specialty chemicals
CEFIC SECTOR GROUPS

EBPF – European Biocidal Products Forum

POSITION PAPER

6th April 2017

Cefic – EBPF Comments on CA Document CA-April17-Doc.3.1.a & b: Draft criteria for the determination of endocrine-disrupting properties under the BPR

Cefic-EBPF is disappointed that the Commission has retained the term 'substance' instead of the term 'active substance', despite the legal and procedural arguments made by Industry in December[1] 2016 and February 2017[2].

Given the legal arguments, the open questions around the implementation of the criteria and the likely consequence of exceeding the legal timeline for granting a Product Authorisation, Cefic-EBPF requests the Commission to revert to the original wording of 'active substance'. Certainly the authorities but also the citizens should be reassured and also recognise that the assessment for biocides is very thorough as a result of the very high data requirements and the very worst case scenarios taken into account in the risk assessments. The BPR legal framework, by its processes, ensures the protection of human health and the environment. As an additional guarantee for this, the BPR includes well-established processes for addressing all of the substances of concern in a biocidal product.

Additionally, Cefic-EBPF supports the exemption for substances that have an intended mode of action to control the target organisms via their endocrine system and believe it should not exclude vertebrates for the reasons explained in this paper.

Industry's arguments with regards to the extension of the scope have not changed and are well explained in our previous position papers. We invite both the Commission and Member States to address our concerns during the 7th of April CA meeting.

This current paper mainly focuses on the exemption for substances that have an intended mode of action to control the target organisms via their endocrine system and brings additional arguments why this exemption is relevant.

Cefic-EBPF supports the wording of paragraph (3) of section B of the Annex to the draft act. We strongly believe that consistency with PPPR should be kept and we therefore encourage Member States and the Commission to maintain this consistency. Moreover, among the PT18 biocides, there are substances in the review programme or already approved which act via an endocrine mode of action. Specifically, those substances act on different growth stages of the insect life cycle and are therefore complementary to other PT18 substances, and as such are vitally important to keep.

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[1] https://circabc.europa.eu/sd/a/c3ad250e-70c9-44af-883f-615be99a0300/CA-Dec16-Doc.3.1ah-Cefic.pdf

[2] https://circabc.europa.eu/sd/a/0394f81e-98b5-4622-af88-cbb072c78c84/CA-Febr17-Doc.3.1.j-Cefic-a.pdf

https://circabc.europa.eu/sd/a/c1bf662a-5d2f-4c62-840f-db281454b01c/CA-Febr17-Doc.3.1.k-Cefic-b.pdf

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We can see some rationale in the latest Danish comment that indeed not having the exemption would still allow approval of the substance (if no ED effects on humans had been demonstrated) but not for general public and the substance would unnecessarily be flagged as an ED. The consequences for consumers (many of us with companion animals, surely also some of the Member States' representatives) are easy to guess since, in domestic situations, active substances acting via an endocrine mode of action are used in products to control against eggs and larvae of insects especially fleas or in baits against cockroaches which can spread harmful bacterial infections.

Such substances, known within the PPP as Insect Growth Regulators (or IGRs), are specifically developed to target and disrupt biological targets in insect growth and development and as such do not 'recognise' mammalian endocrine targets. Another way of looking at it is considering if an insect pheromone could in any way change or modify behaviour in a vertebrate species.

As such, IGRs represent a highly valuable tool in addressing insecticide resistance in target species. IGRs must be retained for amateur use as they represent a valuable tool for dealing with a number of invertebrate pest species including fleas which parasitize our cats and dogs. Moreover, flea faeces contribute allergens to household dust which is linked to provoking and exacerbating asthma in susceptible individuals. As already mentioned, IGRs represent a useful class of insecticide for baits against cockroaches due to their different mode of action from pyrethroids and lack of repellency as well as their capacity to tackle insecticide resistance.

It is therefore not only clear, but also desirable for the health and comfort of many citizens, that substances specifically developed to target and disrupt specified biological targets in insect growth and development must be exempted.

Regarding the latest addition of '…other than vertebrates', it would be of value to understand the rationale behind this addition and why discriminate between vertebrates and non-vertebrates? If we consider a rodenticide acting via an endocrine mode of action, it would be caught under Section A. We therefore believe that excluding vertebrates may prevent innovation for products such as rodenticides, avicides and products to control other vertebrates.

In conclusion, Cefic - EBPF requests the Commission to revert to the original wording of 'active substance' in line with the legal arguments already made by Industry during December 2016, when this change was first introduced and re-emphasised in February 2017.

We believe that IGRs are useful tools for controlling insect pests and should therefore remain available for consumer use. We are confident that Member States authorities would not want to prevent citizens from using such valuable tools in protecting their cats and dogs against eggs and larvae of fleas or prevent people from using baits against cockroaches in their homes. Additionally, flea faeces contribute allergenic proteins to household dust which is linked to provoking and exacerbating asthma in susceptible individuals.

For more information, please contact: Camelia Mihai +32 2.792.75.03 or cmi@cefic.be	About EBPF The European Biocidal Products Forum (EBPF) is a sector group of Cefic, composed of more than 70 companies and trade associations representing the industry that places a wide range of biocidal products on the market for the benefit of EU citizens.