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UPDATE ON THE STATUS OF THE EU REVIEW PROGRAMME ON PLANT PROTECTION PRODUCTS

European Food Safety Authority (EFSA)

Brussels, 24 May 2007

Honourable Chair, honourable members of the working group,

EFSA is grateful to the German Presidency for having invited us to join your working group at its meeting today. We very much welcome such opportunities to update Member States on our work and explain the impact of legislative initiatives on the tasks given to EFSA. In this regard we again acknowledge the Finnish presidency for inviting us to your meeting on 16 November 2006. It gave us the opportunity to share our views on the Commission's proposal for revision of Directive 91/414 and in particular highlight the tight deadlines that were proposed.

Today, we propose to focus on the on-going programme of review on plant protection products, as suggested by the German presidency in its invitation.

EFSA has an important remit in the area of plant protection products and it seems worthwhile to highlight the approach taken to fulfil these tasks.

EFSA has been given a number of tasks in the area of plant protection. Besides the coordination of and participation in the peer review of existing and new active substances used in plant protection products, the Pesticide Risk Assessment Peer Review (PRAPeR) unit also provides scientific support in the context of setting harmonised EU-wide Maximum Residue Levels (MRLs).

EFSA's panel for Plant Protection Products and their Residues (PPR) addresses questions raised on particular scientific issues related to active substances and develops or revises relevant guidance documents with respect to the risk assessment. Furthermore, EFSA's tasks also include scientific work by the Plant Health Panel (PLH) panel on the risks related to plant health from organisms harmful to plants or plant products by peer reviewing or conducting pest risk assessments at European level.

Hence, in close cooperation with the Member States, EFSA provides scientific advice that underpins the legislation in this area and thus contributes to high level of consumers' protection, protection of the environment, and maintenance of consumers' confidence in the EU.

The review of plant protection products is based on a close cooperation between all parties involved: the Member States, the Commission and the EFSA. EFSA's Management Board has identified cooperation with Member States as a top priority. Strengthening the cooperation with Member States will enable us to foster our scientific excellence, will help avoid duplication and will facilitate the risk management process. In that context, the review of plant protection products can be seen as an excellent example.

Now let us turn to the subject of today's discussion. Currently it is foreseen that the review programme must be completed by the end of 2008. A concern exists about the timely completion of this process. To address the concern of timely completion the Commission has drafted a Regulation proposal which aims to speed up the decision process of substances in the third and fourth stages of the review process. Specifically, the Commission has proposed amending Regulations (EC) No 1490/2002 and No 2229/2004 laying down further detailed rules for the implementation of the third and fourth stages of the above work programme.

I would like to take the opportunity of my presence here:

- to update you on the status of the review process
- to discuss the possible impact of the proposed regulation on the review process, and
- to make some suggestions to further increase the efficiency of the review process.

Review of the on-going work and timelines for completion of the full review and other review activities

Table 1 provides in column 3 an overview of the dossiers that are left in stages 3A (n = 41) and 3B (n=71). This does not include the 22 dossiers, from stage 3A, that are nearing completion of the review.

Table 2 shows a summary of the work programme. The calculation is based on a work programme consisting of six review rounds each year and on the expectation (based on our experience in recent years) that in each round about eight draft assessment reports (DARs) can be handled. It shows that 56 additional dossiers can be handled before the end of 2008. Thus,

- the substances in stage 3A, for which a DAR is generally available, can all be completed before the 2008 deadline, and
- most of the substances in stage 3B for which a DAR is already available will be also be completed.

For stage 3B there is however a substantial number substances either without a DAR or for which no decision has been taken thusfar (Table 1, column 4). For these, the 2008 deadline will be missed. It is anticipated though that their review could be completed before the end of 2009.

In summary, continuation of the current programme would result in the completion, by the end of 2008, of the review of at least 69 of the originally 134 substances in the 3rd stage (Table 2). Assuming that 38 substances (Table 1) could possibly be withdrawn and would not need to be further evaluated, this would leave an estimated 27 substances to be assessed after 2008.

In reviewing timelines (Table 2), the workload resulting from the review of both the stage 4 and the new active substances (NAS) needs to be considered as well. This is particularly relevant as these tasks are carried out by the same experts, both in the Member States and in EFSA.

For the stage 4 dossiers more information and discussions are needed to be able to assess their impact on the workload. In particular, the number of potential DARs, currently estimated at 93, may change. Furthermore, the quality of the dossiers and the respective risk assessments may differ from those of substances evaluated in the previous stages.

Similarly, when planning activities for 2008 and beyond, the workload resulting from the review of new active substances (NAS) needs to be considered as well.

Hence, whereas the current review (up to and including stage 3) could be completed before the end of 2009, this would probably imply that there is very limited time left for the evaluation of stage 4 dossiers and new substances during this period.

Therefore, an extension of the deadline of the end of December 2010 for the full programme would seem necessary.

Commission draft proposal for amendment of the regulations of the review programme

As mentioned previously, the Commission is pro-actively considering amending the regulations for stages 3 and 4. The Commission's draft proposal for amendment of the current Regulations creates the possibility to include substances in Annex I to Directive 91/414/EEC based on an evaluation of the assessment report: these are the so-called *green* substances. In addition, the proposal also creates the possibility for the Commission to decide that a substance is not fit for inclusion in Annex I: these are the *red* substances. This would allow the review process to prioritise those substances which need most urgent attention: the *yellow* substances.

Thus, the proposal not only eliminates *red* substances from the review process, but also could be interpreted as setting aside temporarily the *green* substances from the ongoing review. To maintain a high level of consumers' protection and protect the environment, EFSA would like to ensure that the list of *green* substances be subject to the same full and timely review as the *yellow* compounds. Consequently, the same high scientific review standards would continue to be applied by all involved in the review of these *green* substances.

Using the currently available information, the number of DARs in each of these three groups has been identified in Table 1 (columns 5-8) and their impact on the workload is shown in Table 2. Based on our current knowledge, it would seem that the number of *green* substances may be very similar to the number that still would need to be reviewed beyond the 2008 deadline (Table 2). Hence, if the deadline for the completion of the review of all substances can not be extended till the end of 2010, then the proposed amendments of the regulations may be very helpful towards meeting the 2008 timeline for all remaining (*yellow*) substances.

In conclusion, and assuming the same scientific review standard will be applied to the green substances, EFSA very much appreciates the Commission's initiative. It is noted though that the impact of the Commission's proposal depends on the number of substances that will effectively be classified as red and green.

Further increase in the efficiency of the review process

The attached flow charts of the process illustrate that the time needed to conduct the review process can be short indeed. However the time needed to complete a review currently varies considerably and is highly dependent on the nature and the number of issues that need to be addressed prior to and subsequent to the circulation of the DAR.

All experts and organisations involved in the review process have endeavoured to make the system as efficient as possible. However, EFSA is ready to explore, together with Member States experts, ways to further strengthen the efficiency of the review process, while maintaining the scientific quality needed for adequate protection of the consumers.

The evaluation of pesticides is based on close cooperation between several parties involved in the review process: the (co-)rapporteur, the other Member States, the EFSA, the Commission, and also the applicant. Hence, it would seem that a review of the process should look at the role of all parties involved and that all should contribute to the discussion of the efficiency of the process and the avoidance of duplication of effort.

EFSA offers to arrange for such a discussion to take place in the near future and in close cooperation with experts from Member States and with the Commission.

I would like to thank you, on behalf of EFSA, for this opportunity to share with you our thoughts and concerns. We are confident that such an approach will enable us to find solutions and strengthen the peer review process of pesticides, thus protecting consumers and the environment.

Thank you for your attention.

Table 1. Status for substances in the 3rd stage of the peer review: status 22 May 2007*.

Stage (total number)	Withdrawn by applicant	No. left for review	No decision yet or DAR not yet available***	<i>Possibly withdrawn by COM (dark red)</i>	<i>Possibly withdrawn by industry following COM request (light red)</i>	<i>Possibly delayed review (green)</i>	<i>Possibly prioritized for peer review (yellow)</i>
3 A (64)	1	41**	7	8	4	5	17
3 B (74)	3	71	46	3	5	7	10
No decision or no DAR available: <i>Proportional distribution***</i>							
3A (7)				1	1	1	4
3B (46)				6	10	14	16
Total				18	20	27	47

* This classification is based in part on best current information and in part on extrapolation of this information to those dossiers for which no information is yet available.

** This figure excludes the 22 substances already discussed or scheduled for discussion in PRAPeR experts' meetings through July 2007.

*** This is an extrapolation which assumes the same ratio of green, red, and yellow as for those dossiers for which a DAR is already available.

Table 2. Schedule of peer review.

Stage (total number)	Remainder 2007 (2 review rounds)	2008 (5 review rounds)	2008 (last round) and 2009 (6 rounds)	2010 (6 rounds)	Total
3A (27)	16 (yellow)	5 (yellow)	6 (green)		27
3B (47)		26 (yellow)	21 (green)		47
Reserve: Stages 3 (<i>light red</i>) and 4 & NAS		9	29	48	86
Total	16	40	56	48	160