



Agreed in TM IV 08
CA meeting was consulted: agreed in 32nd CA meeting, February 2009

Ispra, 17/11/2008

Harmonising the use of new and old versions of the TNsG on human exposure and of BEAT

FR asked COM to include in TM IV 08 a discussion on the use of the new TNsG on human exposure and BEAT. The current paper is based on the draft document by FR, and on the opinions expressed within the Human Exposure Expert Group (HEEG).

The new version of the TNsG on Human Exposure was endorsed in June 2007, including the database BEAT that is an integrated part of the TNsG. The new TNsG replaced the earlier version and the User Guidance Version 1 of June 2002. The old guidance is nevertheless still being used by Rapporteurs in certain situations. These two sets of guidance are referred to (in this paper) as follows:

- “TNsG 2002” includes 1) *TNsG on Human exposure to Biocidal Products – Guidance on exposure estimation* (June 2002) and 2) *Human exposure to Biocidal Products – User Guidance version 1*.
- “TNsG 2007” includes 1) *TNsG on Human exposure to Biocidal Products* (June 2007), 2) *BEAT* (computerised database of exposure data) and 3) *ConsExpo* (the consumer exposure model).

In order to adopt a common approach in evaluating especially the third and fourth list dossiers, it is necessary to have a discussion on the use of BEAT and the TNsG 2007 in general. The most urgent issue is to agree on when to use TNsG 2007, and in which cases TNsG 2002 will still be acceptable. This is a matter of equal treatment and harmonisation, and it can help us in avoiding additional work and difficult discrepancies at a later stage.

Issues for the different lists of substances:

When using TNsG 2002, indicative exposure values should be taken from *User Guidance version 1*, and if relevant information is not found, then the *TNsG Human Exposure to Biocidal Products - Guidance on Exposure Estimation* (2002) can be used.

First and second list. TNsG 2002 can be used, since changing the guidance would result in discrepancies and questions on equal treatment. TNsG 2007 could however be used when information is not available in TNsG 2002.

Third list. TNsG 2002 can be used since TNsG 2007 was not available when the dossiers were submitted. Nevertheless, it should be possible to use information from TNsG 2007 to complete the assessment when needed. If it is agreed that TNsG 2002 is the reference document, it should be followed unless decided otherwise for specific cases at the TM.

Fourth list. TNsG 2007 (including BEAT) is the reference document as it is/was available when the dossiers are/were submitted. Information from TNsG 2002 should not be used, except if relevant information can not be found in TNsG 2007.

New active substances. For dossiers submitted from now on, the same principles apply as for the fourth list of substances, TNsG 2007 being the reference document. For the dossiers that have already been received, the decision could be made on a case-to-case basis, taking into account the time of submission (relative to availability of TNsG 2007) and the availability of relevant information in TNsG 2002/2007.

Questions:

1. Do you agree with these principles on using TNsG 2002 vs. TNsG 2007?
2. For the completeness check of new dossiers, can the RMS accept an exposure assessment that is done using TNsG 2002? This seems to be the case in many dossiers. If accepted, can such an assessment be accepted in the final CAR, or should it be corrected using TNsG 2007? Should the correction be performed by the RMS or the Applicant?
3. How to deal with differences between the versions, e.g. in exposure data? Which problems will arise if the data used are different between third and fourth list dossiers?

The same questions are relevant for products. Should we use TNsG 2002 or TNsG 2007 in the authorisation of a product whose active substance was assessed using TNsG 2002? This question should perhaps be addressed at the CA level and in the Product Authorisation and Mutual Recognition Facilitation Group.

Training on BEAT and ConsExpo

Several MSs have expressed their need for training on BEAT and exposure assessment. A training workshop will be organised (Oslo, 24-26 February 2009) on BEAT, ConsExpo and general issues related to exposure to biocides. Information to CAs will be distributed.