EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

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DRAFT

Guidance document on the finalisation of the reference specification for technical active substances after the peer review

COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Background

The specification of the technical material used in plant protection products (ppp) is the basis of the assessment according to the criteria of 91/414/EEC. The requirement of Article 4 is that the specified and assessed material and the ppp have no harmful effect on human or animal health, directly or indirectly, no unacceptable influence on the environment, no unacceptable effect on plants or plant products and that they are sufficiently effective[1].

Consequently, the specification of the technical material should be harmonised before the respective active substance is listed in Annex I.

However, the past has shown that this has not always been the case, for different reasons. The causes for not having a harmonised specification are different and vary from missing validation data for certain impurities to a complete absence of batch analysis data. Another aspect is that sometimes the respective data seem to be available but it is not possible to use them during the experts' discussions because of the policy laid down in the Regulations 1490/2002 and 1095/2007.
It cannot be ruled out that active substances will also be listed in Annex I in the future without a harmonised specification.

The situation that active substances are listed in Annex I without a harmonised specification causes problems during the assessment of sources of technical material which are different to those assessed within the Annex I peer review process.
There are two cases where this assessment could be necessary:

- Within the re-registration procedure: if an authorisation holder indicates that he is using technical material from a different source to the one listed in Annex I.
- After the re-registration procedure: if a new source is introduced either by an authorisation holder or with a new application from a further applicant.

In both cases, the mandatory reference specification is missing to enable an equivalence assessment according to Sanco/10597/2003.

Procedure

There are three main situations that need to be considered. The first two cases are related to the fact that an active substance is already listed in Annex I in the special case of the so-called "green track" substances. The third situation covers the active substances where the scientific part of the review process has been finalised but a decision in the SCFCAH is pending. The difference between the cases is mainly the point of time at which the RMS/DMS starts its activity to develop a harmonised reference specification.

A. Active substance already listed in Annex I
The RMS/DMS starts work to develop a harmonised specification as soon as possible but at the latest when a new source[2] is identified. If it is necessary to request

[1] The assessment is based on the stipulations of Good Agriculture Practice.
[2] In this context a "new source" means a source of technical material that is different to the one described in the DAR as a basis for the decision on inclusion in Annex I. This could be a new manufacturing site and/or process from the original applicant or a source from another applicant that was not involved in the review process.

new data, the deadlines within the re-registration procedure should be taken into account.

B. Active substance already listed in Annex I - Special case green track substances
The RMS/DMS starts work to develop a harmonised specification as soon as the EFSA view (according to Regulation 1095/2007) is available and concerns are clearly identified. In cases where a reference specification is needed before the EFSA view is available (e.g. within the re-registration procedure), the RMS/DMS has to make use of the available data to conclude on a reference specification. If it is necessary to request new data, the deadlines within the re-registration procedure should be taken into account.

C. Active substance not listed in Annex I, but the scientific peer review is completed
The RMS/DMS starts work to develop a harmonised specification as soon as the EFSA conclusion is available.

In all cases the RMS/DMS that starts to resolve the issue on a harmonised reference specification should inform all MSs and the COM to avoid the duplication of work. If more than one MS have indicated their willingness, the respective MSs should come to an agreement and inform the MSs and the COM on the consensus. However, the RMS/DMS should ensure that the deadlines mentioned in this document are met. The final conclusion on the reference specification should be reported to the COM and the MSs and it should be ensured that the agreed specification is accepted by the SCFCAH.

Independently of the cases stated above, the following procedure should be used to achieve a harmonised reference specification. The numbering of the particular steps and different cases refers to the depicted scheme.

1. No harmonised reference specification

   There are two main causes:
   a) Either the conclusion on the specification was not possible because of insufficient data and because additional studies (e.g. current batch analyses) could not be taken into account, due to the stipulations of Regulations 1490/2002 and 1095/2007,
   b) or a conclusion on the specification was not possible because insufficient data were submitted and additional data were not available.

2. The RMS, or another designated MS (DMS), that has to conclude on the equivalence first describes the situation including the revealed problems in detail in a report (report on the reference specification[3]). This report should also contain the required data according to Sanco/10597/2003, as appropriate.

[3] Due to the fact that circumstances that need to be described and discussed can be very different, a general format of the "report on the reference specification" cannot be given. However, the purpose of the report should be clearly stated and the actual situation including the conducted assessment by the RMS/DMS should be given as transparently as possible to ensure that other MSs can develop a reliable opinion on the report.

3. In case a) the RMS/DMS should use, if available, the assessment of the studies in addenda to the DAR that were not taken into consideration during the peer review process. If the studies were not evaluated, the RMS/DMS has to conduct the assessment.
   In case b), it is necessary for the RMS/DMS to contact the applicant in order to clarify the open issues.

   However, the RMS/DMS should always explain the conclusion and the original objections to the technical specification as well as the basis of the assessment as transparently as possible to ensure that other MSs can develop a reliable opinion on the report. This should include a verification that the proposed new reference specification is fully covered by the toxicological studies which have been evaluated during the Annex I inclusion process. This should comprise both purity of the active substance and contained impurities. In addition, a list of the used studies is necessary.

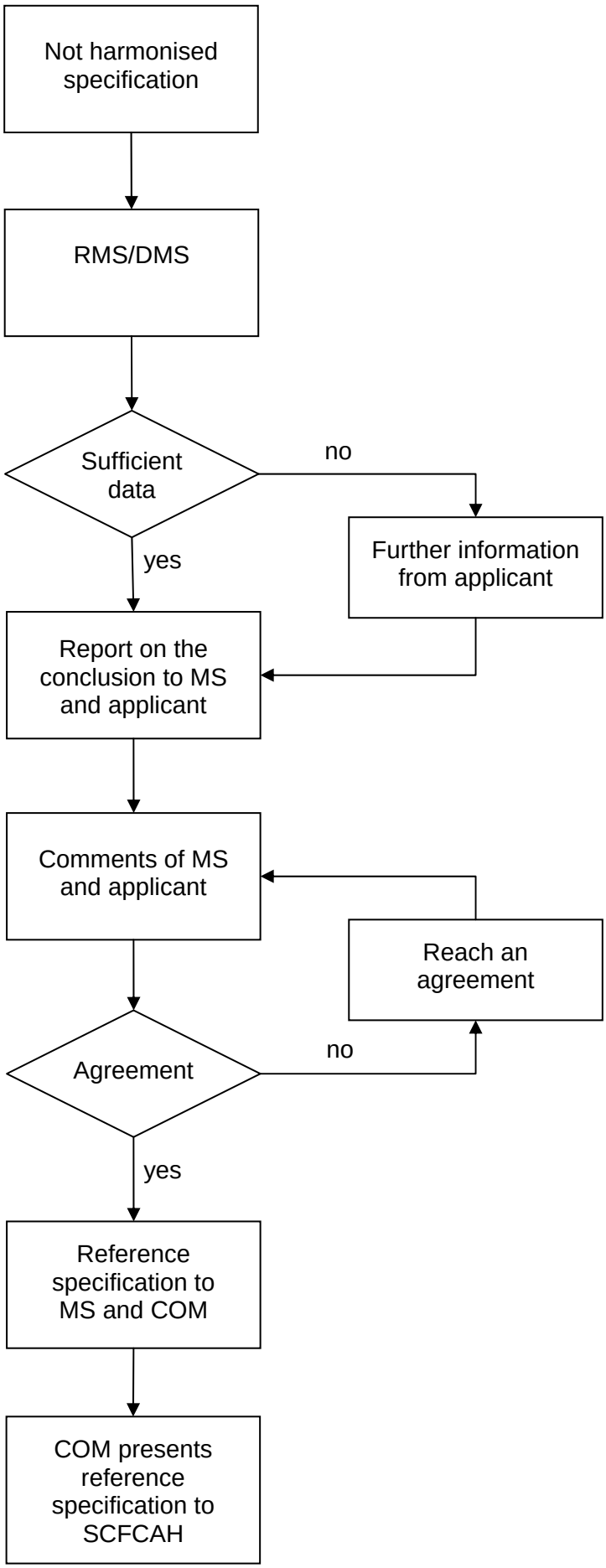
   The RMS/DMS should contact the applicant to resolve the issues on the technical specification as soon as the scientific peer review process has finished.

4. After finalisation of the report, the MSs and the applicant have the possibility of commenting on the assessment within 30 working days. Provided that no objection to this conclusion is raised, the reference specification used is regarded as the harmonised reference specification.

5. In cases where one or more MSs do not agree with the conclusion of the report, the RMS/DMS must try to come to an agreement on the conclusion with the MS(s) concerned within 30 working days. Where necessary, the applicant should have the possibility of commenting on the reasons for the disagreement.

6. The MS that has written the report should ensure that the deadlines are met and should also report the final conclusion on the reference specification to both the Commission and the MSs.

7. The COM should present the result concerning the harmonised reference specification to the SCFCAH. In order not to loose track on the agreed specification, COM should amend the review report accordingly.


Not harmonised specification
1.
RMS/DMS
2.
Sufficient data
no
Further information from applicant
3.
yes
Report on the conclusion to MS and applicant
Comments of MS and applicant
4.
Reach an agreement
5.
Agreement
no
yes
Reference specification to MS and COM
6.
COM presents reference specification to SCFCAH
7.