Agreed at BPC-4
12 February 2014

ARTFood project plan

1 Introduction

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 the BPC has established and agreed upon the mandate of the Ad hoc WG on the Assessment of Residue Transfer to Food (ARTFood).

According to the mandate, ARTFood shall facilitate the harmonisation of assessments in relation to direct and/or indirect food exposure to biocdal products. This document presents the project plan of ARTFood to be agreed by the BPC. Annex I lists the participants of ARTFood.

2 Project plan

There are three draft guidance documents developed by DRAWG that will be finalised by ARTFood. The scope, status, deliverables and timelines for each document are presented separately.

1.1 Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products

Scope: Where it is considered that residues of active substances in biocidal products used in animal husbandry might have the potential to lead to consumer health concerns a consumer safety evaluation must be undertaken with, where appropriate, the derivation of maximum residue limits (MRLs) in edible products derived from the animals.

A step-wise procedure is used to determine whether an MRL assessment is required for a biocidal substance used in animal husbandry. The procedure uses a threshold concept for external exposure of food producing animals to identify those substances for which a more detailed evaluation is needed. If the estimated external exposure of a food producing animal to the pharmacologically active substance and/or its toxic degradation products and/or any substance of concern contained in the biocidal product exceeds the trigger value (of 4 µg/kg bw), this is interpreted as indicating that a more detailed consideration of the potential for residues in edible products is required and an estimation of the worst case consumer exposure (WCCE) is undertaken and compared to the ADI. If this indicates that exposure reduction measures are needed in order to ensure that consumer exposure remains sufficiently low then a formal MRL procedure would be triggered. If, on the other hand, the external exposure is below the trigger value then, in most cases, there will be no need for an MRL evaluation.

Status: The draft guidance document is closely linked to the draft on “The Risk characterisation and assessment of Maximum Residue Limits (MRL) for biocides” developed under the umbrella

of the European Medicines Agency. This latter document introduces the process by which a decision is taken on whether an MRL evaluation is needed and details the approach taken for the MRL evaluation. Both documents went through Public Consultation (ended in 30 June 2012). The key result of the Public Consultation was that the available experience shows the trigger value is exceeded in the majority of the cases when the draft guidance is followed. Consultation with the working group established under EMA on the revision of the guidance started.

Procedure foreseen: The draft document will be finalised by the working group, taking into account the issues discussed during the March 2014 workshop on MRLs for Biocides hosted by the German BfR. The final draft document will go through the ECHA transitional consultation procedure (1-3 months; includes the CAs and Accredited Stakeholder Organisations).

Deliverables: draft guidance document.

Timelines: the draft guidance document is foreseen to be finalised by ARTFood in Q2-Q3 2014. (In addition, 1-3 months consultation may be necessary).

1.2 Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses

Scope: The document will cover only representative non-professional biocidal use scenarios in a domestic environment (household), where biocides may come into contact with food and where this food is consumed within that particular household. For each scenario, assessment models are presented in this guidance. The document describes methods for estimating dietary exposure for the various use scenarios without a specific quantification of residues in food and details the reference values to which the exposure estimates are compared in order to determine risk.

The methods described in this guidance are to be seen as recommendations for performing assessment of biocide transfer into food. Applicants wishing to propose other methods for assessment may do so as long as these other methods are substantiated, well documented and in line with the general principles of this guidance document.

Status: A draft guidance was drafted by DRAWG and presented to the Technical Meeting (September and November 2013). ECHA and industry has submitted comments and the TM has agreed that ARTFood should finalise it. The document is proposed to be tested.

Procedure foreseen: Once finalised by the ARTFood after the March 2014 workshop on MRLs for Biocides, the draft document should be published on the ARTFood website as a “pilot project” open for commenting (e.g. for 18 months). This would allow Applicants and Member States to gain experience with the approach proposed; send their comments and in light of the experience the guidance could be finalised through the ECHA guidance consultation procedure (9-12 months).

Deliverables: draft guidance document

Timelines: draft guidance document to be published as a “pilot project” in Q2 – Q3 2014.

1.3 Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses

Scope: Professional use scenarios cover all biocidal uses outside of the domestic environment (except biocidal use on livestock), where biocides may come into contact with food. The scope of the document is to give guidance to estimate transfer of biocidal active substances into

foods. Pending policy decision on MRLs assessment the document may incorporate recommendations when a formal MRLs procedure is to be initiated. Otherwise, a separate guidance should follow.

Applicants wishing to propose other methods for assessment may do so as long as these other methods are substantiated, well documented and in line with the general principles of this guidance document.

Status: The draft prepared by DRAWG was originally part of the draft "Guidance on Estimating Transfer of Biocidal Active Substances into Foods" which was discussed at TMIII12. In that discussion, it was decided to divide the draft into two separate documents, one on professional and one on non-professional uses (see above). The draft has been separated, yet some significant issues need to be agreed upon. The German BfR (Federal Institute for Risk Assessment) will host a workshop on the establishment of MRLs for active substances used in biocidal products on 18-19 March 2014 in Berlin. The workshop will deal with MRLs setting issues which may have an impact on the scope of the document. ARTFood will carry on finalising the document following the workshop.

Procedure foreseen: to be decided at a later stage.

Deliverables: draft guidance document

Timelines: the draft guidance document is foreseen to be finalised by ARTFood in Q3 – Q4 2014.

1.4 Other guidance documents

Initiation of the drafting of other guidance documents or recommendations with the agreement of BPC may be possible.

1.1. Annex

Members and observers of ARTFood

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