

Mandates for BPC Ad hoc Working Groups - Human Exposure and Assessment of Residue Transfer to Food

(Revised 25 August 2014)

1. Introduction and objectives

The Biocidal Products Committee (BPC) Ad hoc Working Group (WG) - Human Exposure and Ad hoc WG - Assessment of Residue Transfer to Food (ARTFood) shall operate in a manner that is efficient and delivers its output in accordance with BPC working procedures to ensure the output is delivered in a timely manner. The Ad hoc WGs shall report to the BPC.

In order for the two BPC Ad hoc WGs to be efficient and effective, the members are expected to carry out work on a continuous basis throughout the year, mainly by electronic exchanges or virtual meetings.

The two BPC Ad hoc WGs shall consist of members without distinction between core members and flexible members. The Chairs of each of the Ad hoc WG will be from the Agency.

The BPC Rules of Procedure (RoPs) and the ECHA Conflicts of Interest policy apply to the BPC Ad hoc Working Groups (WGs).

All members of the Ad hoc Working Groups of the Biocidal Products Committee (BPC), their advisers and invited experts participating in the meeting shall declare at each meeting any interest which could be considered to be prejudicial to their independence with respect to any point on the agenda.

The Eligibility Guidelines for members of ECHA bodies (MB/45/2013 final¹) shall apply by analogy to all members of Working Groups of the BPC that are appointed on a long-term basis.

2. Ad hoc Working Group - Human Exposure

Scope

The Ad hoc WG - Human Exposure will focus on matters related to human exposure to biocides. It will support the BPC and its WGs (especially the permanent WG - Human Health) during the scientific and technical peer review process in relation to the following, where appropriate:

- Approval, renewal and review of biocidal active substances
- Inclusion of biocidal active substances into Annex I of the BPR
- Applications for Union authorisation, as well as the renewal, cancellation and amendments of these

¹ http://echa.europa.eu/documents/10162/13555/final_mb_45_2013_eligibility_crit_guid_en.pdf.

- Technical or scientific matters in relation to mutual recognition
- Any other questions that arise from the operation of BPR in relation to human exposure to biocides

In particular, the work of the Ad hoc WG - Human Exposure will cover the following areas:

- Technical or scientific matters in relation to human exposure assessment for biocides
- Generic or specific methodological issues in relation to human exposure assessment for biocides
- Harmonisation of the approach for assessing human exposure to biocides
- Integration of the approach followed under the biocides regime with other legislative frameworks across the EU, where appropriate (for example, REACH and plant protection products)
- Implementation of the strategies to assess human exposure to biocides (for example, development of the Human Exposure Scenario Documents)
- Support the implementation of the IT tools (e.g. Bayesian Exposure Assessment Tool [BEAT] and ConsExpo) used to assess human exposure to biocides, where appropriate
- Identification of the needs to revise the existing guidance documents on human exposure to biocidal products and contribution to the revision, where appropriate.

Output and reporting

The members of the Ad hoc WG - Human Exposure will be appointed for a three year term and will report to the BPC.

The deliverables of the Ad hoc WG - Human Exposure are written recommendations or draft guidance documents. A recommendation can be developed when issues concerning human exposure related matters require a more in depth investigation. They will not be legally binding documents, but will provide guidelines toward a harmonised approach to biocide exposure assessment for both applicants and Member States Competent Authorities.

The Ad hoc WG may be consulted upon request of the WG - Human Health or of the ECHA dossier manager in cooperation with the evaluating Competent Authority during the evaluation phase. The Ad hoc WG could also be consulted during an ad hoc follow up of the WG discussion. The Chair of the Ad hoc WG on Human Exposure will be responsible for referring the identified issues to the Ad hoc WG and for prioritising and organising consultations.

The Ad hoc WG - Human Exposure will send recommendations to the WG - Human Health within the agreed timelines for agreement and shall for relevant cases respect the applicable time frames of the BPC working procedures. The recommendation of the Ad hoc WG on Human Exposure must be agreed upon by the WG - Human Health before it can be implemented. The agreed recommendations, except those on individual dossiers, will be made available on the ECHA website. The recommendations may be integrated later into guidance, where relevant, following the standard ECHA Consultation Procedure on Guidance. When the Ad hoc WG - Human Exposure drafts guidance, this will be forwarded directly to the ECHA Secretariat for further processing through the standard ECHA consultation procedure on guidance.

3. Ad hoc Working Group - Assessment of Residue Transfer to Food

The former Dietary Risk Assessment Working Group (DRAWG) operating under EC Directive 98/8/EC was created due to the absence of a harmonised methodology for dietary risk assessment for biocides. As this group did not finish its work it was proposed at BPC-2 to establish the Ad Hoc WG - ARTFood. ARTFood shall facilitate the harmonisation of assessments in relation to direct and/or indirect food exposure to biocidal products. It is proposed that ARTFood will initially prepare a project plan. This project plan shall be forwarded to the BPC for agreement. The project plan will detail the scope, the timelines and the deliverables of ARTFood.

Scope

- ARTFood shall contribute to ensuring harmonised biocidal risk assessments under the BPR; in particular the assessment of biocidal residue transfer to food. This may include drafting, amending and revising guidance documents.
- ARTFood may contribute to guidance documents related to dietary risk assessment and maximum residue limit setting of biocides prepared by other relevant bodies such as EMA and EFSA. This may include participation in joint expert groups.
- ARTFood may be consulted by the BPC and its WG Human Health on general issues relating to the assessment of risks posed by direct or indirect food exposure to biocides or on the implementation of relevant guidance documents, on a case-by-case basis.

Output and reporting

The deliverables of ARTFood shall primarily be draft guidance documents. After ARTFood has prepared the guidance documents they will be forwarded to the BPC for agreement that they are in line with this mandate. Following BPC agreement, the guidance documents will be published following the ECHA procedure(s) for guidance development.

oOo