Data gaps identified in the EFSA Conclusion

Introduction

The question how to deal with the data gaps identified in the EFSA Conclusions has been discussed several times.

The Guidance Document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) is giving some guidance in this regard. This guidance document aims to give a systematic overview on the different reasons for submissions of further active substance data after its approval and the handling of such data with respect to (a) authorisation of plant protection products (Regulation (EC) No 1107/2009, Article 29) and (b) potential consequences for the approval. The guidance identifies some types of new active substance data not to be evaluated immediately (prior to renewal):
"New active substance data made available by an applicant after the approval of an active substance are not to be evaluated immediately (prior to renewal); these data will be considered in the next "scheduled" peer reviewed EU procedure for this active substance, i.e. when the approval is reviewed (renewal of approval of the active substance) or in the procedure of MRL-setting according to Regulation (EC) No 396/2005.
This procedure applies to:
- Data submitted by applicants who are not the notifier for approval – compliance check (step 1 procedure);
- Active substance data listed in the EFSA conclusion other than confirmatory data;
- Additional active substance data submitted by the notifier not essential for authorisation."

The question has been further discussed at the PAI meeting of September 2013. In the meeting's minutes is written:
"There was discussion about the email circulated in advance of the meeting from 5.1.2.e Woo regarding when the UK will assess identified EFSA data gaps as part of a product assessment. Other MS were asked if they agreed. The proposal was:

- If the EFSA data gap results in a confirmatory data requirement being specified at approval, data must be submitted and evaluated in accordance with the confirmatory data GD
- If the EFSA data gap relates specifically to the representative product, then the (product) data must be evaluated at re-registration (renewal of authorisation)
- If the EFSA data gap relates to an area that 'MS must pay particular attention to...' (as specified in the approval regulation), then the data (active and product) must be evaluated at re-registration, or for a new product.
- In all other instances the data (if submitted) should not be assessed, but deferred to renewal of the active substance/product authorisation. The applicant should not be required to address these data gaps until renewal.

The proposal was agreed in principle with MS and COM. The proposal can be included in the new data post approval guidance document. UK had already offered to propose wording for this document."

Both in the current guidance of 2012 and in the proposal made in the September 2013 PAI meeting, an important element is the question whether the data gap results in a confirmatory data requirement or

not. In this regard, it is important to note that the Regulation (EC) n° 1107/2009 only foresees in the possibility of requesting confirmatory information where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge. There is growing tendency with the Commission of applying this provision very strictly. As a result, data gaps which in the past would undoubtedly have led to confirmatory information requests are nowadays simply ignored, or it is mentioned in the review report that Member States may request such data. Sulfosulfuron is an example. In the review report for this substance, COM has written in section 7: "Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions such as the need for further data to assess the toxicological relevance of some potential groundwater metabolites".

Considering the discussions in the September 2013 PAI and the change in approach with regard to the confirmatory data requests, we feel it is necessary to proceed with a revision of the GD SANCO/10328/2004– rev 8. The intention of this note is to give some input for a discussion in preparation of the revision of the GD.

Legal consideration

Art. 33 (3) (a) and (b) of Reg. 1107/2009 prescribes that an application for authorization of a PPP shall be accompanied by a complete dossier for each point of the data requirements for both the PPP and the a.s.

The GD SANCO/10328/2004– rev 8 seems to suggest that a.s. data gaps identified by EFSA but not leading to a request for confirmatory data can be ignored. This is not in line with the above mentioned legal requirement. Moreover, the Commission's review reports systematically mention that:
"No further information was identified which is at this stage considered necessary in relation to the approval of active substance X under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page X)."

There is something contradictory with on the one hand COM highlighting in its review reports the list of data gaps in the EFSA Conclusion and the possible need to address these at MS level, and on the other hand COM suggesting in a GD that data gaps not leading to a confirmatory information request can be simply ignored.

It should be made clear in the GD that a complete dossier is always requested (as prescribed by art. 33), i.e. a study report or a scientific or technical rationale for not submitting such report for each data requirement, and that merely stating that the identified data gap did not lead to a confirmatory information requirement cannot be accepted as a valid waiver.

Ways Commission is dealing with data gaps identified in the EFSA Conclusions

It is important to understand that the Commission is dealing in different ways with the data gaps identified in the EFSA Conclusions. These are:

- Ignore the data gaps because they are not of relevance for the a.s. approval. This is typically the case for data gaps with regard to the representative plant protection product;
- Listing of the issue related to the data gap in the section “Member States shall pay particular attention to”; this is often the case for environmental risk assessments which could not be finalized;
- Request for confirmatory information;
- Where the data gap is relevant to only some of the representative uses, deletion of these uses from the table in annex to the review report listing the uses supported with available data;
- Highlighting that there may be a need for requesting the data at national level (cf. example of sulfosulfuron above).

Some of these situations have already been discussed in the September 2013 PAI meeting, and the recommendations from that meeting are addressing them adequately. The first 3 bullet points of the PAI meeting minutes cited above correspond indeed to the first three items listed above in this section.

However, the two last items listed above need some further consideration.

Deletion of representative uses from the table with uses supported by available data: cyantraniliprole is a good example. In the EFSA Conclusion the table with representative uses is listing a wide range of uses, both outdoor and in glasshouses. However, in the draft review report, only one outdoor use and some glasshouse uses have been listed in the table with uses supported by available data. The other uses have been deleted because of data gaps. Obviously, in the context of applications for national authorization for the uses not listed, these missing data may be necessary. For reasons of transparency, it would be good if the Commission could identify in the review report the representative uses not listed in the table of uses supported by available data, giving the reasons why they have not been listed.

The more complex issue is the one of the type of data that in the past would have been requested as confirmatory data, but that nowadays, because of the restriction of art. 6 (f) of Reg. 1107/2009, is no longer requested as such, as for instance data to assess the toxicological relevance of some potential groundwater metabolites. We have seen that in the case of sulfosulfuron, the Commission has addressed this in section 7 of the review report, but it should be checked whether this is done systematically for all similar cases. Normally, one would expect that the issue is also listed in the section “Member States shall pay particular attention”. For sulfosulfuron, this is indeed the case, but in a rather general way: “MSs must pay particular attention to the protection of groundwater”, without any reference to the issue of the relevance of metabolites. It is important that the review reports are transparent and coherent in the way they deal with missing data that due to art. 6 (f) are no longer eligible for a requirement for confirmatory data but that nevertheless may be important at national level. Either these data could be systematically listed in section 7 or more explicitly than today is the case in the section “MSs shall pay particular attention”. The GD SANCO/10328/2004 should be amended in order to clarify that such data where relevant shall be requested at national level. These changes would also contribute to the acceptance by Member States of decisions of (renewal of) approval without confirmatory data.

There are thus several situations justifying the request for data related to the active substance in the context of the national authorization procedure. Where the Regulation 1107/2009 fully applies, it can be assumed that the zRMS will assess these data. For applications for which the procedures of the Directive 91/414/EEC still apply because of the transitional measures of art. 80, this is not foreseen. It would however make sense to avoid repetition of the assessment of such data.

Recommendations

There is a need to revise GD SANCO/10328/2004 in order:

- To clarify that a complete dossier is always needed (study report or acceptable rationale for not submitting a study report);
- To address the outcome of the September 2013 PAI meeting;
- To clarify the issue of the deleted representative uses;
- To address the new situation with regard to the confirmatory data.

COM should identify in the review reports:

- the representative uses deleted from the table with uses supported by available data, with a rationale as to why these uses have been deleted;
- the data that may need to be requested at national level.

PAI to discuss ways to cooperate in order to avoid repetition of the assessment of data submitted after the approval.