Coordination Group – CG-30

Agenda item 7.3: Risk assessment for animal health

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1. Background

Based on a question received by ECHA from a MSCA evaluating a biocidal product intended to be used as a repellent for humans and for animals, a pre-meeting consultation took place within the Coordination Group on the authorisation of biocidal products and treated articles having a primary biocidal function for which the risk assessment has to consider any possible effect on the health of animals.

We thank the commenting MSCAs for their input and note the following conclusions from the e-consultation:

- On the assessment of treated articles addressing animal health, one MSCA has conducted a review of a repellent-treated article. No additional cases of assessment of treated articles addressing animal health have been reported.
- In most cases the assessment of animal health in biocidal active substances/products is assumed to be covered by the human health risk assessment.
- The following examples were provided by MSCAs on products for which specific risk assessments for animals were performed:
  - For PT 2, a risk assessment for ornamental fishes was performed for an application for an algaecide used in artificial ponds and aquaria. Oral exposure of companion animals drinking treated water was also assessed.
  - For PT 3, exposure of livestock animals getting in contact with a disinfectant after teat treatment or animal housing disinfection was also performed for product authorisation.
  - For PT 18, two MSCAs noted that for several products a qualitative assessment was performed for domestic pets (dogs and mainly cats). This qualitative assessment could result in additional RMMs.

    A MS has evaluated a number of PT 18 products, where a companion animal risk assessment was performed in a quantitative manner.

    Another MS also assessed the risks to companion animals in the CAR for a PT 18 active substance. In this case, cats were particularly sensitive to the active substance and the assessment was undertaken for a worst-case (potential exposure of a kitten), considering that it covers other companion animals.
  - For PT 19, a quantitative risk assessment for horses and dogs was performed for an application on those animals for a repellent. Another MS has assessed PT 19 products specifically intended to be used as fly repellent on horses.

- A MS has evaluated a PT 19 article (article impregnated with repellent). The human health assessment was considered to cover the animal health assessment in this case as toxicity is similar between species and the estimated exposure of humans by far exceeds the likely animal exposure.

- Regarding the setting of reference values, two MSCAs have the view is that it is not appropriate to use AELs for companion animals and proposes to use the corresponding animal NOAELs (from which the AELs are derived). A margin of exposure (MOE) should then be calculated, which may be less than 100 as it could be argued that protection goals for these animals are less than those for humans.
- On dermal absorption, a MS mentioned that a possible applicant has discussed the option of providing additional data to reduce the dermal absorption value, due to differences in thickness of skin and hair coverage.

2. Proposal

Based on the input provided by MSCAs, it becomes apparent that in some cases the risk assessment for animals can be covered by the risk assessment for human health, noting the examples above.

In those cases where the risk assessment for animals is not covered by the risk assessment for human health, ECHA SECR proposes the following approach:

- Information requirements:

  Where necessary and in order to perform the risk assessment, additional information might be requested to applicants based on Annex II of the BPR, which indicates in Section 8.15 that information might be requested to assess "Toxic effects on livestock and pets" as Additional Data Set. The information requirements for biocidal products (Annex III of the BPR) does not mention the toxic effects on livestock and pets as Core Data set nor Additional Data Set.

- Guidance on exposure and risk assessment:

  The existing guidance from the BPR provides support on performing the exposure assessment. For example, the Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products[1], while intended for other purposes (setting MRLs) includes default values for different animal species such animal body weights and surfaces, and drinking water and feed intake which can be used in the risk assessment for animals.

  Guidance available from other regulatory frameworks (veterinary medicinal products and animal nutrition[2]) can be used in developing the use scenarios and the risk assessment. EFSA developed a guidance in 2009 on the risk assessment for birds and mammals[3].

[1] Guidance on BPR: volume III part B+C. Section 6 https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094

[2] Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5021

[3] Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438. https://www.efsa.europa.eu/sites/default/files/engage/171106.pdf

- In those cases where MSCAs consider that they lack expertise in specific issues not covered by the guidance mentioned above, MSCAs are invited to indicate it in the relevant fora so that additional methodology for addressing those specific issues in the risk assessment for animal health could be developed.
- The Coordination Group is invited to consider whether development of guidance addressing the risk assessment for animal health could be prioritized considering the number of existing products on their market as well as the number of on-going applications for authorisation under the BPR of biocidal products for which the risk assessment has to consider any possible effect on the health of animals.
- The Coordination Group-30 meeting agreed with the document and the proposal. This document presents a public version of the document agreed at CG-30 meeting.