Consistent terminology should be used for risk characterisation, see p. 8, numbers 24 et seqq.

Frequency of adverse events:
From “often” to “unknown to have occurred”

Severity of an adverse effect:
From “serious” to “mild”

Probability of occurrence:
From “certain” to “practically impossible”

Evidence of risk:
From “generally accepted proof” to “no indications of risk”

Source of data:
e.g. publication, own study

Quality of data:
e.g. systematic review
In quantitative risk assessments, this section is to list and if necessary explain the calculations and mathematical models that were used. In cases where alternative models would have been useful, the effect on the result should be determined as part of the assessment of uncertainty.

Since natural variability in individuals (e.g. biological sex, lifestyle), populations or systems is relatively high, those influences that have the greatest effect on the assessment’s result should be identified and explained. The underlying data should therefore be analysed statistically as far as this is possible. Biological relevance should be taken into account as well.

In order to depict the product risk, it may be necessary to evaluate product-related consumer information. Product distribution conditions, e.g. the marketing of a product to children or for disease prophylaxis could have an essential influence on the risk and the risk assessment.

Assumptions upon which the assessment is based should be documented and explained. Other alternative assumptions that may also be possible are a form of uncertainty and should be documented together with other uncertainties.

The relevance and influence of perspectives and assumptions on the assessment result should be stated. It is to be stated whether and why further assessment or additional need for research appears necessary and what information or research is required thus.

This subchapter is optional. It includes additional remarks that go beyond the scope of the risk assessment detailed above if this constitutes a necessary explanation for the result. Such remarks especially concern misleading consumer information or further discussion on the extent to which the risk is perceived as a particular threat by the population (risk perception).

This section may also serve to provide information on health benefit, e.g. for the assessment of foods or ingredients that are claimed to have positive effects on health (“health claims”) or Opinions on certain diets that are alleged to offer health benefits if the aim is to assess whether or not the claimed health benefit is in reasonable proportion to the risks. However, an exceedance of health-relevant food safety limits cannot be justified by the potential health benefit of a product. This is an essential difference between foods and medicinal products.

The presumed effectiveness of governmental control measures can be discussed if these are connected with the potential emergence of risks or the information has been requested by a risk management authority. In addition, detection and control methods can be depicted here, as well as whether the methods that are recommended for official controls ensure success through reasonable efforts.
(59) **Comparative risk assessments** can, as far as they are needed, be carried out here. This may be the case if malnutrition or a lack of vital nutrients threatens the consumer and these must be weighed against other potential risks.

4.3 **Risk management options, recommended measures**

(60) This section provides information as to what extent **recommendations or options for action** could be derived from the risk assessment that could be incorporated in measures of risk management. If no measures are necessary, this is also briefly noted here.

(61) The following are examples of what may be taken into consideration as **recommendations in the interest of consumer protection**:

- Restrictions in regard to distribution or professional use;
- Regulatory limits/standards (e.g. maximum levels in foods when placed on the market, plate count in foods at the time of consumption);
- Labelling, consumer product information, recommendations and conditions for use;
- Measures to avoid or reduce entry and/or growth of the pathogen, reduction of the pathogen in the food chain during production and trade (e.g. HACCP, hygiene or control measures) as well as by the consumer;
- Action against misleading advertising;
- Increased consumer education.

(62) If BfR provides an Opinion containing recommendations/options for action as a basis for an **administrative decision in procedures regulated by law**, the reference to legal provisions should be as clear as possible. BfR Opinions together with administrative decisions are subject to review by administrative courts.

(63) In other cases goals, strategies and options for action can be suggested. If several risk reduction measures that appear equally adequate come into consideration, BfR merely provides the responsible authorities with **risk management options**.

(64) If **recommendations for action or dietary recommendations for consumers** are provided, they should be as specific and practical as possible. If different recommendations apply to different subgroups of the population, definitions and explanations should clearly differentiate between these. If caution is recommended in regard to the consumption or use of a food or product with which most consumers previously did not associate any or low risk, the text should explicitly substantiate why the previous assessment no longer applies and, if need be, why the scientific assessments have changed.

(65) If applicable, the **potential consequences** for the consumer of each measure/option should be stated (e.g. avoiding the risk for the entire population, for careful readers of product labels, etc.). Predictable trends in regard to future distribution of the product in question are stated and taken into consideration for the recommendations.

(66) BfR provides recommendations for consumer protection measures even when state of data is insufficient, if the actual indications are sufficient to cause concern, see p. 5, (4).
5 References

(67) If the text of the Opinion contains a quotation, the source of this is to be provided at the end of the document. Only original quotations should be used. In individual cases it may be appropriate to cite reviews or assessments of expert panels. Citing should be uniform throughout the document and also comply with external standards of citation.

(68) Example of citation style for the list of references:

Example of internal citation within the text of the Opinion:
(Schellhorn et al., 1998)
### III Scope of the guidance document

The guidance document applies to at least the following BfR Opinions:

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<td>1.2</td>
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<td>Novel Foods Regulation, Reg (EC) 258/97, Commission Recommendation 97/618/EC</td>
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<td>Genetically modified food and feed</td>
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* Recipients are usually the Federal Office of Consumer Protection and Food Safety (BVL) or the Federal Institute for Occupational Safety and Health (BAuA).
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<td>2.10</td>
<td>Pharmacologically active substances</td>
<td>§ 10 LFGB, Reg (EC) 2377/90, Dir 96/22/EEC, Dir 96/23/EEC, CODEX, JECFA documents</td>
</tr>
<tr>
<td>2.11</td>
<td>Additional substances, products and noxious substances that are of interest to BfR</td>
<td>BfRG, food law, chemical legislation and legislation on product safety, also for control purposes and in connection with professional norms and standards</td>
</tr>
</tbody>
</table>

* Recipients are usually Federal Ministries
IV Examples of typical risk assessment terminology

The following terms are often used in risk assessments. In BfR Opinions, these should be used as coherently as possible, i.e. in similar contexts, they should be used in the same sense. In order to avoid misunderstanding, it should be noted that on occasion the same term has different meanings in different disciplines. Life sciences, communication science and legal science do not always speak the same language. For risk managers, the use of legal language influenced by legislation is preferred in difficult cases.

<table>
<thead>
<tr>
<th>Limits relevant for human health</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADI</td>
<td>Acceptable Daily Intake (acceptable daily intake of a substance, e.g. a food additive, an active substance in a plant protection product or similar [mg/kg body weight])</td>
</tr>
<tr>
<td>AOEL</td>
<td>Acceptable Operator Exposure Level [mg/kg KG/d]</td>
</tr>
<tr>
<td>ARfD</td>
<td>Acute Reference Dose [mg/kg KG]</td>
</tr>
<tr>
<td>DNEL</td>
<td>Derived No Effect Level (exposure amount derived/calculated from (toxicological) studies and observation data below which there are no adverse effects to human health [mg/kg BW/d])</td>
</tr>
<tr>
<td>MID</td>
<td>Minimal Infectious Dose</td>
</tr>
<tr>
<td>PTWI</td>
<td>Provisional Tolerable Weekly Intake (provisionally tolerable weekly intake amount of contaminants or residues in foods [mg/kg BW])</td>
</tr>
<tr>
<td>TDI</td>
<td>Tolerable Daily Intake (tolerable daily intake of contaminants or residues in foods [mg/kg BW])</td>
</tr>
<tr>
<td>TWI</td>
<td>Tolerable Weekly Intake (tolerable weekly intake of contaminants or residues [mg/kg BW])</td>
</tr>
</tbody>
</table>
### Epidemiological and statistical parameters

- **General:** Estimates are stated with a 95% confidence interval.
- **Analytical limit of detection**
- **Analytical limit of quantification**
- **Diagnostic sensitivity and specificity**
- **Limit of quantification**
- **Incidences**
- **MOS:** Margin of Safety
  (Ratio of the estimated exposure dose and NOAEL)
- **MOE:** Margin of Exposure
  (Ratio of the estimated exposure dose and NOAEL for carcinogenic properties of a substance)
- **Odds Ratio**
- **Prevalence and other frequency measures**
- **Relative risk**
- **Risk difference**

### Toxicological parameters

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMD</td>
<td>Benchmark Dose</td>
</tr>
<tr>
<td>LO(A)EL</td>
<td>Lowest Observed (Adverse) Effect Level</td>
</tr>
<tr>
<td>NO(A)EL</td>
<td>No Observed (Adverse) Effect Level</td>
</tr>
</tbody>
</table>

### Microbiological parameters

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU</td>
<td>Colony Forming Units</td>
</tr>
<tr>
<td>MPN</td>
<td>Most Probable Number</td>
</tr>
<tr>
<td>PFU</td>
<td>Plaque Forming Units</td>
</tr>
<tr>
<td>Legal terms specified for certain contexts</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>“intended use”</strong>&lt;br&gt;<strong>“foreseeable misuse”</strong></td>
<td>Products: Annex I of Dir 2006/42/EC</td>
</tr>
<tr>
<td><strong>“hazard”, “risk”, “risk analysis”</strong></td>
<td>Food: Art. 3 Reg (EC) No 178/2002</td>
</tr>
<tr>
<td><strong>“injurious to health” (food)</strong>&lt;br&gt;<strong>“harmful effects on health” (food)</strong>&lt;br&gt;<strong>“harmful” (chemical substance)</strong></td>
<td>Food: Art. 14 § 2 b Reg (EC) No 178/2002,&lt;br&gt;chemicals: Art. 2 Dangerous Substances Directive 67/548/EEC</td>
</tr>
<tr>
<td><strong>“limit”, “maximum limit”, “threshold value”, “reference point for action”</strong></td>
<td>These terms are used differently in different legal contexts.</td>
</tr>
<tr>
<td><strong>“Misleading by claiming effects that are not sufficiently based on generally accepted scientific evidence”</strong></td>
<td>Art. 13 Reg (EC) 1924/2006, § 11 LFGB</td>
</tr>
<tr>
<td>dangerous “in accordance with established scientific knowledge”</td>
<td>Chemicals: § 13, 1 German Chemicals Act and defined in EU Commission Case 208/85, § 16</td>
</tr>
<tr>
<td><strong>“safe”</strong></td>
<td>Food: Art. 14 § 1 Reg (EC) No 178/2002</td>
</tr>
<tr>
<td><strong>“current scientific and technical knowledge”</strong></td>
<td>Plant protection products: Art. 4 § 1 Dir 91/414/EEC</td>
</tr>
<tr>
<td><strong>“normal or reasonably foreseeable period of its use”</strong></td>
<td>Consumer products: Art. 5 § 1 Nr. 1 a General Product Safety Directive 2001/95/EC</td>
</tr>
<tr>
<td><strong>“a serious direct or indirect risk to human health”</strong></td>
<td>Food: Art. 50 Reg (EC) No 178/2002</td>
</tr>
</tbody>
</table>

**“precautionary principle”, “precaution”, “prevention”:**

These terms are used in different ways. They are sometimes understood to mean that a governmental control measure is inadmissible if it is carried out “only as a precautionary measure” instead of “for health reasons”, if there is no specific legal basis for the precautionary measure. Sometimes “precautionary principle” refers to the circumstance that for a consumer protection measure to apply, it is not always necessary to have irrefutable proof, but only enough factual indications for causality between a presumed risk source and adverse health effects. Measures by the legislative authority that restrict the sale of a product and are not even based on the precautionary principle can be contested according to world trade law. The European legislative basis for the precautionary principle in consumer protection is a Communication of the EU Commission, Commission of the European Communities, Communication of the Commission on the precautionary principle, COM (2000) 1 final, Brussels, 2000.
V Selection of guidance documents in regard to risk assessment

For risk assessments of BfR, the following documents are especially relevant:

**Biocides:**
- Webpage: European Commission – Environment – Biocidal Products  
  Status: 6.12.2010
- Webpage: Ex-European Chemicals Bureau: Biocides  
  Status: 6.12.2010
  Contains guidance documents for the assessment of biocides.

**Chemicals:**
- Webpage: REACH Navigator – Home  
  Status: 6.12.2010
  Contains guidance documents for the assessment of chemicals.

**Chemicals (including residues, contaminants) in foods:**
- WHO International Programme on Chemical Safety (IPCS): Principles for the safety assessment of food additives and contaminants in food (EHC No. 70, 1987)  
  Contains definitions of terms and explains the methodological requirements for the assessment of chemicals (contaminants, residues, etc.) in foods.

**EFSA list of guidance documents:**
  This is to be updated on a regular basis.
  Contains a guidance document on the use of sources in regard to “emerging risks”.
- European Food Safety Authority: Application of systematic review methodology to food and feed safety assessments to support decision making, EFSA Journal 2010; 8(6):1637. [90 pp.]
  Contains a guidance document on systematic review.

**Genetically modified organisms:**
  Contains definitions of risk analysis terms in regard to GMO.
Guidance Document for Health Assessments

**Microbiology:**
- [Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30, 1999](#)
  Contains definitions and explains how risk assessments of microbiological risks are to be carried out.

**Plant protection products:**
  Contains guidance documents on the assessment of plant protection products.

**Review:**
  Contains an explanation on the methodological procedure when reviewing scientific opinions.

**Risk analysis of foods:**
  Contains definitions of risk analysis terms in regard to food.
  Contains definitions of risk analysis/assessment of biological/bacterial hazards and uncertainty/variance.
  Defines risk management terms in food safety.

**Risk communication:**
- [OECD Guidance Document on Risk Communication for Chemical Risk Management, 2002](#)
  Contains definitions and recommendations on risk communication in the area of chemical safety.
  Contains definitions and recommendations on risk communication in the area of food safety, especially in regard to the Codex Alimentarius.

**Terminology:**
  Contains terminology for chemicals (in foods).
Transparency:


Contains general requirements regarding the transparency of EFSA risk assessments, i.e. on the structure and content of an assessment or the documentation of the data upon which it is based.

Use of mathematical models:


Contains guidelines on the selection of models and integration of mathematical modelling into the answer of a request by way of example in the area of animal health (generally accepted specifications).
VI Subject index

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