10 June 2014
EMA/CVMP/337469/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Call for scientific data for use in CVMP assessment work of diflubenzuron: review of the CVMP opinion for the establishment of maximum residue limits

Submission period: 10 June 2014 – 30 September 2014

Pursuant to Article 11 of Regulation (EC) No 470/2010 the European Commission requested the CVMP to review its previous opinion for the establishment of maximum residue limits (MRLs) for diflubenzuron in view of concerns relating to the metabolite 4-chloroaniline and recent evaluations by the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

The CVMP invites all interested parties such as pharmaceutical industry, learned societies, governmental institutions as well as EU and EEA-EFTA Member States to submit scientific data for use in the review of the consumer safety assessment of diflubenzuron. The CVMP is seeking to obtain any relevant data available on the metabolism of diflubenzuron and the formation of the genotoxic metabolite 4-chloroaniline, species differences in the metabolism of diflubenzuron and their relevance in relation to human exposure to 4-chloroaniline, and the depletion of diflubenzuron in salmon or other fin fish species with information on relevant metabolites. Information is also sought on the possible effects of sample processing and storage on the formation of 4-chloroaniline.

Scientific contributions should be sent to:

By post	**By email**
European Medicines Agency 7 Westferry Circus Canary Wharf UK-London E14 4HB Att.: Veterinary applications either one CD-rom or paper prints	vet.applications@ema.europa.eu

A list of all scientific contributions and their references should be enclosed.

The name and contact details of the interested party providing the scientific contributions is required.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Unpublished data may be included. However, the consent of the data owner is a necessary requirement. The owner of the data will be given the opportunity to review the assessment report to remove any confidential data. The CVMP will consider such submissions on a case-by-case basis. Submitting parties are bound to obey existing copyrights. Contributors should also take duly into account the rights of interested parties, as the documentation provided will be used for the review of the assessment for the establishment of MRLs for diflubenzuron. Such revision is underpinned by an assessment report, which will be made public in accordance with measures taken by the Agency to ensure an appropriate level of transparency.

As regards **copyright**, it is important to clarify that the use by the CVMP of the bibliographic material is entirely for a non-commercial purpose. As its non-commercial use by the Committee is guaranteed, any interested party will not incur any liability as to the use intended by the CVMP by forwarding the bibliographic literature to the Committee. The CVMP is in all cases willing to confirm in writing the non-commercial use of documents sent in by interested parties.

Documents should be submitted in **English** where possible since this is the working language of the CVMP, but documents in other official languages of the European Union will be accepted. In order to facilitate the assessment, the CVMP appreciates the submission of an abstract in English when original references are provided.

Conditions for data submissions

Scientific contributions should be relevant to the purpose of the assessment.

The acceptance of scientific contributions will be based on compliance with the following general criteria:

1. Scientific contributions should be classified by the interested party as (i) peer-reviewed data; or (ii) non peer-reviewed data. The Agency encourages submission of peer-reviewed data/publications (not just the reference) as the most relevant and reliable documents. Non peer-reviewed data can be taken into consideration provided that they are of an adequate quality.
2. A document providing a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search should be enclosed.