EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Consumer Products Safety and Quality

Cover note "Workshop on environmental risk assessment for Product Types 1 to 6" endorsed at the 31rd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (27-28 November 2008)

On 11 March 2008 the workshop entitled "Workshop on environmental risk assessment for Product Types 1 to 6" took place. One of the topics discussed at the workshop was cumulative assessment based on Article 10 (1) of the Biocidal Products Directive where it is stated that "an active substance shall be included in Annex I, IA or IB if it may be expected that the biocidal products will fulfil the conditions laid down in Article 5 (1) (b), (c) and (d), *taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances*".

In the workshop the following was concluded as laid down in Section 2.4 of the report:

> In conclusion, it was decided to start performing cumulative risk assessments for PT 01 to 06 with wide dispersive uses based on the available information. An identified risk should be flagged in the CAR.
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> MS asked the Commission to give a clear opinion on the fact that according to Article 10 of the BPD the cumulative risk assessment should be carried out, where relevant, for the purposes of Annex I inclusion. In addition, the Commission was asked for an opinion on the possible decisions to be taken with respect to Annex I inclusion based on the outcome of a cumulative risk assessment. It was strongly recommended to discuss this issue at the next CA meeting.

At the 29th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market, which took place on 28-30 May 2008, this issue was discussed based on a document prepared by the Commission (the document is attached below), which aimed to clarify how and when to perform a cumulative risk assessment.

At this meeting there was a large consensus to perform cumulative risk assessment only on a non-routine basis. Some Member States however expressed concern that this issue might not be addressed during the Review Programme despite the Biocidal Products Directive placing an explicit obligation upon them regarding cumulative exposure from biocidal products. It was recognised that more guidance is needed on data requirements and methodology although cumulative risk assessment for the environment has been performed for several years under other regulatory frameworks. At the policy level the possible consequences of identifying unacceptable risks as a result of an assessment on cumulative exposures shall be further investigated.

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL
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Directorate B - Protecting the Natural Environment
ENV.B.3 - Biotechnology, Pesticides and Health

29th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market
Cumulative (Combined) risk assessment

1. Background

According to Article 10(1) of the BPD substances shall be included in Annex I, IA and IB also taking into account, **where relevant,** cumulation effects from the use of biocidal products containing the same active substances.
It has to be noted that this refers to both environmental and human health risk assessment and refers to one active substance contained in different products of the same Product Type (PT) or of different PTs.
Additionally in the TNsG on Annex I inclusion it is stated that:
"For the first evaluation of the active substance the applicant (in the dossier) and the Competent Authority (in the report) should consider what combination of exposures to the active substance from all the representative uses is ***realistically*** *possible. This should be based on the combined exposures for each use. A relevant time period for the pattern of use of the products and the nature of the active substance should be decided and explained in each case. The assessment should reflect normal lifestyles and emission patterns. Realistic worst case possible combinations of exposures should also be considered."*
During the workshop on Environmental Risk Assessment for PT 1-6 on 11th March 2008 the need for the performance of cumulative risk assessment for Annex I inclusion of active substances was extensively discussed. The need for performing cumulative risk assessment was generally accepted. However, it was decided to first consult the CA meeting on this issue, before starting to perform such assessments.
The present document discusses the regulatory need for the cumulative risk assessment based on the workshop stated above and earlier discussions on this subject.

2. Pros and cons of cumulative risk assessment

While there is clearly a need for cumulative risk assessment, which is also recognised in the BPD, there are several pros and cons of the assessment to be distinguished in technical and regulatory terms. The technical pros and cons with respect to the environment were discussed in the above mentioned workshop. With respect to cumulative human health this has not yet been discussed at a TM. With respect to the technical pros and cons, it is concluded for the moment that performing a cumulative risk assessment is technically possible, although further methodological development is needed for environmental as well as human health cumulative risk assessment. Guidance developed in other frameworks (REACH or IPCS) can be useful in this respect. There may also be a need for harmonisation of terminology with other frameworks or a more precise definition within the BPD.
With respect to the regulatory aspects of cumulative risk assessment the following remarks can be made:

- Decision making process on outcome of cumulative risk assessment: if an unacceptable risk is identified in the cumulative risk assessment a decision shall be taken on Annex I inclusion. However, no criteria are available at the moment for this process.

- If cumulative risk assessment shall be performed it must be noted that several active substances appear in PTs for which the evaluation is finalised (most relevant for PT8) or has not yet started (the fourth list). In other words: how to deal with substances already included in Annex I and how to perform a cumulative risk assessment for active substances appearing on the fourth list? In principle, a cumulative risk assessment shall be performed including all PTs in which the active substance occurs in the Review Program. In the cumulative assessment it can subsequently be decided to exclude certain PTs due to their minimal contribution to possible cumulative effects. However, a priori PTs cannot be excluded based on the fact there is an Annex I inclusion (PT8 and 14) or no evaluation (fourth list).

Delay of evaluation in the Review Program: it is clear that the performance of cumulative risk assessment will most likely delay the review process. First of all, the RMS may have to request additional data from the applicant. Especially a request for data on tonnage will require a lot of efforts from the applicant(s), as concluded at a previous CA meeting (27th CA Nov07 Doc 6.3)[1]. In the case of more than one applicant defending the same active substance the cumulative risk assessment, including how to deal with confidentiality of such sensitive data as companies volume sales, may become very complex. Second, the RMS has to perform the cumulative risk assessment which may require additional methodological development and discussions at TM level.

3. Conclusions

According to Article 10(1) a cumulative risk assessment shall be performed where relevant.
However, if the risk assessment is carried out per use within a PT or per PT, there is very clearly a possibility that the risk will be underestimated. On the other hand, if all the different uses of a substance in the different PTs have to be considered, it will be very complicated to carry out such a comparative risk assessment, given the way the Review Programme has been organised.
The Commission services would therefore suggest that for these reasons cumulative risk assessment should not be carried routinely in the Review Program. The Commission would suggest instead that, where a cumulative risk assessment might prove useful, substances should be identified as candidate for a cumulative risk assessment, which could be carried out, at the earliest, once authorisations of products have been granted, modified or cancelled in accordance with the provisions of Article 16, at the latest, on the occasion of the Annex I inclusion renewal.

[1] Although applicants have to provide such data in the dossier submitted, the quality and usefulness of the data can be doubted. It is unrealistic to require industry (producers and downstream users) at this point of time in the Review Program to provide these data.