**Approval process for active substances - decision-making process**

Rules for cooperation of the Ministry of Agriculture and Rural Development with applicants

revised version (September 2020)

The rules of cooperation between the Ministry of Agriculture and Rural Development (Department of Climate and Environment) and the applicants were discussed at the meetings with the Polish Crop Protection Association (PSOR) held on 19 November 2018 and were reviewed at the meeting held on 19 April 2020 taking into account the experience gained in this regard.

The procedure for the evaluation of active substances can be divided into two main stages:

1. the process of drafting an assessment report (DAR[[1]](#footnote-1), dRAR[[2]](#footnote-2)) and scientific peer review by Member States (covering the entire cooperation with EFSA[[3]](#footnote-3), i.e. the preparation of comments by Member States, participation in PRAPER expert meetings[[4]](#footnote-4), comments on draft conclusions on EFSA's request[[5]](#footnote-5)),
2. decision-making, starting at the time of publication of the Scientific Report of EFSA, and covering all work within the Standing Committee on Plants, Animals, Food and Feed, section: plant protection products - (PAFF) legislation, and possibly the Appeal Committee.

Re 1

Poland participates in commenting on substances placed on the market in Poland (in the case of so-called existing substances) and new substances which have not been placed on the market in respect of plant protection products and which are undergoing different stages of the peer review procedure. In the event of a potential non‑approval/non‑renewal of the approval of such substances, applicants are invited at this stage to submit any reservations to RMS conclusions[[6]](#footnote-6) contained in DAR/dRAR in accordance with the procedure set out in Regulation 844/2012[[7]](#footnote-7), i.e. to EFSA and RMS, not to the Ministry of Agriculture and Rural Development. For these substances, if the EC proposes not to approve them, it will be possible for manufacturers to submit their positions to be assessed by competent entities (so-called rescue data) – the procedure described in section 2 applies.

In the case of an existing substance which has not been placed on the market in Poland in respect of any plant protection product, Poland is not involved in the peer review process. This means no comments on the draft Renewal Assessment Report (dRAR) at any stage, no participation in the PRAPER expert meetings, no comments on the draft scientific report of EFSA. For these substances, Poland will also not be actively involved in the legislative work at the decision-making stage of the European Commission - the procedure described in section 2 does not apply here. Poland will support the European Commission's proposal, whether for renewal or non-renewal of the approval of this substance.

This approach is presented in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Placed on the market in Poland | Poland’s participation in peer review | Possible “rescue data” (see section 2) |
| Existing substance | YES | **Yes** | **Yes** |
| NO | **No** | **No** |
| New substance | YES | **Yes** | **Yes** |
| NO | **Yes** | **Yes** |

Re 2

For substances placed on the market in Poland (in the case of so-called existing substances) and so-called new substances (whether or not placed on the market in the Republic of Poland), in the event of a potential non‑approval/non-renewal of the approval of the substance, applicants are invited to submit to the Ministry of Agriculture and Rural Development any reservations to EFSA conclusions as soon as the Authority's conclusions are published. Applicants can also submit their positions at the early stages of the work of the Standing Committee on Plants, Animals, Food and Feed, i.e. as soon as the active substance is included in section A of the agenda[[8]](#footnote-8). Submission of reservations at later stages of the procedure, for instance as late as when the European Commission presents draft legislative acts, may prove too late and does not guarantee that they will be taken into account and considered by the Ministry.

Applicants are invited to comment on EFSA conclusions (in particular: critical areas of concern and issues that could not be finalised), setting out their reservations and concerns as to how the evaluation has been carried out. In the above procedure it is not possible for Poland to assess test reports which have not been evaluated at the EU level. Please also provide in the materials submitted information on the relevance of a given substance in the chemical protection of crops in Poland. In particular, please identify those uses which, in the event of withdrawal, will remain without chemical protection or such protection will not be sufficient. These issues are always taken into account by the Ministry of Agriculture and Rural Development when deciding on the Ministry's active involvement in the EU legislative process. Due to the absence of resources, such involvement is not possible for each molecule. It should be noted that Regulation (EC) No 1107/2009 of the European Parliament and of 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* (OJ EU L 309, 24.11.2009, p, as amended) and consistent actions on the part of the Ministry primarily seeks to ensure a high level of protection of human and animal health and the environment, which is crucial to maintaining a high level of safety of Polish food.

Businesses forming a task force are asked to prepare one joint position/dossier.

The dossier must be submitted to the Ministry of Agriculture and Rural Development in the form of a single, consistent data package in a hard-copy format or via ePUAP, and also sent to: [aneta.choderska@minrol.gov.pl](mailto:aneta.choderska@minrol.gov.pl). Please do not send data in several portions.

When submitting the dossier, please also identify the competent entity to which the dossier will be submitted and which will carry out a scientific, independent evaluation of the above data and confront the applicant's arguments with the EFSA proposals/legislative proposal of the European Commission. In the absence of such information, as a result of the choice made by the Ministry of Agriculture and Rural Development, the dossier will be sent to the competent entity which prepared the comments at the DAR/dRAR comment stage. Once the Ministry has approached the entity authorised to evaluate the data concerned, the applicant is, as a rule, no longer allowed to send other documents.

In the event of that the EFSA scientific report and/or draft EC legislative acts are reviewed and new arguments are put forward therein for non-renewal of the approval of substances which the applicant has not had the opportunity to comment on, it is permissible to submit the applicant's position to the Ministry (and not directly to the competent entity) in a hard-copy format or via ePUAP and additionally to: [aneta.choderska@minrol.gov.pl](mailto:aneta.choderska@minrol.gov.pl).

Meetings of experts from competent entities with applicants, with the participation of the Ministry of Agriculture and Rural Development, are possible at the request of experts evaluating the submitted dossiers.

The evaluation of the applicant's position by the competent entity is made available to the applicants by that entity. The evaluation is based on a finding whether the substance fulfils the criteria for renewal/approval laid down in Article 4 of Regulation No 1107/2009. This means that there may be a situation where, after considering the applicant's arguments, the expert evaluation (and, consequently, Poland's position) shows that the substance does not fulfil the abovementioned criteria and, as such, cannot (again) be approved for use in plant protection products. In such case, Poland's position and the expert evaluation may reinforce the arguments for non-renewal.

On this basis, following its thorough analysis and potential consultation of the Ministry of Agriculture and Rural Development with experts in due course, this provides the basis for the Ministry to draw up comments from Poland relating to the EFSA scientific report or draft EC legislative acts (draft review report, draft EC implementing regulation). The comments include information whether Poland shares the reservations put forward by EFSA/EC and the scientific justification, supported by the substantive assessment made by the competent entity. Once approved by the Under Secretary of State overseeing the Department of Climate and Environment and the Counsel General, they are forwarded during the SCoPAFF legislative process to the European Commission and made available to the Member States via the CIRCABC platform. As this document is typically drawn up by the Ministry at the early stages of the legislative procedure, it does not essentially include Poland's voting position, but merely indicates the direction in which, in Poland's view, the work should continue. The comments can be made available to the applicant, for example, under the law on access to public information.

Poland's final position on the EC's final legislative proposal is based on previous comments prepared in the period immediately preceding the SCoPAFF vote. This position is published on the website of the Ministry of Agriculture and Rural Development in the form of a summary report on the proceedings of the Standing Committee on Plants, Animals, Food and Feed and made public as part of the information on the approval of active substances (Ministry of Agriculture and Rural Development > What we do >Plant production > Plant protection >[Active substances](https://www.gov.pl/web/rolnictwo/substancje-czynne)> Current information on the approval of active substances [https://www.gov.pl/web/rolnictwo/aktualne-information-on-approval-of-active-substances](https://www.gov.pl/web/rolnictwo/aktualne-informacje-dotyczace-zatwierdzania-substancji-czynnych)).

If the assessment of data confirming safe use (so-called *confirmatory data*) or EC projects identify the possibility of significantly reducing the use of a given substance, applicants are asked to keep the Ministry of Agriculture and Rural Development informed of the subsequent stages of the process. Since there is no uniform approach by Member States acting as RMS, the Ministry does not always receive the above information from the EU level.

1. draft Assessment Report [↑](#footnote-ref-1)
2. draft Renewal Assessment Report [↑](#footnote-ref-2)
3. European food Safety Authority [↑](#footnote-ref-3)
4. Pesticides Peer Review Experts' Meetings And Teleconferences [↑](#footnote-ref-4)
5. draft EFSA conclusion [↑](#footnote-ref-5)
6. a country performing the role of the rapporteur (Rapporteur Member State — RMS) [↑](#footnote-ref-6)
7. Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 *setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (*OJ EU L 252, 19.9.2012, p. 26) [↑](#footnote-ref-7)
8. The meeting agendas are published by the European Commission at:

   https://ec.europa.eu/food/plant/standing\_committees/sc\_phytopharmaceuticals\_en [↑](#footnote-ref-8)