Risiken erkennen – Gesundheit schützen

BfR Catalogue of Criteria for Notifications pursuant to the General Administrative Regulation on the Rapid Alert System for Food and Feed (Allgemeine Verwaltungsvorschrift Schnellwarnsystem, AVV SWS)

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If it emerges that a food or feed poses risks to human health, immediate action must be taken. The RASFF (Rapid Alert System for Food and Feed) ensures the speedy passing on of information about harmful food and feed within the European Union.

In accordance with the General Administrative Regulation on the Implementation of the Rapid Alert System Food and Feed[1] (AVV SWS, § 7 para 4, § 7 para 5 and § 8 para 3), the Federal Institute for Risk Assessment (BfR) has made a Catalogue of Criteria available to the federal states as the basis for notifications within RASFF. These notification criteria help the public agencies responsible for food control to assess whether foods contaminated with pesticide residues or with fungal toxins, bacteria or viruses pose a risk to human health. Furthermore, the public agencies are given notification criteria for the assessment of feed in which the maximum levels of undesirable substances, which can carry over to the food of animal origin, have been exceeded. If the public agencies of the federal states responsible for food control establish the fulfilment of the BfR criteria for a food or feed, they notify this to the national RASFF contact point within the Federal Office of Consumer Protection and Food Safety (BVL). It then passes on the notification to the European Rapid Alert System for Food and Feed.

Here is the BfR catalogue of notification criteria.

1 Criteria for notifications of foods pursuant to § 7 para 4 AVV SWS (General Administrative Regulation on the Rapid Alert System for Food and Feed)

1.1 Provisions of the AVV SWS

§ 7 para 4 AVV SWS stipulates:

The Federal Institute draws up notification criteria for foods with residues pursuant to § 2 No. 1 letters b and c with details of ARfD or ADI values and makes them available to the competent public agencies.

§ 7 para 2 No. 1 letter b AVV SWS concerns foods which contain residues of pesticides or their degradation/reaction products for which an ARfD has been set that was exceeded in the consumption of the food.

§ 7 para 2 No. 1 letter c AVV SWS concerns foods which contain residues of pesticides or their degradation/reaction products for which no ARfD but for which an ADI was set that was considerably exceeded in the consumption of the food.

[1] General Administrative Regulation for the Implementation of the Rapid Alert System for Food and Feed and for Notifications about Feed (AVV Rapid Alert System – AVV SWS) http://www.verwaltungsvorschriften-im-internet.de/bsvwvbund_20122005_315860130001.htm

1.2 BfR criteria

Case A: An ARfD was set for the active substance examined and/or its degradation and reaction products.

A notification is posted in the Rapid Alert System when the legally specified maximum residue level is exceeded and if, at the same time, an intake calculation in accordance with 1.3 confirms that the ARfD has been exceeded.

Case B: The setting of an ARfD is not necessary because of the low acute toxicity of the active substance and its degradation/reaction products.

The active substances for which no ARfD has been set because of their low toxicity are indicated in the BfR list of the toxicological limit values (BfR 2006 c). In these cases the ADI is not to be used either for assessment purposes instead of the ARfD. There is no serious direct or indirect risk to human health.

Case C: An ARfD has not been set for other reasons.

If the food contains residues of active substances of this kind for which no ARfD has been set for other reasons, the ADI will be used on precautionary grounds to estimate the risk.

As the ADI is generally far lower than the corresponding ARfD, this can lead to a major overestimation of the risk. Hence in these cases the toxicological assessment should be undertaken with the involvement of BfR in order to clarify whether there is in fact a serious direct or indirect risk.

It should be noted that these cases are probably relatively rare as assessments of acute toxicity have since been undertaken for most active substances by BfR, EU, WHO or US EPA.

1.3 Intake calculation and risk assessment for Case A under Section 1.2

For the assessment of the risk from pesticides or their degradation/reaction products in or on foods, short-term consumer exposure is estimated for the purposes of inclusion in the Rapid Alert System. The calculated intakes are expressed as NESTIs (National Estimated Daily Intakes) and compared with the corresponding toxicological limit value of the active substance (ARfD) (WHO, 1997; Harris *et al*., 2000).

BfR proposes the following procedure for the assessment of residue data:

Regarding the national consumption data, the BfR model is used to estimate the short-term intake of German children aged between two and up to the age of five (Banasiak *et al*., 2005).

To calculate intake the BfR VELS model is used with the stipulated details on intakes, weighting of individual units, standard variability factors etc. The model is available on the Internet (BfR, 2006a).

An Excel file containing a compilation of processing factors for numerous active pesticide substances, foods and processing methods can be accessed on the BfR website (BfR, 2006b). This programme is regularly updated.

The customary variability factors used in the marketing authorisation procedure for pesticides are to be used for data evaluation. The factors corresponding to the respective cases have already been indicated in the BfR VELS model.

Risk assessment is to be undertaken on the basis of the measured value without taking into account analytical measurement uncertainty or the recovery rate.

The above-mentioned procedure for the assessment and intake calculation of residue data from official food control and internal controls was developed by BfR with the participation of representatives of the federal states and published in January 2007 (Banasiak *et al*., 2007).

Regularly updated information on the toxicological limit values of active substances (ARfD, ADI) can be accessed on the BfR website (BfR, 2006c). More in-depth information about the setting of an ARfD has also been published (Solecki *et al*., 2005).

1.4 References

Banasiak, U., Herrmann, M., Hohgardt, K., Michalski, B. und Sieke, C. (2007) Abschätzung des akuten Risikos durch Pflanzenschutzmittel-Rückstände in Lebensmitteln auf der Basis von Daten aus amtlicher Überwachung und Eigenkontrollen, J. Verbr. Lebensm. 2 (2007): 54-60

BfR (2006a) BfR-Berechnungsmodell zur Aufnahme von Pflanzenschutzmittel-Rückständen (Tabellen zur Berechnung der Langzeit- und Kurzzeitaufnahmemengen von Pflanzen-schutzmittel-Rückständen durch Kinder), http://www.bfr.bund.de/cm/218/bfr_berechnungsmodell_zur_aufnahme_von_pflanzenschutzmittel_rueckstaenden.zip

BfR (2006b) BfR-Programm zu Verarbeitungsfaktoren von Pflanzenschutzmittel-Rückständen (Programm zur Auswahl von Verarbeitungsfaktoren für Pflanzenschutzmittel-Wirkstoffe in verarbeiteten Lebens- und Futtermitteln), http://www.bfr.bund.de/cm/218/bfr_programm_zu_verarbeitungsfaktoren_von_pflanzenschutzmittel_rueckstaenden.zip

BfR (2006c) Grenzwerte für die gesundheitliche Bewertung von Pflanzenschutzmittelrück-ständen, http://www.bfr.bund.de/cm/218/grenzwerte_fuer_die_gesundheitliche_bewertung_von_pflanzenschutzmittelrueckstaenden.pdf

Harris C.A., Mascall J.R., Warren S.F.P. and Crossley S.J. (2000) Summary report of the international conference on pesticide residues variability and acute dietary risk assessment. Food Addit Contaam 17: 481-485

Solecki R., Davies L., Dellarco V., Dewhurst I., Raaij M., Tritscher A. (2005) Guidance on setting of acute reference dose (ARfD) for pesticides. Food Chem Toxicol 2005; 43(11): 1569-1593

WHO (1997) Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation Geneva, Switzerland 10-14 February 1997. Issued by World Health Organization in collaboration with Food and Agriculture Organization of the United Nations.

Programme of Food Safety and Food Aid, World Health Organization, Geneva 1997, WHO/FSF/FOS/97.5

2 Criteria for notifications on foods pursuant to § 7 para 5 AVV SWS

2.1 Provisions of AVV SWS

§ 7 para 5 AVV SWS specifies:
The Federal Institute draws up a catalogue of criteria for the assessment of foods pursuant to para 2 No. 2 and makes this available to the competent public agencies.

§ 7 para 2 No. 2 concerns foods in which fungi or fungal toxins, bacteria or toxins produced by them, algal toxins, parasites, metabolites or viruses have been determined by type, number, amount or prions that are injurious to human health.

2.2 BfR criteria

Case A: Criteria from Regulation (EC) 2073/2005, amended by Regulation (EC) No. 1441/2007 are met.

If examinations within the framework of internal controls or official controls establish that safety criteria, which are mentioned in Annex 1, Chapter 1, Nos. 1.1 - 1.27 of Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs amended by Regulation (EC) No. 1441/2007, were not complied with in the case of a food then a notification is posted in the Rapid Alert System.

Case B: Exceedances of maximum levels for marine biotoxins pursuant to Regulation (EC) 853/2004.

If limit values for foods of animal origin, which are mentioned in Annex III, Section VII, Chapter V, No. 2 of Regulation (EC) 853/2004, are exceeded then a notification is posted in the Rapid Alert system (paralytic shellfish poison, amnesic shellfish poison, okadaic acid, dinophysistoxins, peptone toxins, yessotoxins, azaspiracids).

Case C: Other micro-organisms and toxins which are not listed in Regulation (EC) No. 2073/2005

For a series of other micro-organisms and toxins there are currently no microbiological criteria in the legal provisions although they can also pose a serious direct or indirect risk to human health. The micro-organisms and toxins mentioned below are examples and do not constitute **an exhaustive list**. Furthermore, for many combinations of micro-organisms and foods a decision about whether a rapid alert or information is to be posted in the Rapid Alert System must be taken on a case-by-case basis. Correct use of a food is also to be taken into account.

- Detection of pathogenic bacteria in food:
  - *Salmonella*
  - *Campylobacter jejuni/coli/lari*
  - *Yersinia enterocolitica* (serovars O:3; O:5, 27; O:8; O:9)
  - Verotoxin-producing (enterohaemorrhagic) *Escherichia coli*

- *Vibrio cholerae (Vibrio cholerae* O1 or O139 – detection of toxin-producing capacity; if this determination has not been carried out, detection of the species will suffice)
- *Vibrio parahaemolyticus* with positive Kanagawa phenomenon
- *Shigella spp.*
- *Brucella spp*.

When assessing whether a food is injurious to health, consideration must be given to the type of use and the information provided to the consumer (Article 14 of Regulation (EC) No. 178/2002).

- Determination of bacteria (spores) in foods at concentrations which, on uptake, are known to be able to trigger disease:
  - presumptive, toxin-producing *Bacillus cereus* strains above 10^5 CFU/g during the shelf life indicated
  - *Clostridium perfringens* above 10^6 CFU/g during the shelf life indicated

In terms of germ counts, consideration should be given where appropriate to margins of exposure in conjunction with the food's residual shelf life.

- Detection of heat-stable bacterial toxins in all foods:
  - *Staphylococcal enterotoxin*
  - *where appropriate Botulinum toxin*

- Detection of heat-labile bacterial toxins in ready-to-eat foods[2]:
  - *Botulinum toxin*

- Detection of parasites in ready-to-eat foods[3]:
  - *Trichinella*
  - *Giardia*
  - *Cryptosporidium*
  - *Toxoplasma*

- Detection of viruses in ready-to-eat foods[4]:
  - *Norovirus*
  - *Rotavirus*
  - *Hepatitis A Virus*

- Detection of Specified Risk Material (SRM) in all foods

- Foods which are not suitable for consumption because of decay or which were produced using ingredients that are not suitable for consumption.

[2] Ready-to-eat food means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern (definition pursuant to Article 2 letter g of Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs).
[3] ibid.
[4] ibid.

3 Criteria for notifications on feed pursuant to § 8 para 3

3.1 Provisions of AVV SWS

§ 8 para 3 AVV SWS specifies:
The Federal Institute draws up a catalogue of criteria for the substances pursuant to para 2 Nos. 1 and 2 bearing in mind carry-over rates and makes it available to the competent public agencies.

§ 8 para 2 No. 1 AVV SWS concerns feed with exceedances of the maximum levels of undesirable substances specified in Annex 5 to the Animal Feed Regulation and in the residues of pesticides regulated in Annex 5a to the Animal Feed Ordinance when these substances are teratogenic, genotoxic or carcinogenic and it can be proven that they can carry over to the food of animal origin.

§ 8 para 2 No. 2 AVV SWS concerns feed with other undesirable substances, additives that are not authorised for the target animal species or category, and the carry-over of veterinary medicinal products to the extent that the conditions listed under No. 1 are met.

3.2 Procedure for examining whether there is a serious direct or indirect risk to human health (decision-making tree)

The analytical results of the examination of an active substance in feed may be abnormal in the following ways:

a) exceeding of the maximum level of an undesirable substance (Annex 5 of the Animal Feed Regulation),
b) exceeding of the maximum residue level for a pesticide (Regulation (EC) No. 396/2005),
c) when this concerns "another undesirable substance" in the feed,
d) when this concerns "an additive which is not authorised for the animal category" and
e) when this concerns the carry-over of a veterinary medicinal product.

Before examining whether the potentially dangerous substance (agent) can pose a serious direct or indirect risk to human health, it must be first clarified whether the feed is on the market in a Member State.

If an abnormality (a-e) is identified, it must be clarified whether the abnormality refers to a complete feedstuff, a complementary feedstuff, a feed material, a premixture or a feed additive.

If it is determined that the potentially dangerous substance (agent) was analysed in a complete feedstuff, it must be clarified whether the complete feedstuff is intended for administration to animals that are kept for the production of food of animal origin, e.g. fattening stock, laying hens or lactating ruminants.

If it is determined that a complete feedstuff is to be fed to those animal categories of food-producing animals that are "close to the food chain", e.g. fattening pigs, fattening poultry, fattening cattle in the final fattening period, laying hens, dairy cows, dairy sheep or dairy goats, then the proportion that the food of animal origin "contaminated" with a potentially dangerous active substance (agent) contributes to the overall exposure of the consumer must be clarified.

Finally, the scale of this contribution must be assessed from the angle of human health.

When examining whether there is a serious direct or indirect risk to human health, a similar procedure is to be adopted when the agent was not detected in a complete feedstuff but in a complementary feedstuff, a feed material, a premixture or a feed additive or when the food-producing animals concerned are not "close to the food chain".

3.3 Use of the decision-making tree when examining whether there is a serious direct or indirect risk to human health

a) Based on the decision-making grid it is to be examined whether the potentially dangerous substance was found as a contaminant in a complete feedstuff, a complementary feedstuff, a feed material, a premixture or a food additive. When considering the proportion of a feed material in the daily feed ration or the admixture rate of an additive via a pre-mixture in a **complete feedstuff**, it can be estimated whether the maximum level in the complete feedstuff has been exceeded.

b) For undesirable substances in animal feed, maximum levels serve to prevent threats to human health, animal health and the environment (Article 3 paras 1 and 2 of Directive (EU) No. 2002/32): "*Products intended for animal feed may only be … used if they … do not represent any danger to human health, animal health … when used correctly and do not adversely affect livestock production.*" The setting of maximum levels for undesirable substances by the regulator means that a certain level of undesirable substances is accepted in feed for various reasons. One reason can be, for example, the geogenic contamination of an additive. Hence for example the mere **exceeding of the maximum level** of lead in zinc oxide (current maximum level 400 mg/kg, 88% TS) by 10 mg/kg does not necessarily lead to an alert in the European Rapid Alert System. Lead compounds have been classified as mutagenic and carcinogenic, have been shown to carry-over to animal tissue and therefore fulfil the provisions of § 8 para 2 No. 1 of AVV SWS. Nevertheless, they would have to be re-examined in individual cases subject to the provisions of § 8 para 1 AVV SWS.

Does the exceeding of this value pose a serious direct or indirect risk to human health? Before answering this question, consideration must be given to the proportion that the animal product contaminated with lead contributes to the overall exposure of the consumer. In this case the question whether the exceeding of a maximum level of lead in zinc oxide leads to a serious direct or indirect risk for human health would have to be emphatically answered in the negative.

c) Another example concerns persistent **environmental contaminants** (e.g. DDT). Here, too, when establishing maximum levels consideration would also have to be given to the current contamination values of the environment (background contamination). This demonstrates once again that the exceeding of a maximum level of an undesirable substance does not necessarily mean that there is a serious direct or indirect risk for human health.

d) When considering "further specific conditions" that turn a potentially dangerous substance into a risk for the consumer, it should be borne in mind whether the "contaminated" feed is intended for administration to an **animal category** of a species of food-producing animal that is close to the food chain, i.e. close to the production of foods of animal origin. In the case of the species cattle this would be, for instance, the lactating dairy cow, the cattle for fattening in the final fattening period or also the calf for fattening.

In the case of pigs this would be, for example, the pig for fattening at the end of the fattening period and in the case of poultry the poultry for fattening or the laying hen.

The need to consider "further specific conditions" means that when administering "contaminated" feed to specific animal categories of food-producing animals over the timeline of food production, a serious direct or indirect risk for consumers cannot be generally assumed. This may apply, for instance, to ruminants e.g. for cows during drying period or under certain conditions also to the lactating dairy cow in a suckler cow herd. In the case of poultry the corresponding examples would be the parent animals and in the case of pigs the sow for reproduction. In the case of show horses with an equidae passport under medicines law, there is clearly no intention to slaughter them for food production either.

e) Maximum residue levels for **pesticides a**re, in principle, established in accordance with the ALARA principle. Toxicological assessments of substances in conjunction with good laboratory practice are the basis for this. The different procedures mean that the maximum residue level established for a pesticide does not necessarily constitute a toxicologically substantiated limit value. Determination of the exceeding of the maximum residue level of pest control substances in foods of animal origin need not, therefore, necessarily constitute a direct or indirect risk for human health although it can be proved that the substance has been carried over from the feed to the food from the animal.

The application of the current maximum residue levels to feed in Annex 5a of the Animal Feed Regulation is, therefore, to be questioned from the angle of consumer health protection as the establishment of maximum residue levels is also oriented, as outlined above, to other goals. Furthermore, arbitrary non-calculable maximum levels in accordance with depletion or accumulation through processing and the proportion in the mixture are admissible by law for processing products and mixed feed. Hence the equating of the exceeding of a maximum residue level of a pesticide in a feed, which can be carried over to animal tissue, with a serious indirect or direct risk for human health, as outlined in § 8 para 2 AVV SWS, is not plausible. Even in the case of the detection of a banned pesticide in feed for food-producing animals, the establishment of a serious direct or indirect risk for human health will be difficult from the scientific angle and requires a case-by-case consideration.

f) In § 8 para 2 No. 2 of AVV SWS reference is made to the hazard potential of feed additives that are "not authorised for the target animal species or target animal category".

A large number of authorised additives have been approved for **all** animal species and categories. Hence examination for the purposes of inclusion in a catalogue of criteria concerning a direct or indirect risk for the consumer would not, therefore, be necessary for these additives which have been authorised for all animal categories according to the provisions of § 8 para 2 No. 2 of the AVV Rapid Alert System.

In the case of the detection of residues of specific additives or veterinary medicinal products (e.g. ionophores) in feed, which were carried over via cross-contamination to compound feed, consideration is to be given to the analysed concentrations of these residues in feed and the resulting possible residues in food of animal origin in comparison to those concentration values established in the course of procedures to set maximum residue levels for these active substances in veterinary medicinal products (MRL processes).

3.4 Comments on the substance groups

Within the framework of the work done on drawing up the BfR Catalogue of Criteria with the participation of the federal state authorities, it was not possible to examine each individual substance, i.e. the undesirable substances pursuant to Annex 5 to the Animal Feed Regulation, residues of pesticides pursuant to Annex 5a to the Animal Feed Regulation, other undesirable substances, additives not authorised for the target animal species or target animal category, and carry-over from veterinary medicinal products with regard to their toxicological properties and their carry-over behaviour.

Not all substances or substance groups, which can be characterised as potentially dangerous, develop into a serious direct or indirect risk for human health in feed. From the different substance groups active substances were initially identified where it can be assumed that they have a hazard potential because of their effects or properties.

a) Undesirable substances pursuant to Annex 5 to the Animal Feed Regulation

Out of the undesirable substances the substances listed below are the ones for which a teratogenic, mutagenic or carcinogenic effect has been described and which, after intake via feed, are carried over to the food of animal origin.

- Arsenic
- Lead
- Cadmium
- Dioxins
- Organochlorine compounds in general
    - Aldrin/Deldrin
    - Camphechlor
    - Chlordane
    - DDT (some DDT, TDE and DDEE isomers)
    - Endosulfan
    - Endrin
    - Heptachlor
    - Hexachlorobenzene
    - Hexachlorocyclohexane (alpha, beta, gamma isomers)
- Aflatoxin B1

b) Aflatoxin

When a feed has been found to be contaminated with aflatoxin, an individual assessment should in principle be undertaken. On this basis it is to be estimated whether the conditions are met that would permit a potentially dangerous substance to develop into a serious direct or indirect risk for human health.

c) Pesticide residues

After examining the data material available, no active substances could be identified that constitute a general hazard when the maximum level is exceeded. For the individual cases in which the exceeding of pesticides in feed was determined in this way, that seem to require risk assessment by BfR, the suggestion is made to the competent senior federal state authorities that they should consult BfR about this problem.

d) Carry-over of veterinary medicinal products

The carry-over of veterinary medicinal products generally leads to contamination of feed on a scale of up to 10% of the dose authorised for the target animal species. Carry-over of (authorised) veterinary medicinal products are not generally deemed to have any hazard.

e) Additives not authorised for the target animal species or category

Bearing in mind the provisions of AVV SWS no additives, which are not authorised for the target animal species or category, are included in the catalogue of criteria.

Because of the substance-specific effects of individual additives, e.g. accumulation in the food of animal origin (vitamin A) or direct carry-over to the food of animal origin, there may be a hazard for specific consumer groups (e.g. in the case of iodine).