German Federal Institute for Risk Assessment

FAQ

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Questions and answers on plant protection product residues in food

Plant protection products are used to protect plants from pests and competing weeds. Even when authorised plant protection products are used properly and as intended, residues may remain in the harvested crop and in the food and feed produced from it. To ensure that residues do not harm the health of consumers, either through lifelong daily consumption or through the consumption of large quantities of food on a single occasion, the German Federal Institute for Risk Assessment (BfR) carries out a comprehensive health assessment of plant protection products as part of the authorisation process and, on this basis, develops proposals for maximum residue levels. The permissible amounts of an active substance that a foodstuff may contain are determined in accordance with the ALARA principle ("*As Low As Reasonably Achievable*").

Maximum residue levels are the maximum permissible concentrations of active substances in plant protection products and their degradation products that may remain in food. They are not determined solely on the basis of the health risk assessment, but also take good agricultural practice into account. Compliance with a maximum residue level determines whether a food product is marketable or must be withdrawn from the market.

Against this background, the BfR has compiled frequently asked questions and answers on the authorisation of plant protection products, how maximum residue levels are set, and the consequences of possible exceedances.

Why are plant protection products used?

Plant protection products are intended to protect plants or parts of plants – including fresh fruit, vegetables and seeds – from pests such as fungi, weeds or harmful organisms. They are also used to secure crop yields, protect crops during storage and transport, and ensure good food quality. Although fewer plant protection products are used in organic farming than in

conventional agriculture, even organic farmers cannot do without chemical plant protection products entirely.

What is the difference between plant protection products and active substances?

Active substances are chemical elements and their compounds or microorganisms with a general or specific effect against pests on plants, parts of plants or plant products. Plant protection products are commercially available preparations that may contain one or more active substances and one or more formulation additives in the form of a mixture or solution.

How many plant protection products are authorised in Germany?

An overview of the plant protection products authorised in Germany is available in the online database of the German Federal Office of Consumer Protection and Food Safety (BVL) (https://psm-zulassung.bvl.bund.de/psm/jsp/). This also shows which and how many active substances are contained in a plant protection product. In addition, the BVL also publishes an annual overview of sales of plant protection products in Germany.

The latest information can be found on the BVL website:
https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/01_meldungen_par_64/meld_par_64_2023.pdf?__blob=publicationFile&v=2

How do plant protection products enter the German market?

Before plant protection products can be sold and used in agriculture, they must be authorised in Germany. Authorisation is granted for a specific purpose (indication), i.e. to combat a specific pest on or in a crop. This is therefore referred to as "indication authorisation".

In accordance with the applicable EU regulations, the assessment of the risks that may arise from the use of a given plant protection product is carried out by an EU Member State on behalf of the Member States in a zone. The EU territory is divided into three zones for this purpose, with Germany being part of the central zone. The Member States in each zone are directly involved in the assessment of the plant protection product through their comments. The actual authorisation of the plant protection product is carried out at national level. In Germany, it is granted by the German Federal Office of Consumer Protection and Food Safety (BVL). The Julius Kühn Institute – Federal Research Centre for Cultivated Plants (JKI), the German Federal Environment Agency (UBA) and the German Federal Institute for Risk Assessment (BfR) are involved in the authorisation process and carry out partial assessments within the scope of their responsibilities. The BfR assesses the health risks for consumers, operators, workers, residents and bystanders. (More information can be found in our FAQ on the plant protection product authorisation process).

Are active substances also subject to authorisation?

Active substances are not authorised nationally, but are approved at EU level for use in plant protection products under a regulation following a comprehensive joint assessment involving all Member States and the European Food Safety Authority (EFSA). Once approved, these active substances are generally available for authorisation and use in plant protection products.

What are plant protection product residues?

Plant protection product residues are the remnants of active substances and their degradation products that are found on or in food. Degradation products can be formed in plant metabolism or, for example, under the influence of sunlight.

Why can the use of plant protection products lead to residues on harvested products?

Even with good agricultural practice and the proper, intended use of plant protection products, residues on harvested products cannot be completely avoided. Plant protection products are used at different times during the growing season. Their active substances degrade at different rates. Residues are particularly likely to be present at harvest time if plant protection products are used shortly before harvesting or if their active substances are relatively long-lasting. However, these residues must be low enough to ensure the health of consumers.

Are plant protection product residues permitted in food?

Plant protection product residues in food are permitted up to the legally specified maximum residue levels. According to current scientific knowledge, no adverse health effects are to be expected if the maximum residue levels are complied with.

Which foods may contain plant protection product residues?

Plant protection product residues can be found in plant-based foods. Foods of animal origin may also contain such residues if the animals have previously consumed plant-based feed containing plant protection product residues.

What is meant by "good agricultural practice"?

The principles for implementing "good agricultural practice", also referred to as "good professional practice in plant protection", are to be understood as guidelines and apply to anyone who carries out plant protection measures. They stipulate that plant protection products must be used in a manner appropriate to the location, crop and situation, and that their use must be limited to what is strictly necessary. The products should only be used if

there is an infestation that warrants control. The necessary plant protection measures must be carried out and documented in an appropriate manner.

What influence does the BfR have on the authorisation of plant protection products?

The BfR is involved in the authorisation process as a competent authority. Among other things, it only supports the authorisation of a plant protection product if the residues that may remain on food after proper use are harmless to health according to current scientific knowledge and if suitable analysis methods exist with which the residues can be monitored. Proper use must also not lead to unacceptable effects on operators, workers, bystanders and residents. The BfR's vote is taken into account in the decision on authorisation.

How does the BfR determine potential consumer risks in the authorisation process for plant protection products?

The BfR conducts a health risk assessment in order to determine potential consumer risks posed by plant protection product residues. Two factors are taken into account: the toxicological reference value for the intake of the active substance in the plant protection product and the amount of the active substance that consumers ingest via contaminated products. This intake is referred to as "exposure".

How does the BfR determine the toxic effect of an active substance?

The toxic effect is determined on the basis of study results. These are mostly animal studies that provide information on the acute, subacute and chronic toxicity of a plant protection product active substance. Among other things, they also provide information on possible mutagenic (genotoxic), carcinogenic and reproductive toxicity properties. Two important health-based reference values are derived from these studies as part of the EU active substance assessment: the acute reference dose (ARfD) and the acceptable daily intake (ADI). The ARfD refers to the immediate (acute) effect of a substance, while the ADI refers to its chronic (lifelong) effect.

What is an ADI value?

ADI stands for "Acceptable Daily Intake" and indicates the amount of a substance that a consumer can ingest daily throughout their lifetime without any discernible health risk. The ADI value is used to assess chronic risks.

What is the acute reference dose (ARfD)?

The acute reference dose (ARfD) is defined as the amount of a substance that a consumer can ingest with food over the course of a day without any discernible health risk. The ARfD represents a health-based reference value for short-term exposure of individuals.

How does the BfR derive ARfD and ADI values?

In order to derive toxicological reference values for scientific risk assessment, the BfR evaluates suitable studies. These include studies on laboratory animals. These studies experimentally determine the dose without observable adverse effects (no observed adverse effect level, NOAEL) for the most sensitive animal species and the most sensitive sex. Short-term studies are usually used to derive the ARfD. The ADI value is derived from toxicity studies in which chronic endpoints were investigated. These are often studies looking into carcinogenicity or reproductive or multigenerational aspects. The dose without observable adverse effects derived from the relevant studies is divided by what is known as an (un)safety factor, which takes into account differences between species (i.e. animals and humans) as well as differences between individuals (i.e. individual humans). A factor of 100 is usually used for this purpose.

How does the BfR determine consumer exposure to plant protection product residues in the authorisation process?

Consumer exposure via food (intake amount) is determined from the level of residue in the food and the amount of food normally consumed. The concentration of the residue in the food is derived from studies in which the plant protection product was used under realistic conditions (monitored residue trials). Consumption amounts are available from consumption studies.

What consumption data does the BfR take into account when assessing plant protection product residues?

The amounts of food typically consumed by consumers in Germany were determined in two consumption studies. Firstly, the results of the so-called VELS study, a consumption study of German children aged between two and four years, which was published in 2005, are used. This population group is considered particularly sensitive due to its comparatively high food intake in relation to its low body weight. Secondly, consumption data for the 14 to 80-year-old population in Germany, which was collected in the National Consumption Study II (NVS II), is used. The consumption habits of children in Germany have meanwhile been surveyed again, and additional consumption data for 6- to 17-year-olds in Germany is available from the EsKiMo study. There are plans to update the consumption model used in Germany with this data.

In addition to German consumption data, the BfR also takes into account consumption information from other EU Member States, which is summarised in the EFSA PRIMo model.

When does the BfR support an authorisation from the perspective of consumer health protection?

If the risk assessment shows that the residues resulting from the application do not exceed either the ADI value or the ARfD, no health risk to consumers is to be expected. Only then is

the authorisation of the corresponding plant protection product justifiable from the perspective of consumer health protection.

A health risk is not to be expected if the following two conditions are met:

- If the maximum intake of a plant protection product residue remains below the ARfD; the maximum intake is calculated individually for each foodstuff and is based on the highest residue found in the monitored residue trials in conjunction with the maximum consumption amount.

- If the average intake of a plant protection product residue remains below the ADI value; the average intake is calculated from the median of the results of the monitored residue tests in conjunction with an average consumption amount and is summed up for all foods consumed.

Are plant protection products with carcinogenic active substances authorised?

When it comes to carcinogenic substances, a distinction must be made between those that are known or likely to be carcinogenic to humans and are classified in category 1, and those that are suspected of being carcinogenic to humans and are classified in category 2.

For substances in category 1, the cut-off criteria of the EU Plant Protection Products Regulation (EC) No 1107/2009 apply. These substances may only be approved if human exposure to them is negligible.

For substances in category 2, which are carcinogenic but do not damage genetic material, the carcinogenic effect is based on a threshold value determined according to current scientific knowledge. Below this value, a carcinogenic effect is not to be expected.

Do the current authorisation criteria sufficiently rule out risks to consumers?

From a risk assessment perspective, the current authorisation criteria sufficiently rule out health risks to consumers. The European Commission has set a high level of protection for plant protection products in its authorisation regulations. Accordingly, plant protection products may only be authorised if, according to current scientific knowledge, their residues have no harmful effects on human health when used in accordance with good agricultural practice. In order to meet the requirements for authorisation, extensive studies on toxicity, residue behaviour and residue analysis must be submitted for the active substances and plant protection products. Plant protection product active substances are therefore among the chemical substances that are best studied and characterised in terms of potential hazards and risks to health.

Based on the harmful effects of a substance determined in toxicological tests and the dose-response relationships, it is generally possible to characterise and quantify the occurrence of harmful effects on health at a defined exposure level. It is also possible to estimate dose ranges in which harmful effects on health can be ruled out with sufficient certainty.

Is there a health risk for citizens when plant protection products are applied in their vicinity?

The use of plant protection products may cause an unpleasant odour in individual cases. However, according to current scientific knowledge, no adverse health effects are to be expected for citizens as long as authorized plant protection products are used in accordance with good professional practice. The plant protection services of the respective federal states are responsible for questions regarding the use of plant protection products. An overview of the official information centres for plant protection in the federal states is provided by the German Federal Office of Consumer Protection and Food Safety (BVL):

http://www.bvl.bund.de/pflanzenschutzdienste

Further information is available at:

https://www.nap-pflanzenschutz.de/risikoreduzierung/schutz-von-umwelt-und-gesundheit/schutz-von-anwendern-und-verbrauchern?sword_list%5B0%5D=Flyer&no_cache=1

What happens if the ADI value or ARfD for a substance is exceeded due to the intake of residues?

A single exceedance of the ADI value and even a short-term (lasting several days) exceedance of the ADI value does not pose a risk to consumers, because the value is derived on the assumption of daily exposure over a lifetime.

In contrast, a possible health impairment due to a single or short-term exceedance of the ARfD cannot be ruled out from the outset. Whether damage to health can actually occur must be examined on a case-by-case basis.

What are maximum residue levels?

A maximum residue level (also known as maximum residue amount) specifies the maximum permissible concentration of a plant protection product active substance in a foodstuff. Maximum residue levels serve as binding trade standards to ensure the free movement of goods. Foodstuffs are only marketable if they comply with the maximum residue levels.

How are maximum residue levels set?

The EU procedure for setting maximum residue levels is formally independent of the national authorisation procedure for plant protection products. The maximum levels are derived by experts from the Member States and the European Food Safety Authority (EFSA) in a Community procedure, checked for their safety and then published by the European Commission in legally binding EU regulations. This means that the same maximum levels automatically apply in all EU Member States.

Are there national deviations for maximum residue levels?

Yes. As the scope of the German national Maximum Residue Limits Regulation (RHmV) was more comprehensive than EU law, the parts of the RHmV that are not yet regulated in the EU continue to apply and thus supplement EU law. Details on this have been published by the BVL:
https://www.bvl.bund.de/DE/Arbeitsbereiche/04_Pflanzenschutzmittel/01_Aufgaben/07_RueckstaendeHoechstgehalte/03_RHG_Listen_Rechtsgrundlagen/01_RHMV/psm_Regelungen_zu_Hoechstmengen_RHMV_node.html

In specific situations, national maximum residue levels that deviate from the EU maximum levels may be set to support so-called emergency authorisations, if necessary. These maximum residue levels only apply to the market of the respective country and must not pose a health risk to consumers in Germany. We have compiled further information on emergency authorisations for plant protection products in a separate FAQ.

What requirements must maximum residue levels meet?

Before a new maximum level can be set, it must be ensured that compliance with it can be monitored. To this end, the residues must be analytically determinable, if possible, using a quick and simple routine analytical method. Residues at the maximum level must also not pose an acute or chronic risk to consumers. In order to assess this, the toxicological properties and residue behaviour of the active substance must be evaluated before a new maximum level is set.

How does the BfR derive proposals for maximum residue levels?

When determining the permissible amounts of an active substance that a foodstuff may contain, the ALARA principle ("*As Low As Reasonably Achievable*") applies. Maximum levels are therefore never set higher than is necessary according to good agricultural practice. This takes into account the requirement to minimise the use of plant protection products.

The maximum levels are set on the basis of residue trials carried out in accordance with the application of a plant protection product requested for the respective crop and as required to control the pest. The trials are designed under controlled conditions to test the most critical permissible use: the highest permissible application rate, the highest permissible number of applications, the latest permissible application date and the shortest waiting period between the last application and harvest. The test results are used to determine the residue remaining in the harvested crop, and a corresponding proposal for a maximum content is submitted. Under certain circumstances, other aspects, such as changes in the residue during processing, are taken into account. Finally, it is examined whether the derived maximum content is acceptable from a health perspective, i.e. whether residues at this level do not pose an acute or chronic risk to consumers. Only if there is no evidence of a risk to consumers will the BfR propose the maximum residue level.

What are import tolerances?

So-called import tolerances correspond to maximum residue levels, but refer to foodstuffs imported into the European Union (e.g. rice, coffee, tropical fruits). Import tolerances are only granted for the requested active substance-food combinations if, from the point of view of consumer health protection, residues at the requested level do not pose a risk according to current scientific knowledge.

Why are maximum residue levels changed?

The setting of maximum residue levels is a continuous process. As soon as applications for new uses and/or new plant protection products are submitted and corresponding residue trials are presented, the existing maximum levels must be reviewed and, if necessary, changed.

In addition, maximum levels are adjusted in line with scientific findings. For instance, new toxicity studies or new consumption data can lead to a change in existing maximum levels because the risk assessment is updated and the safety of maximum levels is reassessed.

What happens if the residue of a plant protection product in a foodstuff exceeds the maximum residue level?

Exceeding a maximum residue level constitutes a violation of applicable law. The product in question is not marketable. However, this does not necessarily mean that the detected residue also poses a health risk to consumers, as maximum residue levels are not only based on toxicological considerations but also take good agricultural practice into account. Usually, health-based reference values (ADI value or ARfD) are only reached at much higher concentrations.

What are multiple residues in food?

The term "multiple residues" refers to the simultaneous occurrence of residues of different plant protection product active substances in a foodstuff. Consumers can also ingest multiple residues by consuming different foods at the same time or in quick succession.

How do multiple residues occur in food?

Modern plant protection product active substances are characterised by their selective, i.e. targeted, effect on specific pests. The use of so-called broad-spectrum active substances has decreased significantly in recent years, while the use of selective plant protection active substances has increased. As a result of this trend, depending on the infestation situation, many different plant protection products are used, which can lead to residues in the harvested crop. Changing the active substance is also necessary to prevent the development of resistance, as otherwise some pests can no longer be controlled in the longer term.

The continuous development of residue analysis has led to more and more active substances being detected in ever lower concentrations. This has also led to a greater focus on multiple residues.

Why might the simultaneous intake of several substances be assessed differently from a toxicological point of view than the intake of individual substances?

Individual active substances have been very well studied from a toxicological perspective. If several substances occur simultaneously, there are basically four ways in which these substances can interact:

- They can have different effects that are independent of each other.
- Their effects may be similar/identical and add up (additive effect).
- They can reinforce each other's effects (synergistic effect).
- They can weaken each other's effects (antagonistic effect).

Plant protection product residues in food normally occur in very low concentrations, well below the threshold at which the individual substances have an effect on health (effect threshold). It can be assumed that, in this low concentration range, additive effects are predominantly relevant for the assessment of a health risk. According to the current state of knowledge, synergistic and antagonistic effects can be neglected in this concentration range (see also BfR Communication No. 025/2023).

From the BfR's point of view, there is already a wealth of scientific knowledge available on the effects of multiple residues of plant protection products. Based on this knowledge, there is no reason to assume that the assessments currently being carried out are not sufficiently conservative (i.e. that they tend to overestimate the risk). Despite this, these testing and assessment strategies are subject to continuous further development and are the subject of corresponding research projects.

What have been the results of monitoring samples with multiple residues so far?

Experience gained by the BfR and the European Food Safety Authority (EFSA) has shown that, when evaluating food samples containing multiple residues, many substances occurred only in very low concentrations and the total residue was usually dominated by one active substance. If samples contained several active substances, the joint evaluation of these substances did not generally lead to a fundamentally different result than the individual substance evaluation.

Who monitors compliance with maximum residue levels for food?

Anyone who places a foodstuff on the market is obliged to guarantee compliance with the maximum residue levels in foodstuffs. Trading companies typically carry out their own internal quality controls. The official food monitoring authorities of the federal states use

extensive monitoring programmes to check whether companies are fulfilling their duty of care and whether consumers are adequately protected.

Where can I find information on applicable maximum residue levels and approved active substances?

Up-to-date information is provided online by the European Commission at:

https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en

How do consumers estimate the risks posed by plant protection product residues in food?

Many consumers assume that food should not contain any plant protection product residue. This is the result of a representative survey of the German population on the topic of "plant protection product residues in food", which was conducted on behalf of the BfR.

Consumers in Germany consider plant protection product residues in food to be a relatively high health risk. However, according to current scientific knowledge, no adverse health effects are to be expected if the maximum residue levels are complied with. Furthermore, the BfR has not received any reports of health effects caused by plant protection product residues in food. Against this background, the BfR continuously informs consumers to enable them to make a realistic assessment of the risk. To this end, the BfR cooperates with a large number of social groups and multipliers.

In recent years, the BfR has also provided health risk assessments and expert opinions on widespread media reports about detected plant protection product residues, including in cereals, strawberries, mulled wine and Christmas trees.

How does the BfR assess the initiatives of food retailers to reduce plant protection product residues on food?

According to current scientific knowledge, foodstuffs do not pose a health risk if the legally applicable maximum levels for plant protection product residues are complied with. Regardless of this, some retail chains impose additional requirements on their suppliers for maximum plant protection product residue levels in foodstuffs that are far stricter than the legal requirements (so-called secondary standards).

In principle, the BfR welcomes all efforts that contribute reducing the use of plant protection products in agriculture and reducing residues on food. However, the BfR sees a risk that secondary standards may have undesirable consequences for the use of plant protection products in agriculture. Consciously refraining from changing active substances (with the aim of keeping the total number of detectable active substances in food as low as possible) can lead to an increased occurrence of resistance in pests. These can then no longer be controlled, or only with great difficulty. In order to reduce residues in crops, producers are also increasingly forced to use plant protection products preventively and early in the growing season instead of according to need and situation, which is no longer in

line with "good agricultural practice". The establishment of secondary standards can also lead to uncertainty among consumers, as they may lose confidence in the legal regulations and official risk assessments.

About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the remit of the Federal Ministry of Food, Agriculture and Rural Affairs (BMLEH). It protects human health preventively in the areas of public health and veterinary public health. The BfR advises the Federal Government and the federal states on issues relating to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.

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