Risiken erkennen – Gesundheit schützen

Questions and Answers on Residues of Plant Protection Products in Food

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Plant protection products, i.e. pesticides, are used to protect crops against harmful organisms. Even when authorised plant protection products are used properly and in line with their intended purposes, residues can remain in the harvested crops and in the processed plant commodities used as food and feed. To ensure that levels of residues in food are not harmful for consumer health, either through lifelong daily food intake or short-term consumption of large portions of food, the BfR estimates a comprehensive risk assessment as part of the authorisation procedure and recommends maximum residue levels on the basis of this risk assessment. In addition, the determination of acceptable quantities of an active substance in food items follows the ALARA principle (As Low As Reasonably Achievable).

Maximum residue levels are the maximum concentrations permitted in foods and animal feeds of the active substances contained in plant protection products and their degradation products. They are not determined solely on the basis of the health risk assessment but also take into account good agricultural practice. Compliance with a maximum residue level is the decisive factor when determining whether a food is fit for sale or must be removed from the market.

In this context, the BfR has compiled frequently asked questions regarding the authorisation of plant protection products, the setting of maximum residue levels and the possible consequences if these levels are exceeded.

Why are plant protection products used?
Plant protection products are intended to protect plants or parts of plants, including fresh fruit, vegetables and seeds, against the damage caused by such things as fungi, weeds and harmful organisms. They are also used to protect the harvested crops during storage and transport and to guarantee that food is safe and of a high quality. Although far fewer plant protection products are used in organic farming than in conventional farming, even organic farmers cannot manage completely without the aid of chemical plant protection products.

What is the difference between plant protection products and active substances?
Active substances are chemical elements and compounds or micro-organisms with general or specific effects on harmful organisms on plants, parts of plants or plant products. Plant protection products are commercially available preparations which, as mixtures or solutions, can contain one or more active substances and one or more adjuvants.

How many active substances does a plant protection product contain?
Of the plant protection products authorised in Germany, 66 percent contain only one active substance, 27 percent two active substances, 6 percent three and 1 percent four active substances (as of November 2014).

How many plant protection products are authorised in Germany?
In November 2014, 775 different plant protection products were licensed in Germany. These products contained a total of 276 different active substances.
The latest details can be found in the online database of the Federal Office of Consumer Protection and Food Safety (BVL):
http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/01_OnlineDatenbank/psm_onlineDB_node.html.

How does a plant protection product find its way onto the German market?
Plant protection products must be authorised in Germany before they can become available on the market or used in agriculture. Authorisation is granted for a certain purpose (indication), i.e. to counteract a specific pathogen in a cultivated plant, which is why it is referred to as an authorisation “for indicated uses only”. The assessment of the risks that can arise from the use of a plant protection product is made by an EU member state as a representative of the member states of an entire zone in line with the applicable EU regulations. The territory of the EU is subdivided into three zones - with Germany being a member of the central zone. The member states of each zone are directly involved in the evaluation of the plant protection product by means of comments, but actual authorisation is issued at the national level. In Germany, this is governed by the Federal Office of Consumer Protection and Food Safety (BVL). The Julius Kühn Institute (Federal Research Centre for Cultivated Plants - JKI), the Federal Environmental Agency (UBA) and the Federal Institute for Risk Assessment (BfR) are involved in the authorisation procedure and conduct partial assessments within the scope of their jurisdiction. The BfR assesses the health risks for consumers, operators and non-professional users, local residents and bystanders.

Do active substances also need to be authorised?
Active substances are not authorised at the zonal or national level, but rather they are approved at EU level for use in plant protection products after a comprehensive joint evaluation involving all of the member states. After approval, these active substances are available for authorisation and use in plant protection products.

What is meant by pesticide residues?
Pesticide residues is the term used for any remains of active substances and their degradation products in or on food and feed. Degradation products can be formed during plant metabolism (“metabolites”) or, for example, under the influence of sunlight.

How is it possible that the use of plant protection products can leave residues on the harvested crops?
Residues on harvested crops cannot be completely avoided, even in the case of good agricultural practice and the proper use of plant protection products. Plant protection products are used at different times during the growth season and the degradation rates of their active substances vary. Residues are to be expected at the time of harvesting, particularly when plant protection products are applied shortly before harvesting or when their active substances are persistent. However, the levels must be low enough that they do not pose a risk to human health.

Are residues of plant protection products allowed in food?
Residues of plant protection products are allowed in foods up to each legally prescribed maximum residue level. According to the latest levelcurrent state of scientific knowledge, negative effects on consumer health are unlikely if the residue levels remain below these maximum permissible residues.

Which foods can have pesticide residues?
Pesticide residues may be found on foods of plant origin. Foods of animal origin can also contain residues, however, if the animals have eaten feed of plant origin that contained residues.

What is meant by “good agricultural practice”?
The principles of "good agricultural practice", also called "good plant protection practice", should be regarded as instructions applying to all persons who carry out plant protection

measures. They stipulate that plant protection products must be used in a manner that is adequate to suit the location, crop and situation, and that their use must be kept to the necessary minimum. The products should only be used when there is a case of infestation that "requires control". The necessary plant protection measures must be carried out appropriately and be well documented.

What influence does the BfR have on the authorisation of plant protection products?
The BfR is involved in the authorisation procedure as an advisory authority. It only agrees to the authorisation of a plant protection product if the residues remaining on foods after correct use do not pose a health risk according to the current state of scientific knowledge and suitable analysis methods exist with which the residues can be monitored. In addition, proper use may not have unacceptable effects on either operators or non-professional users, workers, bystanders or local residents. The BfR vote is taken into account when a decision on authorisation is made.

How does the BfR determine a possible risk to consumers during the authorisation procedure?
The BfR carries out a risk assessment to establish a possible consumer risk from pesticide residues. Two factors are taken into account here: the toxicological limit value for the intake of an active substance of the plant protection product and the amount of this substance ingested by a consumer from contaminated products. This intake quantity 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, subchronic and chronic toxicity of a pesticide active substance. They also provide information on possible mutagenic (genotoxic) and cancer-causing (carcinogenic) properties of the substance as well as whether it has toxic effects on the process of reproduction. The BfR derives two important toxicological threshold values from these studies within the scope of the EU active substance examination: the acute reference dose (ARfD) and the acceptable daily intake (ADI). The ARfD refers to the acute and the ADI to the chronic effect of a substance

What is an ADI?
ADI stands for Acceptable Daily Intake and indicates the amount of a substance that a consumer can ingest daily over an entire lifetime without any recognisable health risk. The ADI value is used to assess the chronic risk.

What is meant by the acute reference dose?
The acute reference dose (ARfD) is defined as the quantity of a substance in food that a consumer can ingest in the course of one day spread over one or more meals without any appreciable health risk.

How does the BfR derive the ARfD and ADI?
In order to derive toxicological limit values for the scientific risk assessment, the BfR evaluates suitable studies, including studies on test animals. By means of these studies, the “No Observed Adverse Effect Level” (NOAEL) is established for the most sensitive species and the more sensitive gender. Short-term studies are normally used to establish the ARfD. The ADI is derived from toxicity studies in which chronic endpoints were examined. These are often carcinogenicity, reproduction or multi-generation studies. The *No observed adverse effect level* established from the relevant studies is then divided by a so-called (un)certainty or safety factor, which takes into account both inter-species differences (i.e. between animals

and humans), as well as differences between individuals (i.e. individual humans). The most common uncertainty factor is 100.

How does the BfR determine consumer exposure to pesticide residues within the authorisation procedure?
Consumer exposure via food (intake quantity) is established from the level of residue in a food and from the amount of this food normally consumed. The concentration of residues in food is derived from studies in which the plant protection product was used under real conditions (monitored residue experiments). Consumed quantities are available from so-called consumption surveys.

Which consumption data does the BfR take into account when assessing pesticide residues?
The quantities of food currently relevant for consumers in Germany were determined in two consumption surveys. One such study is the VELS study (Consumption Survey of Food Intake among Infants and Young Children), a consumption survey of German children aged between two and four years published in 2005. The results of this survey are used since this population group is categorised as particularly sensitive due to the comparatively high food intake in relation to a low body weight. Secondly, consumption data for 14 to 80-year old consumers in Germany collected in the National Nutrition Survey II (NVS II) are used. Beginning in 2015, the consumption data for 6- to 17-year old consumers in Germany from the Eating Study as a KiGGS Module (EsKiMo) will additionally be taken into consideration, which is part of the National Health Interview and Examination Survey for children and adolescents (KiGGS).

In addition to the German consumption data, the BfR also takes consumption data from other EU member states into account.

When does the BfR agree to authorisation from the point of view of consumer health protection?
A health risk for the consumer is unlikely if the risk assessment concludes that neither the ADI nor the ARfD are exceeded as a result of residues from the use of the plant protection product. Only then can the authorisation of a plant protection product be justified from the point of view of consumer health protection.

A threat to consumer health is not to be expected if the following conditions are met:

- The estimated maximum intake quantity of a pesticide residue remains below the ARfD. The maximum intake quantity is calculated individually for each food from the highest amount of reside that occurred in the supervised residue trials in conjunction with the maximum quantity consumed.

- The estimated average intake of a pesticide residue remains below the ADI. The average intake is calculated from the median of the results of the supervised residue trials in conjunction with an average intake quantity and is added up for all foods consumed.

Are plant protection products with carcinogenic active substances authorised?
A difference must be made between carcinogenic substances that are known to or are likely to have a carcinogenic effect on humans and are classified as carcinogens category 1 and those that are suspected of being able to cause cancer in humans and are classified as carcinogens category 2.

The exclusion criteria of the EU active substance regulation apply to Category 1 substances. These substances may only be approved if human exposure to them is negligible.

With Category 2 substances, which have a carcinogenic effect but do not damage genetic material, the carcinogenic effect is based on a threshold value in line with the current status of scientific knowledge. Below this level, a carcinogenic effect is not to be expected.

Do the applicable authorisation criteria exclude consumer risks to a sufficient extent?
From a risk assessment perspective, the applicable authorisation criteria eliminate consumer risks with a sufficient degree of certainty. With the authorisation provisions, the European Commission has stipulated a high safety level. Plant protection products may only be authorised if, after the application of good agricultural practice, their residues have no adverse effects according to current scientific knowledge. To satisfy the prerequisites for authorisation, comprehensive test results on the toxicity, residue behaviour and the analysis of residues must be presented for the active substances. The active ingredients contained in plant protection products are thus among the best analysed and characterised chemical substances where potential hazards and health risks are concerned.

Based on the adverse effects and dose-response ratios that have been determined through toxicological testing, it is generally possible to characterise and quantify the occurrence of adverse effects as a result of a defined exposure. It is similarly possible to estimate the dose ranges in which adverse health effects can be practically excluded.

Is the health of local residents endangered if plant protection products are used near their homes?
In isolated instances, an unpleasant odour can occur when plant protection products are used. According to current scientific knowledge, however, local residents have no need to fear any health impairments as long as authorised plant protection products are used in line with good professional practice. The plant protection services of each respective federal state are responsible for answering questions on the use of plant protection products. An overview of the official information centres for plant protection in each federal state is available from the Federal Office of Consumer Protection and Food Safety (BVL):
http://www.bvl.bund.de/pflanzenschutzdienste

For further information:
https://www.nap-pflan-zenschutz.de//fileadmin/user_upload/_imported/fileadmin/SITE_MASTER/content/Dokumente/Downloads/Aktuelles/Flyer_Pflanzenschutzanwendung-2.pdf

What happens if a residue exceeds the ADI or ARfD?
A onetime exceedance of the ADI is not relevant and even the short-term exceedance (lasting for a few days) of the ADI does not constitute a risk for consumers, because this value is established on the assumption of daily lifelong exposure.

In contrast, possible adverse health effects cannot be automatically ruled out if there is a single or short-term exceedance of the ARfD. Whether adverse health effects could actually occur must be determined on a case-by-case basis.

What are maximum residue levels?
A maximum residue level (also maximum residue quantity) indicates the maximum admissible concentration of an active substance of plant protection products in a food. Maximum residue levels serve as binding trade standards to guarantee the free movement of goods. Foods may only be marketed if they comply with maximum residue levels.

How are maximum residue levels set?
The procedure for setting maximum residue levels is formally independent of the authorisation procedure for plant protection products. Maximum levels are derived in an EU procedure by experts from the member states and the European Food Safety Authority (EFSA) and tested for their health safety. They are then published in legally binding form by the European Commission. Since these are EU regulations, the same maximum levels automatically apply in all member states.

Which requirements must be met by maximum residue levels?
Before a new maximum level can be established, it must be ensured that its compliance can be monitored. To do so, it must be possible to determine the residues analytically, preferably through a fast and easy routine analytical procedure. Furthermore, residues that reach the maximum level may not constitute either an acute or a chronic risk for consumers. In order to assess this, a toxicological assessment of the active substance and its residue behaviour must be carried out before determining a new maximum level.

How does the BfR derive its proposals for maximum residue levels?
The ALARA principle (As Low As Reasonably Achievable) applies when determining the permissible quantities of an active substance in a food item. Accordingly, maximum levels are never set higher than is necessary in line with good agricultural practice. This complies with the principle of minimising the use of plant protection products.

The basis for setting maximum residue levels is formed by residue tests conducted in line with the application for use of a plant protection product in the manner necessary to control a harmful organism. The tests are designed in such a way that, under controlled conditions, the most critical permissible application is tested, i. e. the highest admissible application quantity, the highest admissible number of applications, the latest admissible time of application and the shortest interval between the last application and harvesting. From the test results, it is derived which pesticide residues may remain on the harvested crops and a corresponding maximum level is proposed.

Under certain circumstances, additional factors, such as changes of the residue during processing, are also taken into account. Finally, the derived maximum residue level is tested for its acceptability with regard to human health, i.e. whether or not residues of this amount constitute an acute or chronic risk to consumers. Only when there are no indications of a consumer risk does the BfR propose the maximum residue level.

What are import tolerances?
So-called import tolerances are the same as maximum residue levels, but they apply to foods imported into the European Union (e.g. rice, tropical fruits). Import tolerances are also only granted for active substance-food combinations for which applications have been submitted if residues at the levels applied for do not pose a hazard from the point of view of consumer health protection based on current scientific knowledge.

Why are maximum residue levels altered?
The setting of maximum residue levels is a continuous process. As soon as authorisation for new uses and/or new plant protection products has been applied for and corresponding residue studies have been submitted, the existing maximum level must be re-evaluated and amended if necessary.

Furthermore, maximum residue levels are adapted to reflect improvements in scientific knowledge. New toxicity studies or new consumption data, for instance, can lead to a change in existing maximum levels because risk assessment has been updated and the safety of maximum residue levels reviewed.

What happens if a residue exceeds the maximum residue level?
The exceedance of a maximum residue level constitutes a violation of applicable law. The product in question is not marketable. This does not necessarily mean, however, that the identified residue constitutes a risk for consumers, since maximum residue levels are not toxicological threshold values. As a rule, far higher residue concentrations would be needed to reach toxicological threshold values (ADI or ARfD).

What is meant by multiple residues in foods?
The term “multiple residues” is used to describe the simultaneous occurrence of residues of different plant protection products in one food. Consumers can also ingest several residues through the simultaneous consumption of different foods, however, or through the consumption thereof shortly after one another.

How do multiple residues occur in foods?
Modern active substances in plant protection products distinguish themselves through a targeted effect on specific harmful organisms. Substances of earlier generations often had a wider effect with more side effects. The use of broadband active substances has decreased significantly in recent years with a corresponding increase in the use of plant protection products with a specific effect. The result of this trend is that, depending on the infestation situation, many different plant protection products are used, residues of which can remain in the harvested crops. A change of active substance also makes good sense to prevent the formation of resistance, as some harmful organisms could not be controlled otherwise.

Multiple residues have existed for quite some time. The focus has been placed on them in recent years because the use of different active substances is increasing and the development of residue analysis has resulted in increasing amounts of active substances being detected in increasingly lower concentrations.

How can the simultaneous intake of several substances have different effects from a toxicological point of view than the intake of individual substances?
Individual active substances are very well tested from a toxicological perspective. If several substances occur simultaneously, there are four basic possibilities as to how they can interact with one another:

- They can be independent of one another and have different effects
- Their effects can be similar/identical and accumulate (additive effect)
- They can enhance the effect of one another (synergetic effect)
- They can diminish the effect of one another (antagonistic effect)

Pesticide residues normally only occur in foods in very low concentrations well below the threshold at which the individual substances can affect health (effect threshold). It has to be

assumed that in this low concentration range, mainly additive effects are relevant for the assessment of the health risk of multiple residues. The current level of knowledge indicates that synergetic and antagonistic effects can be ignored.

With what results have monitoring samples of multiple residues been assessed up to now?
The experiences made by the BfR and European Food Safety Authority (EFSA) have shown that when assessing food samples containing multiple residues, many substances only occurred in very low concentrations and that overall residue was usually dominated by one substance. When samples contained several active substances in approximately equal concentrations, the joint assessment of these substances did not usually lead to a fundamentally different result than the individual substance evaluation.

Who monitors compliance with the maximum residue levels for food?
Everyone commercially involved in the sale of food to consumers is obliged to guarantee compliance with maximum residue levels. Trading companies normally conduct internal quality controls. The official food monitoring authorities of the federal states establish in elaborate monitoring and surveillance programmes whether companies fulfil their duty of due diligence and consumers are sufficiently protected

Where can I find out about the applicable maximum residue levels and authorised active substances?
The latest information is provided by the European Commission in the internet under: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/.

How do consumers estimate the risks they face through residues of plant protection products in food?
Many consumers assume that no pesticide residues may be contained in foods. This is the result of a representative survey of the German population on the subject “Pesticide Residues in Food” conducted on behalf of the BfR.

Pesticide residues in food are regarded by consumers as a relatively big health problem; however, according to current scientific knowledge, adverse health effects are unlikely if the established maximum residue levels are complied with. The BfR is not aware of any reports of impaired health caused by pesticide residues in food. Against this background, the BfR provides consumers with continuous information to enable them to make a realistic estimation of the risk. To achieve this, the BfR collaborates with a variety of social groups and multipliers.

How does the BfR view the initiatives of the food retail sector to reduce pesticide residues on foods?
Based on current scientific knowledge, foods do not pose a risk to health if the legally valid maximum pesticide residue levels are complied with. Despite this, several chain store operators impose additional conditions for maximum pesticide residue levels in foods on their suppliers that are much stricter than the legal requirements (so-called secondary standards).

The BfR fundamentally welcomes all efforts that contribute to a reduction of the use of plant protection products in agriculture and residues on foods, while recognising at the same time that the secondary standards could have undesired consequences for the handling of plant protection products in agricultural businesses. The deliberate abandonment of the practice of changing active substances (with the goal of keeping the total number of detectable active substances in foods as low as possible) can lead to increased resistance in harmful

organisms, which can then only be controlled with great difficulty, if at all. To reduce residues in harvested crops, producers also see themselves increasingly forced to use plant protection products preventively and apply them early in the growing season, instead of as required by each situation, thus straying from the principles of “good agricultural practice”.

The establishment of secondary standards can also lead to uncertainty among consumers who lose trust in the legal regulations and official risk assessments.