NOTAT

Ministry of Environment and Food of Denmark
Environmental Protection Agency

Pesticider og Genteknologi
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Annex to the Nordic Zone Guidance document regarding procedures for renewal of authorizations in accordance with art. 43

Application by authorization holder:

The procedure and the application to renew the authorization should be according to the EU guidance document on the renewal of authorizations according to article 43 of regulation (EC) No 1107/2009, the Nordic Guidance document and this Annex to the Nordic Zone guidance document.

Updates and harmonization of the use of the products in connection with the renewals

According to the EU guidance document regarding renewals of product authorizations pursuant to article 43, only already authorized uses in the individual Member States (MS) and amendments resulting from changes in the evaluation of the active substance should be assessed for applications for renewal in accordance with article 43.

The applicants would sometimes like to update and harmonize the use of the products in connection with the renewals which is something we will try to accommodate in the North Zone. However, the resources of the authorities must also be taken into account, as there will only be nine months to carry out the assessments and many applications must be handled at the same time.

The North Zone will therefore consider GAP changes in connection with the renewals if the following conditions are fulfilled:

1. Changes in uses fall within the Risk Envelope
2. Changes are covered by the efficacy and MRL data previously evaluated in the context of national authorizations
3. Minor formulation changes as defined in the EU guidance document for Minor Changes[1].

We will not accept new uses in areas that fall outside the previously authorized uses as part of the application for renewal. Such an application shall be submitted as an application for amendment and it will be decided case by case when this application for amendment can be submitted.

[1] Not accepted by Sweden

1. Changes, including amendments of the GAP, must be agreed with ZRMS and subsequently with CMS at the same time as the pre-notification. Otherwise, the application may be rejected.

2. If changes/updates related to formulations, new Member States etc. are not acceptable for renewals, then companies should submit applications for authorization of "new" products including new dossiers.

Timelines for application of renewal:

Pre-notification:

Within 2 months from EFSA conclusion authorization holders must submit:

- The pre-notification form to notify intended zonal applications
- Indication of agreement on the studies which are needed and where possible an expected timeframe; If there are CAT 4 studies, it has to be approved by the ZRMS and CMS.
- Indication of which parts of the risk assessment need updating (to be agreed in pre-submission meetings with ZRMS)
- Indication of amendments of the GAP or formulation changes (to be agreed in pre-submission meetings with ZRMS);
- A "data matching list" regarding references relied upon (where relevant).

6 months before the date of application for renewal of the notification form, (according to the Nordic Guidance Document) included the GAP should be submitted to the proposed ZRMS and all CMS´s. If the applicant wants to apply for changes in connection with the renewals, the information should be submitted at least 6 months before the date for application of renewal and discussed with ZRMS and if needed with CMS.

Expiry dates:

MS will extend the expiry dates of all authorizations with AIR II active substances where the authorizations expire 31. December 2015. The expiry date will be 1 year from the entry into force of the renewal date of the active substance.
If the active substance is prolonged e.g. until 30 June 2016, then the product will be prolonged until the same date. SE, LT, LV, EE, NO, FIN will require a letter of intent from the applicant and charge a fee.

In case no application for renewal of an authorization will be submitted, the product will expire at the date it has been extended to. Ordinary periods of grace for retail sale and use will be granted. If amendments of the product are such that the product will be considered as a new product, the old product will expire as explained above.

It is up to the applicant to submit the application for new products in due time (at least 1.5 year before the expiry date of the prolonged authorizations of the previous product). In that way the company, by own risk, can have their "new" products approved before the expiry date. If new applications are submitted before the date of entry into force of the renewal of the active substance, the new application must fulfil the requirements of the renewal decision (e.g. use new endpoints).

Requirements for applications and dossiers

- Cover letter including description of number of CDs and a brief description of the content of each CD
- Application scheme
- Active substance dossier (if not previously submitted)(incl. study reports)
- Product dossier (study reports and dRR for all sections)
- Justification for new data submitted
- GAP and label/use instruction

Dossier format:

- Preferably submission in Caddy.xml format
- Follow the recommended structure (Annex 1) so that the submitted documentation is easy to access
- The folder structure must be simple
- File directory titles (max 100 letters) and document titles must be clear and reflect the content

Dossier content:

- Assessment based on latest active substance endpoints
- Assessments based on guidance in place at dossier submission.
- The sections of the dRR must be targeted and transparent
- Only information and data relevant for the concerned countries/North Zone should be presented

Issues to consider:

Changes in technical guidance documents and their implication for art.43 renewals. Such as:

- Dermal absorption[2] and operator exposure guidance has recently changed – new assessments needed even though a.s. endpoints have not changed
- Fate endpoints from LoEP for a.s. should be used – many will have changed due to new guidance – new PEC calculations will be needed
- Aquatic guidance for higher tiers have recently changed

Mutual recognition is not possible under art. 43

- Previous MR applications must be submitted as zonal dossiers for re-authorisation.

Products containing more than one active substance

Must in principle be renewed for each active substance in accordance with Regulation 1107/2009. But in accordance with the EU Guidance Document:

- If the second active substance expires within 12 months, the product renewal can be postponed till the deadline for the second a.s.
- Only one dossier needs to be submitted at the deadline of the 2. a.s.

If the product contains active substances that are not being renewed, the renewal will primarily be a re-evaluation of the active substance that is renewed. Thus, there should not be new/modified endpoints for the other active substances, new groundwater modeling etc. But on the other hand, there must be an up-to-date risk assessment following the guidance at the time of submission. For example a cumulative risk assessment must be performed for endpoints where there are no product studies. This could mean that new PEC values are needed, if the PEC

[2] It is our experience that a dermal absorption study with the product often needs to be performed, as the default values are more "conservative" in the current guidance.

values have not previously been calculated in accordance with the Nordic Zone Guidance Document.

EFSA exposure calculator:
EFSA Guidance on Pesticides Exposure Assessment of Operators, Workers, Residents and Bystanders must be followed. More specific requirements will be provided when details have been clarified.

MRL issues:
Concerning residues/MRL it is only possible to add a crop if this crop can be extrapolated from a crop already authorized. E.g. rye can be included if wheat is already included provided that the GAP for rye is the same as for wheat.

Efficacy issues:

1. Applicants are strongly encouraged to submit a BAD. Trial reports should be submitted and if a BAD is not submitted, the applicant is obliged to provide information on the origin of the data summarized in the various tables/figures of the dRR. The dRR should be a concise summary of the BAD and if a BAD is not submitted a concise summary of the supporting data. A dRR with all sections must be submitted.
2. The applicants can ask for label extension but only for uses already authorized in at least one of the countries in the Northern zone.
3. The applicants are required to provide an overview of the current authorizations in the Northern zone either as a table inserted in the dRR or by providing the current GAP tables (in English) for each of the concerned countries in the zone. Labels in local language are not sufficient documentation.
4. The countries in the Northern zone belong to two EPPO zones (Maritime and North-East) and if the applicant applies for authorization in both zones, efficacy data from both zones should be submitted. However, as mentioned in the EPPO Standard P1/241 Guidance on Comparable Climate '*data from other zones may in any case be considered acceptable if the actual prevailing conditions are comparable*'. It is up to the applicant to justify that data from one EPPO zone is acceptable for registration in the other EPPO zone. Data from other zones than the Maritime and the North-East zone should not be included in the dRR.
5. Dose extrapolation of +/- 10% are accepted without further justification. Other extrapolations should be justified in the dRR. Concerning extrapolation between pest species and crops, the applicant should consult the Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone.
6. If the active ingredient is candidate for substitution, the starting point for Comparative Assessment (CA) is efficacy. CA is a national issue and not a zonal issue and the data/justification for maintaining the product on the market should be included in the National Addenda, and not in the core assessment.

Applicants are encouraged to contact the ZRMS in case of doubt.