# Questions to be addressed by the Environment and Toxicology WG for the renewal of AVK rodenticides

During the CG-18 meeting, AP 6.3, the CG members were asked to provide technical and scientific questions considered necessary to be discussed in the ECHA BPC Working Groups (WGs) for the renewal of AVK rodenticides.

Following up from the review of the questions received,[1] a list of questions was prepared and was provided for discussion during the September and November WG meetings.

This document consolidates the feedback provided by the relevant Chairs of WG, which is proposed for agreement by CG members before being distributed to ASOs for information and dissemination.

## Environment WG:

### Groundwater assessment for rodenticides

As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:

- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.

- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

## Toxicology WG

### Read-across and worst-case approach for dermal absorption.

As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iii) remain valid, applicants will have to address the dermal absorption issue according to document CA-July13-Doc.6.2.b - Final.

The WG did agreed that it was not possible to set a worst-case approach between different bait formulations. However, WG members discussed whether some specific default values could be agreed for the different bait formulations in order to be used under step 2(a) of document CA-July13-Doc.6.2.b – Final; i.e. in the absence of data under steps 1 or 2(b) of that document.

The legality concerning possible data protection of using studies submitted by applicants at the active substance approval stage or within applications for product authorisation to derive default factors that could then be used by any other applicants at the renewal of product authorisations was raised during the WG meeting and has been subject to discussions

[1] "CG-18 AP 6.3 Followup_Rodenticides Questions and comments final". Published in S-CIRCABC (/CircaBC/echa/Coordination Group/Library/Confidential/Newsgroup archive/)

between ECHA and the Commission.

Pending the clarification of those legal aspects, the WG will consider proposing harmonized default values for bait formulations with the objective of having an agreement by the WG in May 2017.