



Ispira, 27/03/2009

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

This proposal was discussed and agreed upon in TM IV 2008, noting that the principles given in the document should be applied for the dossiers on a flexible basis.

This document and the flexible approach were agreed upon in the 32nd CA meeting in 18-20 February 2009.

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 provide guidance on when to use TNsG 2007, and in which cases TNsG 2002 will still be acceptable.

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.

Issues for the different lists of substances:

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 by 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.