Risk Assessment of Chemical Substances in Food as Basis for Risk Communication

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AUTORS

J. STEINWIDER, E. RAUSCHER-GABERNIG, K. VEJDOVSZKY, U. MAYERHOFER, D. SEITNER, I. KIEFER

Austrian Agency for Health and Food Safety (AGES)

Summary

The assessment of health risks of chemical substances in food is carried out in the process of risk assessment, which consists of hazard identification, hazard characterisation, exposure assessment and risk characterisation. This process includes the derivation of health-based guidance values (such as ADI - acceptable daily intake, ARfD - acute reference dose). The risk assessment is the basis for legal limit values and/or further risk management measures. As part of an interdisciplinary stakeholder dialogue of AGES, a uniform description of possible risks was drawn up for substances for which health-based guidance values are available (such as plant protection products or heavy metals), as well as for genotoxic carcinogenic contaminants (e.g. polycyclic aromatic hydrocarbons, aflatoxin, arsenic). In addition, appropriate communication measures were defined, ranging from clarification to health warnings. Depending on the risk, trust or awareness can thus be created, the level of information about risks can be improved or changes in behaviour can be initiated. This basis for a uniform communication of risk terms also contributes to an increase in the population's awareness of risks, and improves the perception of risks in food. Furthermore, the confidence in food safety in Austria, which makes an essential contribution to the health of the population, will be strengthened further.

Introduction

For the sake of consumer protection, harmful substances should not be present in food or should be reduced as much as possible. Respective regulations or laws define limit values (maximum levels, parameter values etc.) for many substances in food. In case of an exceedance of a defined limit value the product has to be taken off the market regardless of whether there is a health threat or not. Food safety comprises of a legal and a health dimension. Scientific risk assessments evaluate the health dimension and if a substance may harm human health. However, in the public perception the exceedance of a legal limit value or the mere presence of a substance in food, even in very low amounts, are very often equated with a health threat. This leads to cognitive dissonance in consumers as well as to controversial discussions in the media. The media then may generate their own risk-stories conveying a subjective risk estimation deviating from the actual risk, leading to a reinforcement of fears. This is in accordance with findings of the *risk barometer* of the Austrian Agency for Health and Food Safety (AGES) and the Austrian Environmental Agency, a study on the consumers´ perception of health risks (Kiefer et al. 2017). For genotoxic carcinogenic contaminants unintentionally occurring in food, the issues of risk assessment and especially risk communication get even more complicated. From a scientific point of view, health-based guidance values cannot be derived for genotoxic carcinogens. For the sake of consumer protection and the precautionary principle, occurrence of unavoidable contaminants in food should be kept as low as reasonably achievable.

In order to ensure a consistent communication of food safety risks, AGES formulated a clear description of possible risks in cooperation with the Austrian Environmental Agency and representatives of Non-Governmental Organizations

Scientific evaluation of health risks

The scientific evaluation of health risks of a substance is undertaken in the course of chemical risk assessment, a main competence of AGES. Risk assessment is based on scientific knowledge and comprises of hazard identification, hazard characterization, exposure assessment and risk characterization. It forms the basis for regulatory authorities´ risk management decisions as well as for risk communication. Besides regulatory authorities, risk communication lies within AGES´ responsibilities. This complies with the principles of the International Program for chemical Safety (IPCS)

of the World Health Organization WHO (WHO 2009) and it is laid down in the Austrian Health and Food Safety Law as well as in the Regulation (EG) No 178/2002.

Hazard identification – What can harm human health?

In the course of hazard identification the origin of the hazard, hence its formation and its route of entry into the food are evaluated. Health hazards can be of manifold nature. Generally, hazards are divided into biological (bacteria, viruses, parasites, fungi), chemical (residues of plant protection products or veterinary pharmaceuticals, heavy metals, heat toxins, natural toxins etc.) and physical hazards (foreign bodies like stones, glass, etc.). These hazards may get into food or develop in food during agricultural production, food processing, storage and food preparation in private households as well as by environmental pollution. In addition natural food ingredients as well as food additives have the potential to cause undesired health effects.

Hazard characterization – Which effects are caused by these hazards?

Hazards may have different impacts on human health, from abdominal pain to neoplasia. In rare cases, they may even be lethal. Therefore, hazards are extensively assessed concerning their health effects on a scientific basis by using data from scientific research, toxicological and epidemiological studies as well as statistics. AGES also utilizes hazard characterizations that were assessed by international agencies/working groups, provided they have been conducted science-based and transparently.

Whenever possible health-based guidance values that are considered safe for human health are derived. Health-based guidance values indicate the amount of daily intake of a substance over a lifetime that does not lead to any adverse health effects. Examples for health-based guidance values are the Acceptable Daily Intake (ADI) for substances that are added intentionally, the Tolerable Daily Intake (TDI) for substances that cannot be avoided and the Tolerable Weekly Intake (TWI) for substances that accumulate in the human body. For substances with a high acute toxicity that show adverse health effects already after a single or short-term exposure an Acute Reference Dose (ARfD) is derived besides the ADI or TDI. The

ARfD is defined as the amount of a substance that can be ingested via food within a day or one meal without causing any observable adverse effects on human health.

For the derivation of health-based guidance values uncertainties in the extrapolation of the results from animal studies to humans, as well as variances of sensitivity within the human population are taken into account. The resulting safety factor often amounts 100 (factor 10 for the extrapolation of results from animals to humans and factor 10 for individual variances between humans), but it may be higher or lower depending on the available data and toxicological evaluation. Especially if there are sufficient and reliable data on the effects on humans and sensitive population groups available, safety factors sometimes do not have to be applied.

Since health-based guidance values are not applicable for genotoxic carcinogenic substances, alternatively a margin of exposure approach (MOE) is used (EFSA 2005). The MOE represents the ratio or the distance between exposure data from scientific studies and the evaluated exposure of humans.

Exposure assessment - Who may be harmed?

The assessment of exposure (the extent of the burden or ingested dose) of the population is an important part of the risk assessment. The exposure is the combination of the concentrations of the respective substance (analysis data e.g. from AGES) that have been measured in food with the amount of consumption of affected foods (based on the Austrian Food consumption data (EFSA 2020)). However, often it may be necessary to assess the exposure separately for specifically sensitive population groups. Children, for example, might represent a particularly sensitive population group due to different consumption habits, which might lead to higher exposure to specific substances compared to adults. Some harmful substances may be formed or decomposed in food (for example during the cooking process). Therefore, possible influences during storage, processing and preparation should also be taken into account. Additionally, all exposure sources have to be considered. For instance, the exposure to polycyclic aromatic hydrocarbons is not limited to the ingestion of contaminated food, but they are also taken up by humans via the atmosphere and from tobacco smoke.

Risk characterization – Can a foodborne hazard harm human health?

In the course of the last step of risk assessment conclusions concerning the risk level are drawn. If the exposure to a substance is below the defined health-based guidance value, there is no health threat indicated. However, if the exposure to a substance is above the defined health-based guidance value, adverse health effects may arise for consumers or for specific consumer groups.

In case health risks cannot be excluded by risk assessment, measures for risk reduction have to be initiated by risk managers. These may comprise of regulatory limit values (maximum levels, parameter values), recommendations for the population or for specific producers , or the ban of specific substances or production processes. In Austria, this task of risk management falls into the competence of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection, the federal state governments or the European Commission on EU-Level, respectively.

Risk characterization of substances using health-based guidance values

If a compound in a foodstuff does not exceed the existing legal limit value/maximum level, it is compliant with the legal provisions and it may be marketed (zone 1, green area). The consequence of an exceedance of zone 1 is that the marketing of the food product concerned is prohibited irrespective of whether it poses a health threat or not.

In zone 2 (yellow area) the limit value is exceeded, however as long as there is no exceedance of a specific health-based guidance value (e.g. ARfD, ADI) no health threat has to be expected.

In case the ADI and/or ARfD are exceeded (zone 3, orange area), adverse health effects cannot be excluded. The probability of adverse health effects increases with the extent of the exceedance of the ADI or ARfD.

Zone 4 (red area) marks the area between certain exposure levels from toxicological studies. The NOAEL (no observed adverse effect level) is the highest dose in a study at which no adverse health effects were observed. The LOAEL (lowest observed adverse effect level) is the lowest dose at which adverse effects were already

observed. Often, these observations are obtained from animal studies, but they may also come from human studies.

The higher the exposure to a harmful substance (rising from zone 1 to zone 4) the higher is the risk of health effects.

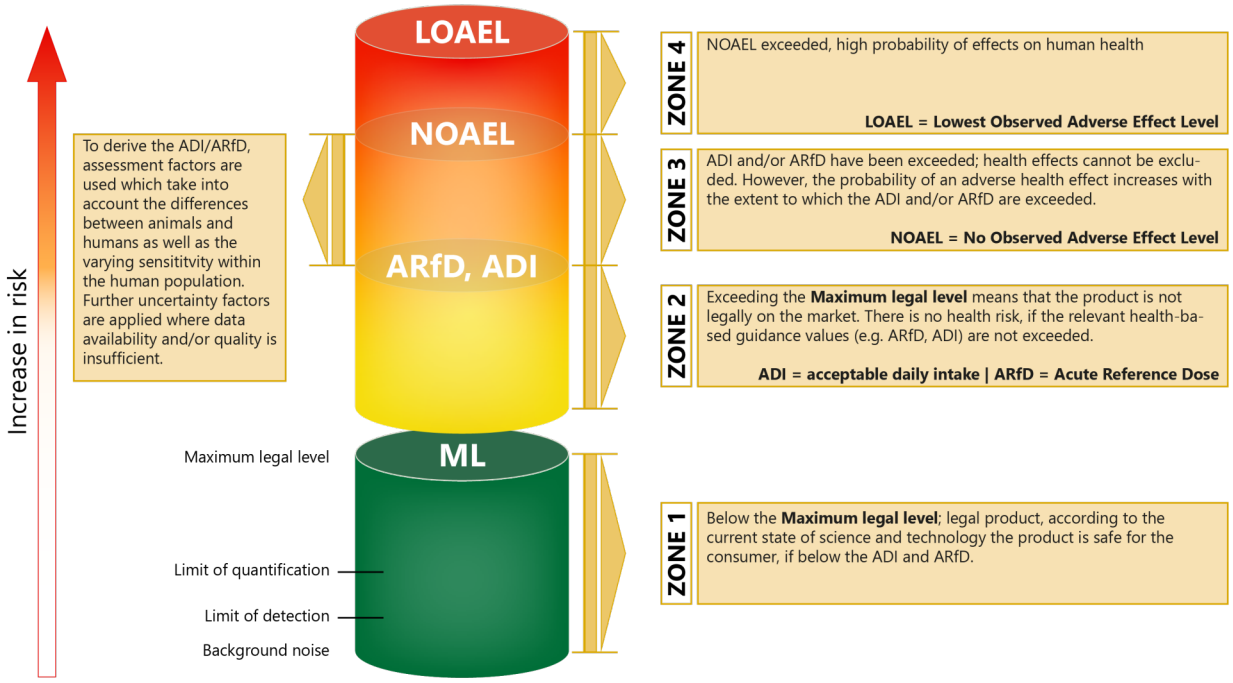

Figure 1: Risk characterization of substances with a health-based guidance value

Risk characterization of genotoxic carcinogenic substances

Genotoxic carcinogenic substances have to be divided into substances that occur in foods unintendedly, such as environmental contaminants or compounds that are unavoidably formed in the course of processing (e.g. acrylamide, furan, polycyclic aromatic hydrocarbons, and benzpyrene) and substances that are added intentionally. An intended use of genotoxic carcinogenic substances is legally prohibited along the entire food chain.

For genotoxic carcinogenic substances, no health-based guidance values can be derived. For this reason, EFSA uses the MOE (Margin of Exposure) approach (EFSA 2005): The MOE is the ratio between the reference point (= the dose that leads to a 10% increase of animals with tumors in comparison to the control group ($BMDL_{10}$), alternatively it might be derived from epidemiological human data) and the exposure level of the population to the relevant substance. The lower the MOE the higher is

the probability of health impairments and consequently the need for action of the risk management increases.

Here, too, the red zone (zone 3) lies above the reference point at which the harmful effects occur with scientific evidence in animal studies or in humans. Health impairments in humans are considered likely or are known to occur. Such high exposure is alarming and thus needs immediate action to be reduced.

However, if the exposure to a harmful substance is below the reference point, the exposure is in zone 2 (orange area). The lower the MOE and consequently the lower the distance to the reference point the higher is the probability of adverse health effects to occur. Measures for reduction of the exposure, like setting of limit values, recommendations for risk reduction, identification and elimination of the contamination source or procedural improvements (Good Agricultural Practice, Good Manufacturing Practice) have to be taken as a priority.

For most genotoxic carcinogens, the distance to the reference point is considered as sufficient, if the MOE is above 10000, (zone 1, green area). The probability of adverse effects is very low and the exposure is considered of low concern for human health. Still, the precautionary principle and the minimizing principle apply.

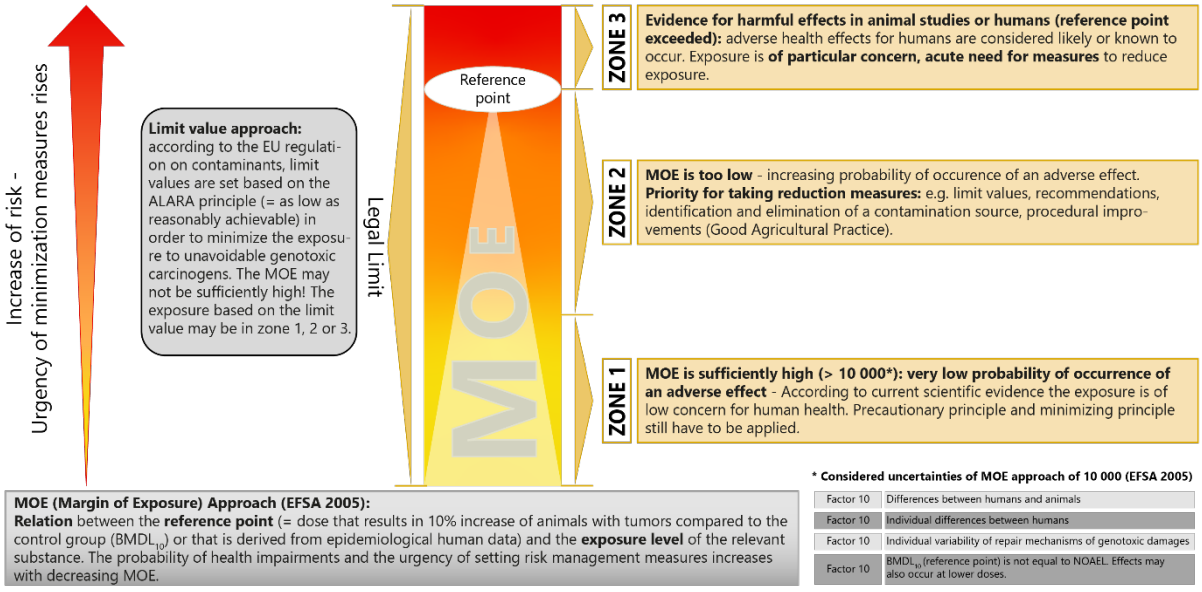

Figure 2: Risk characterization of genotoxic carcinogenic contaminants

Impact of risk characterization on risk communication

Food has never been safer than today. Still, the public perception is often quite different. Due to contradictive information, anxiety-promoting framing, scientific misinterpretation etc., risks are often misjudged by the public. Especially compounds with established maximum levels are perceived as threatening risk, even if the food contains compounds below or slightly above the maximum values. It is important to provide evident information concerning the actual risk, but it is also pivotal to take fast action in case proficient risk assessments confirm a relevant risk of adverse effects to human health. In zone 1 as well as in zone 2 the focus of risk communication is to raise the level of understanding amongst the general population. In case of compliance with the limit value (zone 1), most of all, trust should be built and in zone 2 awareness should be created. In zone 3 risk communication aims at changing the behavior of consumers. This can be achieved by recommendations or warnings. Regarding heavy metals or dioxins in fish as an example, it might be recommended for children and pregnant women to consume only short living fish. A risk-benefit depiction might also be suitable. For instance, the benefit of the intake of omega-3-fatty acids from fish prevails the potential risks of dioxins and heavy metals. In zone 4 the only action that can be taken is to warn consumers, due to the very high probability of health impairments. This zone-dependent communication applies especially to residues of plant protection products, heavy metals and organic compounds as well as food additives and plant toxins.

For genotoxic carcinogenic contaminants that occur in food unintentionally, e.g. aflatoxins, acrylamide, polycyclic aromatic hydrocarbons, furan or ochratoxin A, it is important to create awareness. These risks are often underestimated or neglected. Information concerning risk minimization are necessary, especially since almost two thirds of the Austrian population do not feel sufficiently informed about this issue (Kiefer et al. 2017). The aim is to keep the exposure as low as possible and to inform consumers how to achieve the best protection with adequate behavioral measures in the course of shopping, storage and food preparation. For example, campaigns concerning measures to ensure safe food in private households are important tools.

The aim for genotoxic carcinogenic contaminants in zone 1 is to communicate the risks with risk-benefit depictions and is therefore comparable to zone 3 of substances with health-based guidance values. For instance, the health benefit of nuts (polyunsaturated fatty acids, vitamin and mineral content) prevails the potential risk of cancer.

If the MOE exceeds zone 1, it is necessary to issue health warnings. The aim of risk communication is to discourage consumers strongly from consumption of specific food products. However, it is always essential to consider the total exposure to a specific compound. In some cases specific recommendations can lead to the reduction of exposure. For example, the calculated risk levels of arsenic in rice are in zone 3. Recommendations to wash the rice prior to cooking or steaming or to strain off the water after cooking can greatly reduce arsenic exposure. In general, a well-balanced diet is recommended and can also contribute to lower the exposure to specific harmful substances. Other grain varieties, like wheat (bulgur, couscous), rye, oats, spelt, green spelt, barley or gluten free alternatives like millet, corn as well as pseudo grains like buckwheat, quinoa, amaranth or potatoes should be consumed to provide a better variety in the diet. This reduces the exposure to arsenic which is found in rice in particularly high amounts. In terms of consumer protection, rice products such as rice wafers, rice porridge and rice drinks should be consumed occasionally but not on a daily basis. Hence, the consumer fears can be dispelled by giving them a better understanding of a well-balanced diet and advice for an adequate preparation.

Table 1: Measures and aims of risk communication in dependence on risk characterization of substances with health-based guidance values

	Measure	Aim
Zone 1	Information	Building trust, increasing risk sovereignty, improving level of information concerning risks
Zone 2	Information	Creating awareness, improving level of information concerning risks
Zone 3	Health warning, Recommendation	Behavioral change, understanding harmful effects on human health, risk-benefit depiction (e.g. fish consumption and dioxin content in fish)
Zone 4	Health warning	Behavioral change, understanding harmful effects on human health

Table 2: Measures and aims of risk communication in dependence on risk characterization of genotoxic carcinogenic substances

	Measure	Aim
Zone 1	Information, Recommendation	Behavioral change, provision for prevention and reduction, improving the level of information concerning risks, increasing risk sovereignty, creating awareness, risk-benefit depiction. If a limit value is set (e.g. aflatoxins, polycyclic aromatic carbohydrates): like zone 1 for substances with health-based guidance value: building trust, increasing risk sovereignty, improving level of information concerning risks
Zone 2	Information, Recommendation, Health warning	Behavioral change, provision for prevention and reduction, improving the level of information concerning risks, increasing risk sovereignty If a maximum level is set: like zone 3 for substances with health-based guidance values: Behavioral change, understanding harmful effects on human health, risk-benefit depiction Health warning: if single product is effected Consider all exposures: recommendations for consumption (arsenic)
Zone 3	Health warning	Health warning: if single product is effected Consider all exposures: recommendations for consumption (arsenic)

Conclusion

Food safety is a pivotal issue for the health of the population. The evaluation of chemical substances in food is based on guidance values that are based on scientific studies.These values are derived in the course of risk assessments. Based on the risk

assessment, the legislator sets legal limit values . Despite the fact that food has never been safer, the lack of scientific comprehension of different terms with similar meaning and corresponding discussions among experts contribute to uncertainties among the population as well as misperceptions of risks related to food safety by the consumer.

Therefore, risk communication and risk information play an important role. In order to increase the risk sovereignty of the population, it is crucial to communicate risk terms uniformly. Risk sovereignty requires that risks are judged and interpreted correctly. This assumes that risks have to be communicated in a way to rule out any misinterpretation or distortions and to ensure that the message is understood easily. In general, consumers prefer all-or-nothing-assessments (is a food product healthy or unhealthy), which are often not possible to provide from a scientific point of view. Scientific discussions concerning risk assessment or the discourse of different expert opinions are obstructive for the general understanding of a specific issue. Therefore, AGES developed a uniform description of risks in cooperation with various stakeholders. AGES utilizes this description of risks in the communication to consumers, in which the extent of the specific risk, the exposure to a specific hazard, the possibility of controlling the risk as well as the kind of hazard is considered.

Literature

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