

Legal procedures in the field of plant protection

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In the member states, Regulation (EC) No. 1107/2009 has been underpinned by national laws through the formulation of more precise stipulations at the national level – in Germany, this takes the form of the German Plant Protection Products Act (PflSchG) amended in 2012.

The following pages outline the various European and national legal procedures in the field of plant protection.

BfR is involved in the following procedures in the field of plant protection products:

European procedures for active substances

- Procedure for the approval of active substances in plant protection products:
In this procedure, a decision is made as to which active substances may be used in plant protection products in the EU (EU review of active substances).
- Procedure for setting maximum residue levels:
This procedure stipulates which levels of residues of active substances are permitted in food and feed.

In both procedures, one member state initially has the task of reviewing and assessing all the studies and information submitted by the applicant. This member state prepares an assessment report, which is then forwarded to all other member states for comment. This peer review process is coordinated by the European Food Safety Authority (EFSA). The final decision on the approval of an active substance or on the stipulation of maximum residue levels is made by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) of the European Commission.

Procedures for the approval of active substances in plant protection products

Active substances are approved on the basis of Regulation (EC) No. 1107/2009, which is valid in all member states of the EU.

The EU review of active substances aims to establish a consistently high protection level for the health of humans, animals, groundwater and the environment in all member states and to reduce distortions of competition and trade barriers between individual member states caused by different approval practices. Only approved active substances may be used in authorised plant protection products in the EU. The review of active substances is coordinated in Germany by the Federal Office of Consumer Protection and Food Safety (BVL) and is carried out with the participation of the Julius Kühn Institute (JKI), the German Federal Environment Agency (UBA), and BfR.

BfR compiles or comments on assessments in the following areas:

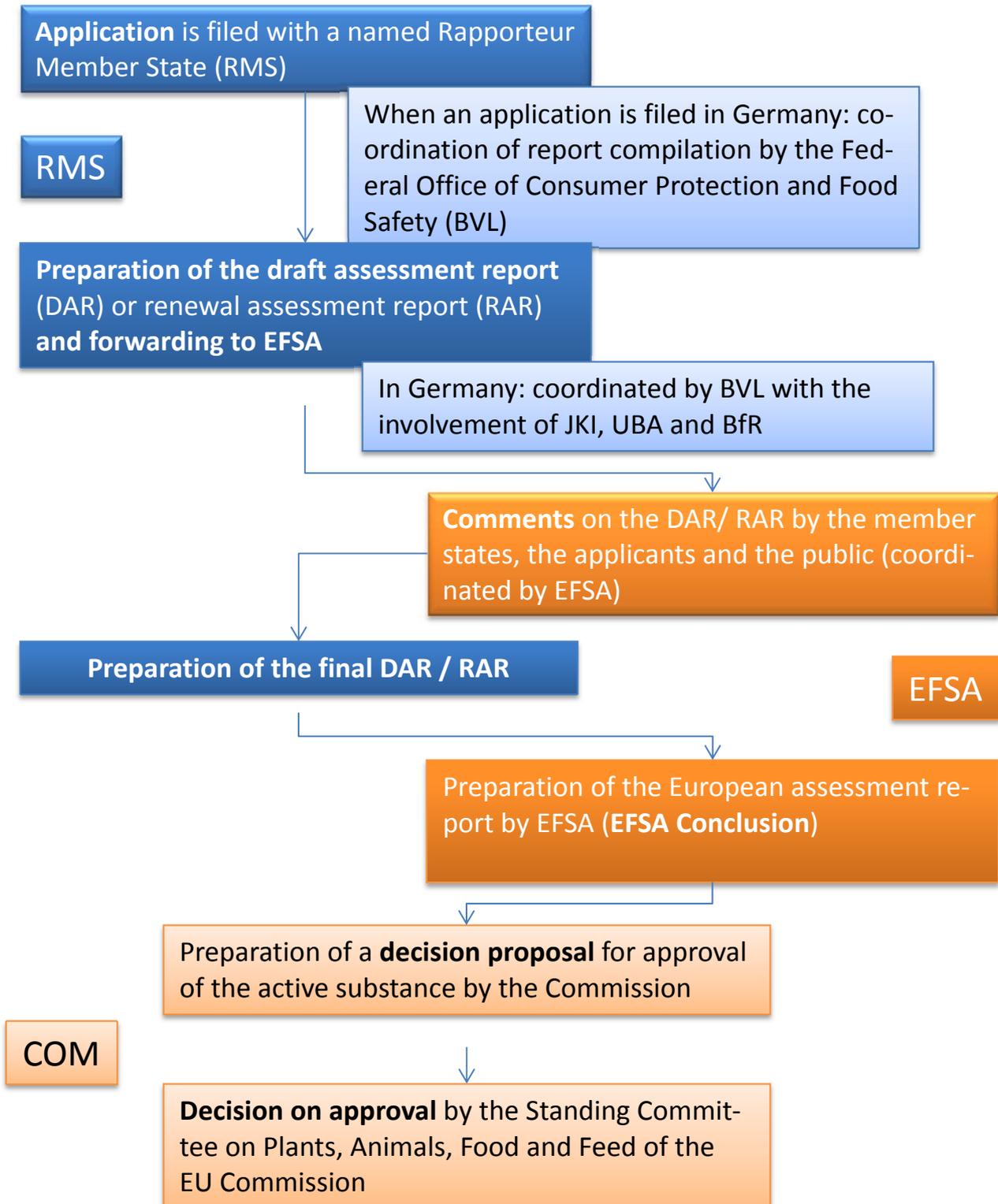
- Toxicology of active substances and products
- Exposure of users, workers, local residents and bystanders
- Residues in food of plant and animal origin
- Analytical methods for monitoring residues in food, body fluids and the environment

In the EFSA peer review process, the assessment for each active substance is carried out in coordination with all member states and includes a public consultation. If necessary, cases may be discussed at an expert meeting (PRAS) organised by the EFSA Pesticides Unit and its *Panel on Plant Protection Products and their Residues* (PPR). The Commission then makes its decision on approval on the basis of the coordinated assessment report. The findings of the EU assessments can be viewed at <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

The first approval is generally valid for 10 years. The active substance is then once again reviewed at EU level and an approval can be subsequently issued for 15 years.

The assessment by the authorities also includes literature research in scientific journals, which means that the findings reported in the literature are also incorporated in the overall assessment.

Diagram 1: Overview of the EU review of active substances



Procedure for defining maximum residue levels

Maximum residue levels are set on the basis of Regulation (EC) No. 396/2005, which is valid in all member states of the EU. Applications for new maximum residue levels or modifications of existing maximum residue levels are filed with one of the EU member states. If this member state is Germany, the application is submitted to the Federal Office of Consumer Protection and Food Safety (BVL). As part of this process, BfR evaluates the following areas:

- The toxicology of the active substance
- Residues in foods of plant and animal origin
- Analytical methods for the routine monitoring of the requested maximum residue levels

BfR proposes maximum residue levels taking into account the above assessments and the planned application conditions of the plant protection product. These are based on the results of monitored field trials that investigate the maximum possible level of residues following correct use of the plant protection product for the intended purpose. In addition, analytical methods of adequate sensitivity for the residues must be available. BfR ensures that residues of the proposed level do not pose an unacceptable risk to consumers.

Based on the assessment report, which is also made available to the other member states and applicants for their comments, EFSA prepares an assessment in which it proposes new maximum residue levels to the European Commission. The final decision lies with the Commission, which adopts a legally binding regulation establishing the MRL for each substance.

National procedures for plant protection products

Authorisation procedures for plant protection products

Plant protection products are authorised on the basis of Regulation (EC) No. 1107/2009. The detailed provisions that establish the procedures in Germany are laid down in the German Plant Protection Act (PflSchG).

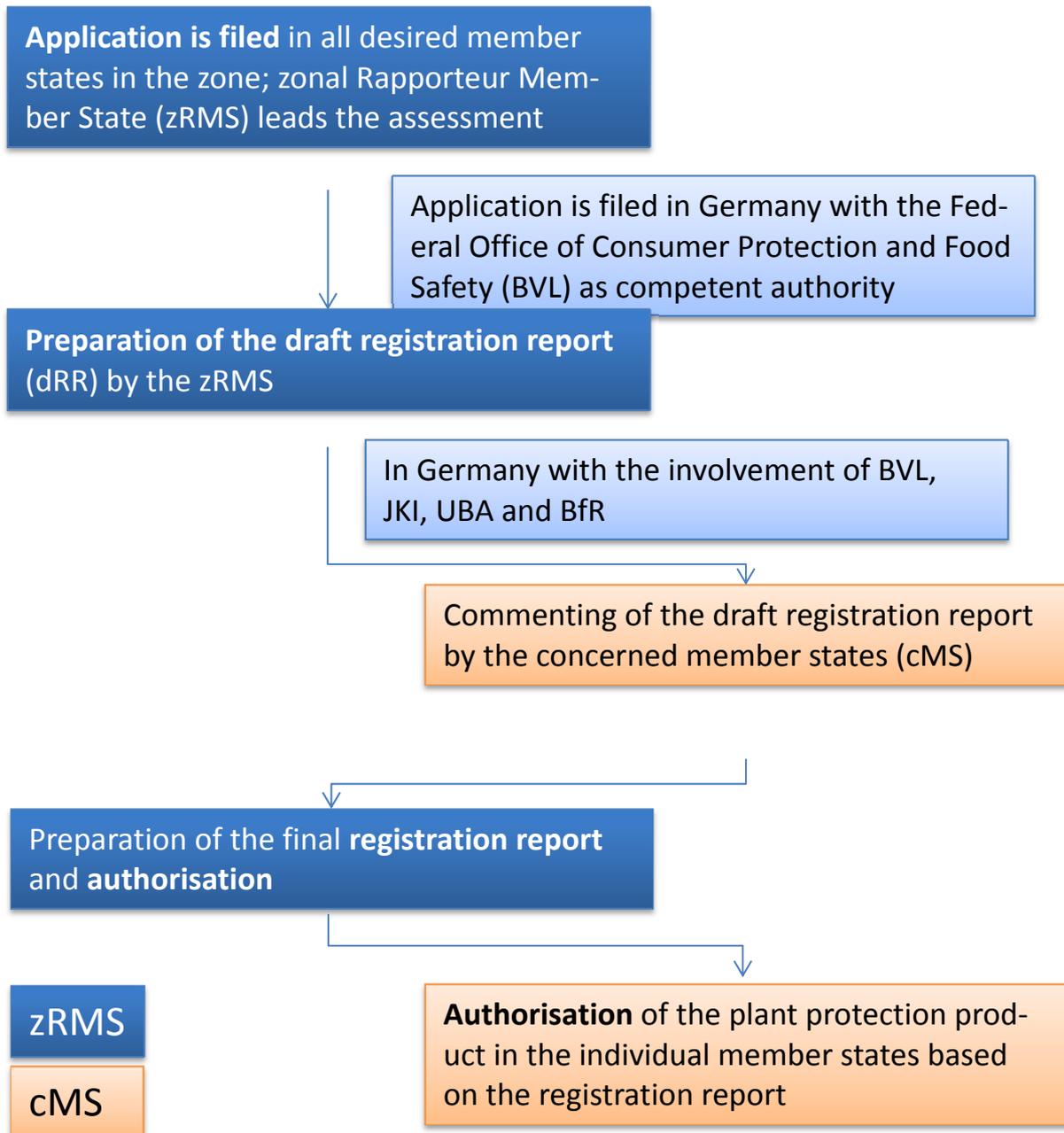
An authorisation for plant protection products is issued at the national level. The Federal Office of Consumer Protection and Food Safety (BVL) acts as the authorisation authority, and the assessment is carried out with the participation of the Julius Kühn Institute (JKI), the Federal Environment Agency (UBA) and the Federal Institute for Risk Assessment (BfR) within their respective legally defined competencies. The assessment authorities review the comprehensive information that is submitted by the companies together with the applications concerning efficacy, toxicology, the residue characteristics and the environmental fate of the plant protection products. The legally stipulated data requirements are so comprehensive that plant protection products belong to the most closely scrutinised products of all. In this procedure, BfR also assesses the health risks for all groups of people who come into contact with a plant protection product, its components and its residues. In addition, BfR ensures that suitable analytical methods are available to monitor residues of the plant protection products in food, body fluids and the environment.

Zonal classification

For the authorisation of plant protection products, the EU has been divided into three zones. Within these zones, authorisations can be transferred more easily to other member states by means of suitably regulated procedures. Several member states are simultaneously involved in the process of zonal authorisation. The authorisation application including all relevant documents is filed simultaneously in the concerned member states. One member state acting as the zonal Rapporteur Member State is responsible for conducting the assessments and preparing a draft for a comprehensive assessment report (draft registration report). This draft is then forwarded to the other concerned member states (cMS) for commenting. These states examine the assessment of the Rapporteur Member State and convey the points that are in their view still open and need further consideration or amendment. The Rapporteur Member State takes all comments into consideration and finalises the registration report. The finalised registration report then forms the basis for authorisation in the concerned member states.

In the event that a plant protection product has already been authorised in one member state, authorisation can also be sought at a later date in a different member state within the zone and granted by way of mutual recognition. In this case, the participating authorities in Germany decide on authorisation based on the assessment by the member state that granted the first authorisation. Specific national characteristics need to be considered for this assessment, which may include agricultural conditions such as soil quality, or risk mitigation measures specified in Germany to minimise user exposure. If no unacceptable risks to the health of humans and animals are identified, authorisation for the product can also be granted in Germany.

Figure 2: Overview of the zonal authorisation procedure for plant protection products



National approval of additional applications

In the case that a plant protection product is already authorised but additional applications become necessary, this is covered by a special, simplified approval procedure. The main aim of this procedure is to make plant protection products available for so-called minor uses. "Minor use" refers to the use of plant protection products in crops that are only cultivated to a limited degree, or to combating pests that only occur in a small regional area. The approval procedure supplements the regular authorisation in order to permit plant protection in those crops and uses that are of no commercial interest to producers of plant protection products due to low application quantities. Applications for the approval of additional uses can be filed not only by producers of the product but also by others acting in the public interest. Before this approval is granted, BfR examines whether the additional uses result in health risks for exposed groups of people.

Listing of additives

Additives are used together with plant protection products in order to modify their properties or effects, for example to improve the wetting of leaf surfaces. Before being sold or used, additives must be included in a list maintained by the Federal Office of Consumer Protection and Food Safety (BVL). Prior to listing, BfR reviews whether the additives can have harmful effects on the health of humans and animals.

References

REGULATION (EC) No. 1107/2009 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:en:PDF>

REGULATION (EC) No. 396/2005 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R0396:20080410:EN:PDF>

German Plant Protection Act (PflSchG), date of issue: 6 February 2012

http://www.gesetze-im-internet.de/pflschg_2012/ (in German)