PLANT PROTECTION

EVALUATION OF ACTIVE SUBSTANCES AT EU LEVEL

Detailed procedure with Belgium involved as Rapporteur Member State (RMS) or co-RMS

Federal Public Service **Health, Food Chain Safety and Environment**
Service Plant protection products and Fertilizers

CONTACT

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DOCUMENT INFORMATION

Evaluation of active substances at EU level: Detailed procedure with Belgium involved as Rapporteur Member State (RMS) or co-RMS
Version 1.1
15/03/2016

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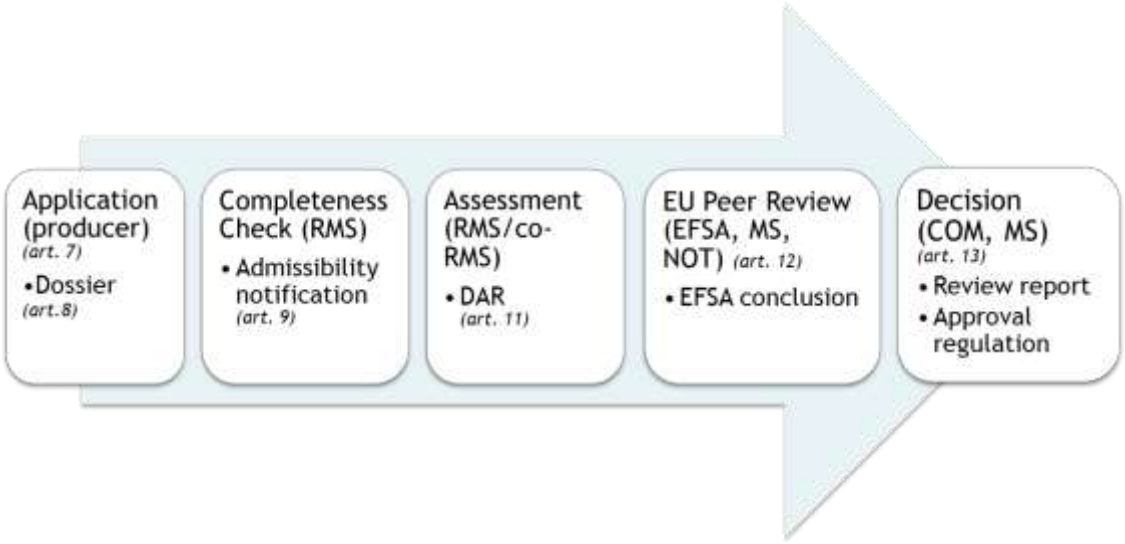
1. Timelines

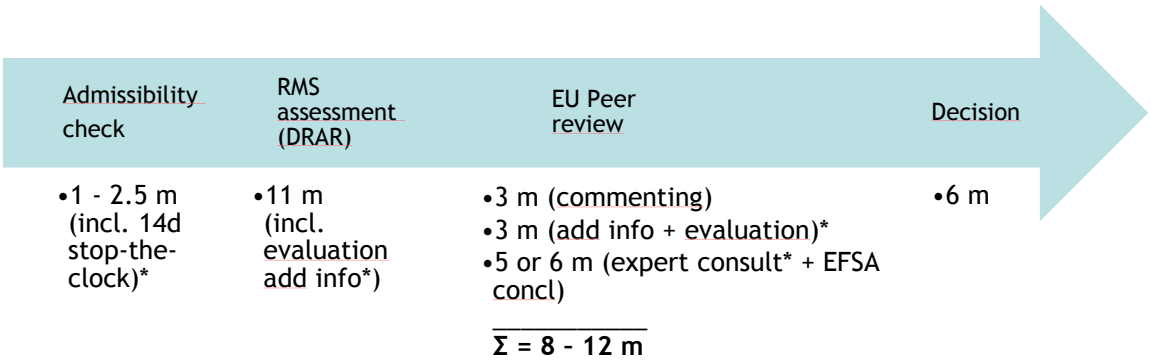
The EU procedure to be followed for the **approval** of an active substance (or for an amendment to the conditions of an approval) is stipulated in articles 7 to 13 of Regulation (EC) No 1107/2009. The different steps are presented in the scheme here below.



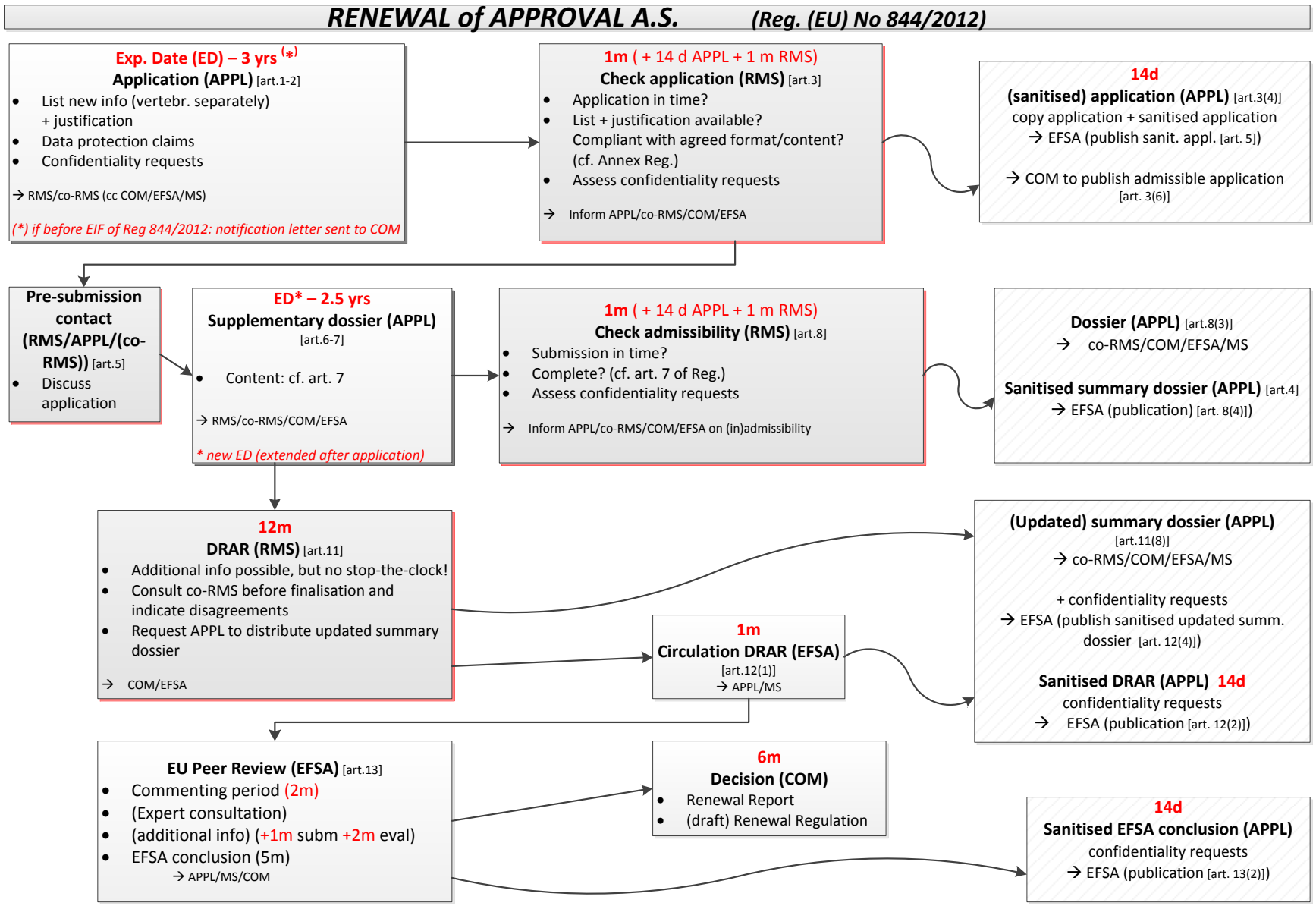
From application to decision on (non-)approval, it normally takes at least **26.5 months**. If additional information is requested from the applicant during the evaluation process and/or an expert consultation is needed (cf. optional steps marked with * in the scheme below), the whole process can take up to **41.5 months** (i.e. approximately 3.5 years).

It is noted that EU Member states (MS) are only allowed to give a provisional authorisation – i.e. authorisation for placing on the market of a plant protection product containing an active substance not yet approved at EU level – if the decision on approval of that active substance is delayed for more than 3.5 months beyond the legally foreseen deadline (cf. art. 30.1(a) of Reg. (EC) No 1107/2009).

The procedure for the **renewal of approval** of an active substance is principally the same, but the timelines are somewhat different (see scheme here below). The detailed procedure is established by the following regulations: Reg. (EU) No 1141/2010 ('AIR2 regulation') and Reg. (EU) No 844/2012 ('AIR3', 'AIR4', …). It is noted that the period for EFSA to finalise its conclusion is slightly different, depending on the specific legal framework applicable to the renewal evaluation process.



A detailed flowchart reflecting the different procedural steps and timelines in the framework of the renewal of approval according to Reg. (EU) No 844/2012 is presented below.


RENEWAL of APPROVAL A.S. (Reg. (EU) No 844/2012)
Exp. Date (ED) – 3 yrs (*)
Application (APPL) [art.1-2]
List new info (vertebr. separately) + justification
Data protection claims
Confidentiality requests
→ RMS/co-RMS (cc COM/EFSA/MS)
(*) if before EIF of Reg 844/2012: notification letter sent to COM
1m (+ 14 d APPL + 1 m RMS)
Check application (RMS) [art.3]
Application in time?
List + justification available? Compliant with agreed format/content? (cf. Annex Reg.)
Assess confidentiality requests
→ Inform APPL/co-RMS/COM/EFSA
14d
(sanitised) application (APPL) [art.3(4)]
copy application + sanitised application
→ EFSA (publish sanit. appl. [art. 5])
→ COM to publish admissible application [art. 3(6)]
Pre-submission contact (RMS/APPL/(co-RMS)) [art.5]
Discuss application
ED* – 2.5 yrs
Supplementary dossier (APPL) [art.6-7]
Content: cf. art. 7
→ RMS/co-RMS/COM/EFSA
* new ED (extended after application)
1m (+ 14 d APPL + 1 m RMS)
Check admissibility (RMS) [art.8]
Submission in time?
Complete? (cf. art. 7 of Reg.)
Assess confidentiality requests
→ Inform APPL/co-RMS/COM/EFSA on (in)admissibility
Dossier (APPL) [art.8(3)]
→ co-RMS/COM/EFSA/MS
Sanitised summary dossier (APPL) [art.4]
→ EFSA (publication) [art. 8(4)])
12m
DRAR (RMS) [art.11]
Additional info possible, but no stop-the-clock!
Consult co-RMS before finalisation and indicate disagreements
Request APPL to distribute updated summary dossier
→ COM/EFSA
(Updated) summary dossier (APPL) [art.11(8)]
→ co-RMS/COM/EFSA/MS
+ confidentiality requests
→ EFSA (publish sanitised updated summ. dossier [art. 12(4)])
Sanitised DRAR (APPL) 14d
confidentiality requests
→ EFSA (publication [art. 12(2)])
1m
Circulation DRAR (EFSA) [art.12(1)]
→ APPL/MS
EU Peer Review (EFSA) [art.13]
Commenting period (2m)
(Expert consultation)
(additional info) (+1m subm +2m eval)
EFSA conclusion (5m)
→ APPL/MS/COM
6m
Decision (COM)
Renewal Report
(draft) Renewal Regulation
14d
Sanitised EFSA conclusion (APPL)
confidentiality requests
→ EFSA (publication [art. 13(2)])

2. Dossier submission and evaluation by the RMS

Pre-submission

In the case of **new active substances**, the notifier has the possibility to choose the RMS, who will perform the initial evaluation of the dossier and will follow up the dossier up to the decision.

In the case of review of existing active substances - e.g. in the framework of the **renewal** of approval – the European Commission (EC) establishes a legislation in which each substance is allocated to a RMS (and co-RMS).

Generally, the notifier who intends to submit his dossier in Belgium is invited to contact the Federal Public Service Health, Food Chain Safety and Environment to discuss the time schedules for submission, the practical details of the submission, etc.

Contact: BE contact person EU applications

Submission of the dossier

Dossiers have to be submitted in the OECD format. Advice on how a dossier should be compiled and structured is provided in the EU Guidance Document SANCO/10181/2013, which can be downloaded from the DG SANTE website (Procedural guidance):

Note that the dossier format for micro-organisms is different from that for chemical active substances.

More information regarding dossier requirements, EU guidelines can be found on the DG SANTE website:
http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm

Scientific peer-reviewed open literature should also be included in the dossier, in accordance with the relevant EFSA guidance document.

The BE experts evaluating the Sections 1, 2, 4, 5, 6 (in the Federal Public Service) and those dealing with Section 3 (toxicologists in the Institute of Public Health) are located in 2 facilities in Brussels. Therefore, the applicants are invited to submit their dossier directly to both addresses (see postal addresses under ‘Contact’), taking into account the specific requirements in Table 1.

TABLE 1: SUBMISSION OF DOSSIERS OF ACTIVE SUBSTANCES FOR WHICH BELGIUM IS RMS OR CO-RMS

Generally, we require: • 1 electronic copy: Caddy XML copy (if available) *or* individual files on CD (summaries doc A, B, C, D, E, F, G, H, I, J, L, M, N, O in Word format; doc K in pdf or Word Format) • 1 paper copy containing the doc A, B, C, D, E, F, G, H, I, J, **K (toxicological studies),** L, M, N, O	The **"toxicological"** dossier should be submitted to Philippe Castelain (IPH)
• 1 electronic copy: Caddy XML copy (if available) *or* individual files on CD (summaries doc A, B, C, D, E, F, G, H, I, J, L, M, N, O in Word format; doc K in pdf or Word Format) • 1 paper copy containing the doc A, B, C, D, E, F, G, H, I, J, **K (all studies)**, L, M, N, O	The **complete** dossier should be submitted to the BE contact person EU applications (FPS)
For *micro-organisms***,** we require: • 1 electronic copy: Caddy XML copy (if available) *or* individual files on CD (summaries doc A, B, C, D, E, F, G, H, I, J, L, M, N, O in Word format; doc K in pdf or Word Format) • 1 paper copy containing the doc A, B, C, D, E, F, G, H, I, J, **K (all studies)**, L, M, N, O	The **complete** dossier should be submitted to both: • the BE contact person EU applications (FPS)

An overview of documents required by EFSA from applicants is given on the EFSA website.

With regard to the **requests for confidentiality**, the applicant is kindly asked to use the form proposed by EFSA for the identification, justification and evaluation of the claims for confidentiality (see http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm). The applicant should justify the claims on the form either by reference to the relevant point under art. 63(2) of Reg. (EC) No 1107/2009, or by providing evidence showing that the disclosure might undermine his commercial interests or the protection of privacy and the integrity of the individual. The completed, signed form should be submitted together with the application to the RMS.

Admissibility check

The admissibility check is the first administrative step in the evaluation of a dossier submitted in view of the approval of an active substance under Reg. (EC) No 1107/2009. The aim of the admissibility check is to verify whether the applicant has effectively submitted all the information (study, risk assessment, rationale) mentioned in the applicant's checklist in order to cover each data requirement. Also the applicant's confidentially requests are checked at this stage.

In case the dossier cannot yet be considered complete, the RMS will inform the applicant in view of reaching an agreement on the additional period needed for completing the dossier (max. 3 months 'stop-the-clock' for submission and evaluation). In case of application for renewal of approval, the applicant can be given an additional period of 14 days to complete the dossier, after which the RMS has again 1 month to decide on the completeness of the dossier and the admissibility of the application.

Once the dossier is considered complete, RMS informs the applicant, EU MS, EC and EFSA[1] on the **admissibility of the application** (incl. the completed form with the evaluation of the confidentiality claims; see above). The admissibility of the application is taken note of at the Standing Committee on the Food Chain and Animal Health (SCFCAH) with subsequent publication of the decision in the Official Journal of the EU.

After receipt of the notification, the applicant should send a copy of the complete dossier to all other EU MS, the EC and EFSA (cf. art. 9.3, §2 of Reg. (EC) No 1107/2009). In addition, the applicant shall submit (within 14 days) a "**sanitized**" version of the **summary dossier** (i.e. dossier without document K and J and without the information for which the confidentiality claim has been accepted by the RMS) in pdf format to EFSA (see 'Contact), which EFSA will make available to the public.

[1] by e-mail to APDESK.applications@efsa.europa.eu with pesticides.peerreview@efsa.europa.eu in CC

Evaluation of the dossier and preparation of the DAR

At the Belgian competent authority, for each active substance approval application, the dossier coordinator is the primary contact person for the applicant and is in charge of the administrative tasks related to the dossier evaluation, i.e. coordinating the contacts with the applicant, organisation of meetings, receipt of documents, sending of evaluations.

Contact: BE contact person EU applications

During the evaluation of each individual section, experts of the company can directly discuss technical issues with our experts. However, in order to keep track of all the discussions, the documents should also be sent by e-mail to the coordinator.

Submission of **additional studies or information** by the applicant during the preparation of the DAR can only be taken into account if officially requested by the RMS. Therefore, justification, amount of data, possible submission date, etc. should be discussed with the coordinator of the dossier and with the expert responsible for the specific part. The RMS has the possibility to grant an additional period for submission of such additional data, but this implies a 'stop-the-clock' in the process (max. 6 months).

Generally, after completion of each part of the evaluation, the individual experts send their evaluation and questions/remarks to the **applicant** for **feedback and comments**. The aim of this unofficial consultation is to solve some issues before the peer review.

In cases where a co-RMS is involved, Belgium as RMS will also send a first draft of the DAR to the **co-RMS** for **commenting**.

The **final version** of the **DAR** is then issued and sent to the European Commission and to the EFSA[2].

[2] by uploading to the Pesticides Peer Review workspace on the EFSA Extranet together with a covering e-mail notifying EFSA of the upload (to APDESK.applications@efsa.europa.eu with pesticides.peerreview@efsa.europa.eu in CC).

3. EU peer review

The evaluation of active substances at EU level consists of a detailed evaluation of the dossier by a RMS (and co-RMS). Afterwards, this evaluation is peer reviewed by the other EU MS and EFSA. EFSA is responsible for the submission of a consolidated risk assessment of the active substance to the EU Commission. EFSA coordinates the EU peer review process, which is summarized in the scheme here below (cf. art. 12 of Reg. (EC) No 1107/2009).

The timeline between receipt of the comments and the final EFSA conclusion is defined by EFSA.

Commenting of the DAR

EFSA organises the distribution of the DAR to the other MS and to the applicant and opens a commenting period for the MS and the applicant. The comments have to be sent to EFSA and to the RMS (and co-RMS) in the table format prescribed by EFSA.

Prior to making the DAR available to the public, EFSA will give the applicant 2 weeks to request that certain parts be kept confidential.

At this stage, the applicant should circulate a copy of his **updated dossier** (where applicable, i.e. if additional information had been submitted during the preparation of the DAR) to each MS, to EFSA and to the EC.

The RMS compiles all comments received by drawing up a **"reporting table"** and gives answers to the questions that have been raised.

Comments requiring further assessment or submission of additional clarification/information are transferred by EFSA into an "**evaluation table**", which is completed during the next steps of the peer review (see below: evaluation of additional info, expert consultation, written procedure).

The answers to questions can be based on additional information and/or clarification submitted by the applicant (see also below), which the RMS may present in an "addendum" to the DAR. Where necessary, RMS also prepares an amended "list of endpoints".

Additional information

In consultation with the EC, the RMS and the applicant, EFSA may ask the applicant to provide, within a certain time period (max. 3 months), additional information. This additional information should be submitted to all EU MS, the EC and EFSA (**updated dossier**).

The RMS will present an evaluation of this additional information in an addendum to the DAR. However, this implies a 'stop-the-clock' (for max. 5 months) in the process. In case of an application for renewal of approval, the 'stop-the-clock' (incl. submission and evaluation) is maximally 3 months.

Expert consultation

To resolve some specific issues, EFSA may (after having consulted the EC and the RMS) organise an expert consultation for one or more of the sections (physical/chemical properties and analytical methods, toxicology, residues, environmental fate, ecotoxicology). The expert consultation takes place via a written procedure, via a telephone-web-conference or as physical meeting of EU experts. Discussions are summarised in a "**discussion table**".

EFSA conclusion

Based on the DAR and the outcome of the peer review, EFSA prepares a summary of the active substance *"Conclusion on the peer review of the pesticide risk assessment of the active substance* […]*"*

Before finalizing, EFSA gives MS the opportunity to comment on the **draft EFSA conclusion** (and the completed evaluation table) via a **written procedure**. The final EFSA conclusion is sent to the EC and the RMS and made available to MS. However, prior to final publication (EFSA Journal and EFSA website), EFSA will submit it to the applicant for consideration of the need for removal of confidential information (2 weeks).

4. Risk management and decision

Normally, the applicant will be given the opportunity by the EC to provide comments on the EFSA conclusion. However, it should be noted that at this stage, generally no evaluation of technical data is performed.

Each individual substance is at least discussed in two meetings of the Working group of Pesticides Legislation (**WG Leg**). This meeting is chaired by the EU Commission (Team pesticides in the Directorate General SANTE) and attended by representatives of each MS and EFSA. On the basis of the EFSA conclusions, discussions in the meetings, the consultations of several directorates of the European Commission and taking into account the comments from the applicant, the Commission prepares a draft **regulation** for either approval or non-approval, which is accompanied by a '**review report'** giving some more details on the proposed decision.

Finally, MS represented at the meeting of the Standing Committee on Plants, Animals, Food and Feed (**SCPAFF**) vote on the proposal of the EC. A qualified majority is needed to pass as proposal, which is then published in the Official Journal of the EU.

If no qualified majority in favour of the EC proposal is reached at the SCPAFF meeting, the proposal is referred to the **appeal committee** – which normally consists of the Permanent Representations of the MS – where further negotiation and discussions take place in view of reaching a compromise among MS. More details on this specific procedure and timelines can be found in Regulation (EU) No 182/2011 and Rules of procedure for the appeal committee (2011/C 183/05).

5. Post-approval issues

List of references relied upon

The RMS will prepare a list of references that were considered relied upon for the approval (or for amendment or renewal thereof) of the active substance (cf. art. 60(1) of Reg. (EC) No 1107/2009). This list will be made available on the DG SANTE website, along with the EU review report.

Normally, Belgium as RMS will give the possibility to the applicant to verify this list before finalising it. The final list is made available to the EC and other EU MS and serves as basis for applying the provisions related to data protection at national level.

Confirmatory data

In some cases, an active substance is approved under the condition that certain confirmatory information be submitted within a certain time limit. The RMS who performed the initial evaluation will also evaluate those confirmatory data and will issue an addendum to the DAR. More details on procedure and timelines are given in guidance document **SANCO/5634/2009**.

The instructions for submission of confirmatory data to Belgium as RMS are in principle the same as those outlined above for a normal application for approval of the a.s.

Finalisation of reference specification

In cases where an agreement on a harmonised specification of the assessed technical material could not be reached before approval of the active substance, a finalisation of the reference specification must be performed, in view of having a basis enabling equivalence assessments. To allow for this finalisation further data/information might be required from the applicant who supported approval of the a.s.

Where data in view of finalisation of the reference specification are not already requested as confirmatory data (see above), the specific procedure and timelines as given in guidance document **SANCO/6075/2009** ("*on the finalization of the reference specification for technical active substances after the peer review*") should be followed.

Renewal / withdrawal / amendment of existing authorization of plant protection products

The voted regulation concerning (non-)approval of active substances stipulates the deadlines for EU MS to renew, withdraw or amend the existing national authorisations of plant protection products containing the concerned active substance.

After publication of the approval in the Official Journal of the EU, all authorization holders of plant protection products containing the active substance will receive detailed instructions of the information they have to submit in order to maintain their authorisations.

New authorization of a plant protection product

Under Reg. (EC) No 1107/2009, a plant protection product can normally not be authorised before the active substance is approved. Theoretically, the examination by the zonal RMS of an application for an authorisation of a PPP containing an a.s. not yet approved shall start as soon as a DAR is available *(cf. art. 37.3 of Reg. (EC) No 1107/2009)*. However, taken into account that the time between the distribution of the DAR and the approval of the a.s. will, in the best case, normally be in a range from 12 to 18 months, the zonal examination of the national application will in practice concur with the EU peer review of the active substance. In this way, the assessment can take into account as much as possible EU peer-reviewed endpoints (EFSA conclusion).

In case the application concerns the same PPP (and the same uses) as the representative formulation evaluated in view of approval of the a.s., a decision on the authorization of the PPP shall be made in the zonal RMS (zRMS) and the other EU MS within resp. 6 and 10 months after approval of the a.s. *(cf. art. 37(3) of Reg. (EC) No 1107/2009)*.

EU MRL setting

The dossier submitted in view of approval of an a.s. should include a copy of the MRL application relevant to the representative uses (cf. art. 8(1)(g) of Reg. (EC) No 1107/2009). The DAR and the EFSA conclusion would in such case serve as an Evaluation Report and EFSA reasoned opinion, respectively (cf. Reg. (EC) No 396/2005, art. 8 resp. art. 11).

However, also copies of MRL applications for relevant uses other than the representative uses can be included in the EU dossier, in view of integrating to the extent possible the MRL setting for these additional uses in the a.s. approval process, which means a benefit for the authorisation holder, as well as for EFSA, MS and EC (avoid duplication of work). Of course, this does not undermine the concept of the representative uses, nor does it lead to the need to submit for these other uses a risk assessment in the areas other than those needed for the MRL

setting. This means the additional uses will be considered separately in the DAR and the EFSA conclusion and solely from a residue perspective for MRL setting purposes and will have no impact on the decision on approval of the active substance.

Therefore, it is highly recommended that available residue data supporting relevant additional uses intended in the future (a.o. metabolism studies, feeding studies, storage stability studies and analytical methods relevant to the range of uses) be already included in the EU dossier submitted in view of approval of a new a.s.

In this regard, applicants are encouraged to include in the EU dossier also residue data supporting possible envisaged uses on minor crops in view of MRL setting, especially for those where extrapolation according to the current guidelines is possible from the residue trials available for the main supported uses.

6. Fees

The fees, which are intended to cover the costs of the evaluations performed by BE (as RMS or as co-RMS), are requested by means of an invoice sent to the applicant. No payment should be done before receipt of the invoice. The applicant, and especially consultancy offices, should indicate the address at which the invoice should be sent out.

For a certain application, the fee may be split up into several invoices, which are sent by the FPS to the applicant at different steps in the process.

E.g.:

- A first invoice related to the admissibility check is sent after the submission of the dossier;
- A second invoice related to the detailed evaluation (DAR) and the subsequent EU peer review is sent after the admissibility has been taken note of at the SCFCAH;

In the case of evaluation of 'post-approval confirmatory data', an 'application for an amendment to the conditions of an approval' or an application for change of an EU endpoint, a fee is foreseen, which may be followed by an additional fee, in the case an EU peer review is organised by EFSA.

Fees for EU applications for which Belgium acts as RMS or co-RMS are stipulated in the Belgian royal decree of January 26th, 2016. For more details on fees: see www.phytoweb.be.

7. Contact

Belgian competent authority

Contact person details			
BE Contact person EU applications	Mr Philippe Castelain	philippe.castelain@health.belgium.be philippe.castelain@wiv-isp.be	+32 2 524 72 64 +32 2 642 50 98

Postal address		
ENG	NL	***FR***
*Federal Public Service Health (**FPS**), Food Chain Safety and Environment* *DG for Animals, Plants and Foodstuffs* *Service Pesticides and Fertilizers* *Eurostation II, 7th floor* *Place Victor Horta, 40, P.O. box 10* *1060 Brussels* *Belgium*	FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu (FOD VVVL) Directoraat Generaal Dier, Plant en Voeding Dienst Pesticiden en Meststoffen Eurostation, Blok II, 7de verdieping Victor Hortaplein 40 bus 10 1060 Brussel België	*Service Public Fédéral Santé publique, Sécurité de la Chaîne alimentaire et Environnement (**SPF SPSCE**)* Direction générale Animaux, Végétaux et Alimentation Service Pesticides et Engrais Eurostation Bloc II, 7e étage Place Victor Horta 40, boîte 10, 1060 Bruxelles Belgique
Scientific Institute of Public Health *Service Toxicology (**IPH**)* Juliette Wytsmanstraat 14 B-1050 Brussels Belgium	Wetenschappelijk Instituut Volksgezondheid (WIV) Afdeling toxicologie Juliette Wytsmanstraat, 14 B-1050 Brussel België	Institut Scientifique de Santé Publique (ISP) Section toxicologie Rue Juliette Wytsman 14 B-1050 Bruxelles, Belgique

EFSA

- All correspondence relating to the submission of the active substance dossier should be sent by e-mail to APDESK.applications@efsa.europa.eu (Applications Desk of EFSA) with pesticides.peerreview@efsa.europa.eu in CC.
- When sending an e-mail to EFSA, the notifier is kindly asked to put also always the BE Contact person in CC.
  All physical correspondence related to the initial DAR and the applicant's dossier should be sent to:

  Dr Karine Lheureux (Head of Unit APDESK)
  EFSA
  Via Carlo Magno 1A
  43126 Parma
  ITALIA

□