Bundesinstitut für Risikobewertung

Questions and Answers on the Authorisation Process for Plant Protection Products

BfR FAQ of 30 December 2014

The regulation of plant protection products in the European Union is split into two parts: whereas active substances are approved by the European Union, the plant protection products containing these active and other substances are authorised on a national or zonal level. The authorisation and use of plant protection products are regulated in Germany by the Plant Protection Act and related ordinances, as well as legal European regulations. The Federal Institute for Risk Assessment (BfR), which evaluates the health risks of the plant protection products, is one of the institutes involved in the authorisation process. The objective of the health risk assessment is to ensure that plant protection products do not cause adverse effects on human or animal health. In addition to this, the BfR is involved in the further development of the test guidelines and assessment concepts.

In light of the broad public discussion of the possible health risks of plant protection products, the BfR has compiled a set of questions and answers on their authorisation process.

How does the approval process for active substances work?
The EU evaluation of the active substance is conducted jointly with the involvement of all member states, the European Food Safety Authority (EFSA) and the European Commission. The assessment of an application is made initially by one member state (Rapporteur Member State, RMS), which prepares a comprehensive assessment report. The other member states and EFSA validate and comment on this assessment report, which is then finalised by the zonal RMS. When necessary, expert meetings coordinated by EFSA are convened at EU level to discuss special issues. EFSA ultimately prepares a summarised report (EFSA Conclusion), which forms the basis for the decision of the European Commission on the approval of the active substance.

With the approval of a substance by the European Commission, the prerequisites for the application for the authorisation of its use in plant protection products in the EU are satisfied.

How does the approval process for plant protection products work?
Unlike the approval of active substances, plant protection product licences are issued nationally in the country in which they are to be marketed or used.

Within the scope of the authorisation process, the EU has been divided into three zones for the assessment of plant protection products. Within these zones, licences can be transferred more easily to other member states by means of suitably regulated procedures. The licensing application is lodged simultaneously in the affected member states with all related documentation. One member state acting as the so-called zonal Rapporteur Member State (zRMS) is responsible for conducting the assessments and preparing a comprehensive assessment report (draft Registration Report, dRR), which is then given to the other concerned member states (cMS) for comment. The authorities of these states examine the assessment of the zRMS and convey the points that are in their view still open and have to be considered further or amended in the assessment. The zRMS finalises the Registration Report (RR) under consideration of the comments received. The finalised RR then forms the basis for authorisation in the cMS.

In the event that a plant protection product is already legally authorised in a member state, a licence can also be applied for at a later date in a country within the zone and granted by way of mutual recognition.

The process builds on the results of the examination of the active substance by the European Commission and contains a health assessment of the specific plant protection product, including all co-formulants.

Who is involved in the authorisation process?
In Germany, plant protection products must be approved for their intended purpose by the Federal Office of Consumer Protection and Food Safety (BVL). The BfR, Julius Kühn Institute (JKI) and the Federal Environment Agency (UBA) are involved in this process by making partial evaluations within their respective areas of responsibility.

What does the BfR assess?
The BfR assesses plant protection products with regard to human and animal health, the avoidance of impaired health through soil contamination and by applying analysis methods to detect residues. All groups of persons that could be affected are taken into consideration here:

- Consumers, as well as pets and domestic animals, who can ingest residues from plant protection products through their food or feed
- Agricultural operators and non-professional users of plant protection products
- People doing follow-up work on a field or in a greenhouse previously treated with plant protection products
- People who live in the vicinity of fields, agricultural areas or greenhouses treated with plant protection products
- Bystanders, such as people who can be exposed when going for a walk while plant protection products are being applied.

The health assessment for these groups of persons, as well as pets and livestock, is intended to ensure that plant protection products do not have any damaging effects on human and animal health.

When do the experts conclude that a plant protection product is “safe”?
Prior to the approval of an active substance or authorisation of plant protection products, the applicants must present extensive data packages for scrutiny by the assessment authorities involved.

Where the health assessment is concerned, toxicological limit values are established initially for each active substance that indicate the level at which the intake of an active substance does not cause any detectable adverse changes in the human body. During the authorisation process, the scientists at the BfR then assess the active substance in the context of its proposed use in a plant protection product. They evaluate the uses of the plant protection product as well as the interactions of the active substance with other co-formulants of the preparation. A plant protection product is only regarded as safe if, when used for the purpose for which the application was submitted, the intake quantity of its active substances by consumers, users or non-involved third parties lies below each toxicological limit value.

As not all endpoints for every agent and every ingredient can be examined in tests with animals, additional empirical safety factors are included in the risk assessments.

More information on this topic can be found in the FAQ “Questions and Answers on Residues of Plant Protection Products in Food”.

http://www.bfr.bund.de/en/questions_and_answers_on_residues_of_plant_protection_products_in_food-60852.html