

Yttrande

Vårt Dnr: SV/01/19

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Utkast extern vägledning Ömsesidigt erkännande

Svenskt Växtskydd har fått ett utkast till ”*Guidance for applications for mutual recognition in Sweden*” för synpunkter. Vi är tacksamma för den möjligheten.

Generellt vill vi uttrycka att Svenskt Växtskydd och våra medlemsföretag uppskattar hur KemI sedan en tid hanterar ömsesidiga erkännanden. Vi menar att KemI:s förhållningssätt när det gäller att hantera ömsesidiga erkännanden tämligen väl också framgår i förslaget till vägledning, vilket är positivt. Vi har trots detta några synpunkter och kommentarer på innehållet. Dessa synpunkter och kommentarer är, precis som utkastet till vägledning, på engelska.

Minor uses

The draft guidance no longer mentions mutual recognition for Minor uses. We think it would be helpful if this was included, similar to the previous version.

2.1.1 – Member State Authorisation

KemI asks for a certified translation of the certificate into English or Swedish. We are a bit surprised that the translation needs to be certified as Part A of the RR is in English, which is part of the reference member state’s decision. What is KemI’s reason behind requesting a certified translation? If KemI would like to confirm the reliability of the documents, they should contact the reference member state.

2.1.2 GAP

Possible GAP changes: We suggest that it should be possible to add new targets (compared to reference MS GAP) if supported by new efficacy documentation.

2.1.3 Label and user instruction

Translation of the reference MS label: Is a translated label from the reference MS necessary? Companies do submit the full RR and documentation, and therefore the

reference MS label does not contain anything new. If the above is still considered necessary, then alternatively could this requirement be fulfilled by submission of the reference label instead, which is in English and the bases for the label in each country. Alternatively, can applicants have a choice between translating the reference MS label or submitting the English reference label?

2.1.4 Composition and sources

Why ask for composition and sources? This is already included in Part C of the RR. KemI request under point 2.1.5 for complete RR, therefore this point is already considered.

3 Swedish requirements and comparable conditions

The following paragraph is contradictory:

“No separate documentation to justify comparable conditions between the reference member state and Sweden is needed. However, the applicant may need to submit supplementary information to address Swedish agricultural and environmental conditions in the environmental risk assessment and efficacy evaluation”.

If the applicant should provide information to address Swedish agricultural and environmental conditions, then a separate document is needed to justify why the information is or is not included.

3.1 Environmental risk assessment

Based on the following statement:

“When field studies are included in the risk assessment, a justification of the relevance of the studies based on Swedish environmental (including climatic) and agricultural conditions and the proposed use, should be provided. Results from field studies not considered relevant to Swedish conditions may be disregarded.”

It would imply that KemI would require a whole new modelling, meaning a new Environmental and fate behavior-section if they do not accept the assessment of reference MS with the field studies included, which defeats the purpose of a Mutual Recognition. If needed can the applicant provide justification?

3.2 Efficacy

Paragraph 1:

If the reference MS to do not belong to NZ - how many additional efficacy evaluation + studies would be required to supplement the RR? Do you require the full package?

Stating *“If the reference member state belongs to the Northern zone, additional efficacy studies relevant for Swedish climatic conditions does not have to be submitted”*- does this imply it needs to be in the Maritime Zone?

In our opinion efficacy data from the Maritime Zone and Poland should be considered adequate documentation, which is why we think that for MR from neighbouring countries (Maritime zone MS and Poland) new efficacy data should not be necessary.

Paragraph 2:

For GAP changes new efficacy data should not be considered necessary if the changes are covered by the original efficacy data, e.g. if

- a reduced dose rate is already covered by the minimum effective dose
- the efficacy of a reduced number of applications can be extrapolated from the original efficacy data.

Svenskt Växtskydd



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