German Federal Institute for Risk Assessment

FAQ

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Emergency authorisations of plant protection products: no adverse health effects are to be expected if used properly

Maximum residue levels for residues of plant protection products on and in plant-based foods are set by the European Commission and are valid throughout Europe for the respective crop/active substance combination. Maximum residue levels are set on the basis of residue trials in accordance with good agricultural practice and are no health-based guidance values, as they are set according to the "as low as reasonably achievable" (ALARA) principle.

In the event of an exceptional situation, the national authorisation authorities (in Germany this is the German Federal Office of Consumer Protection and Food Safety (BVL)) can grant an emergency authorisation for a crop/plant protection product combination upon request. The emergency authorisation is valid for a limited time period. In this exceptional case, it is possible for a maximum residue level set for Germany to deviate from the maximum residue levels set at the EU level.

This has now happened in Germany. An emergency authorisation has been granted for the treatment of stone fruit due to fungal infestation, which makes it necessary to set a national maximum residue level. The BfR has compiled questions and answers regarding the health risk assessment.

What is an emergency authorisation for plant protection products?

Emergency authorisation refers to a temporary, exceptional authorisation of a plant protection product for introduction to the market. Emergency authorisations are granted by national authorisation authorities within the European Union and provide approval for a limited and controlled use in order to protect crops if no regular authorisation or other control options exist. Such an emergency authorisation is only approved if no adverse health effects are to be expected when consuming food and processed products made from that food.

The legal basis is Article 53 of Regulation (EC) No 1107/2009 in conjunction with Section 29 of the Plant Protection Act.

The authority responsible for emergency authorisations in Germany is the German Federal Office of Consumer Protection and Food Safety (BVL), cf. https://www.bvl.bund.de/DE/Arbeitsbereiche/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/02_Notfallzulassungen/psm_ZugelPSM_notfallzulassungen_node.html.

To what extent is an emergency authorisation limited?

An emergency authorisation is always limited in time and amount. The authorisation is granted depending on the occurrence of harmful organisms with a maximum term of 120 days. It can also be granted for a limited area, for example, only for affected geographical regions.

Which situations allow for an application for emergency authorisation?

Emergency authorisations are always required to protect crops if the current occurrence of certain harmful organisms can no longer be controlled with the available plant protection products or alternative methods, i.e. if such a measure proves necessary in view of a danger that cannot be averted in any other way. The German Federal Office of Consumer Protection and Food Safety (BVL) can then authorise limited market availability, intra-community transport, and use of a non-authorised plant protection product. The use of an already authorised plant protection product in another, previously unauthorised application can also be permitted for a short period of time.

Who can apply for an emergency authorisation?

Applications for emergency authorisation can be submitted by associations, authorities, companies and manufacturers of plant protection products.

Can food treated with a plant protection product authorised by an emergency authorisation pose a health risk?

In the case of emergency authorisations, the BVL also checks whether the maximum residue level specified at EU level in Regulation (EC) No 396/2005 is complied with when the plant protection product is used as part of the emergency authorisation. If this is the case, no adverse health effects are to be expected for consumers when consuming the corresponding food. This is checked for each active substance when the maximum residue levels are set at the European level.

If the applicable maximum residue levels cannot be complied with in individual cases, a scientific evaluation of the available residue data is carried out. This involves examining whether health risks are to be expected from the residues in the products from the treated crops. For this purpose, the BfR is regularly consulted to assess the data. An emergency authorisation is only possible if adverse health effects are not to be expected.

Is there a health risk if the maximum residue levels for pesticide active substances in food set as part of an emergency authorisation are higher than the maximum residue levels set at EU level?

Maximum residue levels are no health-based guidance values. They are determined in residue trials with the respective crop under the given climatic and geographical conditions. In these trials, only as much plant protection product is used as is necessary for effectiveness (good agricultural practice). Maximum levels are therefore never set higher than is necessary according to good agricultural practice. The guiding principle is “as much as is necessary for plant protection under the given circumstances and as little as possible”. The ALARA principle (as low as reasonably achievable) therefore applies.

Normally, maximum residue levels set in this way are considerably lower than the health-based guidance values derived from toxicological studies, ADI (acceptable daily intake, i.e. the amount of a substance that can be ingested orally daily over a lifetime without any recognisable health risk) and ARfD (acute reference dose, indicating the estimated maximum amount of a substance that can be ingested with food over the course of a day at one or more meals without any recognisable health risk). Exceeding a maximum residue level therefore breaks the applicable law, but does not necessarily mean that the detected residue also poses a health risk to consumers.

Before a potentially higher national maximum residue level in food is set as part of an emergency authorisation, the relevant authorities check to ensure that this also does not lead to the health-based guidance values being exceeded. A provisional higher national maximum residue level can therefore also only be set if no health risks are to be expected as a result.

The nationally permitted maximum residue levels that deviate from the EU maximum residue levels in the context of an emergency authorisation only apply to the market of the authorising Member State.

How is it determined whether a measured maximum residue level in food is below the health-based guidance values or whether it exceeds them?

Exposure data form the basis for the risk assessment of pesticide residues in food. This data refers to the amount of pesticide residue that a person comes into contact with, i.e. the amount ingested via food. These values are calculated from the empirically collected consumption data for Germany and Europe for the respective food. The BfR generally uses the model of the National Nutrition Survey (NVS) II of the Max Rubner Institute in its health risk assessments for Germany. In addition, the European Food Safety Authority (EFSA) provides the calculation model “PRIMO” (Pesticide Residue Intake Model), which can be used to calculate the acute and chronic risk of pesticide residues on the basis of European consumption data. The models contain data on the consumption habits of different consumer groups such as children, women and men, categorised by age group and weight. The different consumption quantities (low consumers, normal consumers, high consumers) are also included. On the basis of the quantities of the respective food consumed per day, the extent to which the health-based guidance values for the respective pesticide are utilised by consumers due to the quantity of residues actually ingested with the food is then calculated. The health risk is derived and assessed from the results.

Do higher residue levels in apples or pears as a result of an emergency authorisation for the fungicidal active ingredient Folpet pose a health risk in certain growing regions?

The higher maximum residue levels required due to an emergency authorisation for a German cultivation area were assessed by the BfR before the emergency authorisation was granted. As the harvested products (apples, pears) and derived products may only be placed on the market in Germany, the model of the German National Food Safety Study NVS II was used for the assessment. In its assessment, the BfR concluded that no adverse health effects are to be expected at a maximum residue level of 6 mg of the pesticide active ingredient Folpet per kilogramme of apples. The relevant health-based guidance value, the acute reference dose (ARfD), is not exceeded. This assessment also applies to children and frequent consumers, i.e. people who consume a lot of apples and apple products such as drinking apple juice every day.

Theoretically, a person weighing 60 kg could consume 6 kg of apples (approx. 24-40 apples) with a Folpet content of 6 mg/kg within one day without any adverse health effects being expected according to the current state of knowledge.

Further information on the BfR website on plant protection products:

https://www.bfr.bund.de/en/plant_protection_products-579.html

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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