Briefing for stakeholders

EU Biocidal Products Committee:

Recommendation on Anticoagulant Rodenticides for Control of Mice Indoors puts Public Health at Risk, Undermines Businesses

On 23 November 2022, following a dubious deliberation process during the year, the EU Biocidal Products Committee (EU-BPC) concluded that mechanical traps were effective at controlling house mice infestations (in all circumstances).

The scientific basis for the opinion was a single study made in a single agricultural context in a single EU country with a single set of products and promoted by a manufacturer of traps with a direct commercial interest in a ban on AVK rodenticides.

If the European Commission, based on the EU-BPC opinion, opts not to extend the existing exemption for AVK rodenticides under the EU Biocidal Products Regulation, Pest Control Operators (PCOs) will no longer have access to these products as of July 2024. This would lead to potentially devastating consequences on public health and food safety, as infestation will no longer be controllable.

CEPA represents professional environmental public health protection companies in Europe. It is mobilizing stakeholders to counteract this worrying development for public health in Europe through an advocacy effort targeting the Commission. This memo provides a detailed background briefing and supplies some background materials in attachment.

Attachment 1: ***CEPA Viewpoint_Jan2022*** (Access to a full Toolbox)
Attachment 2: ***CEPA Viewpoint_Nov2022*** (Misrepresentation in EU-BPC Sept 2022 meeting)
Attachment 3: ***ECHA Statement on BPC Opinion_Nov2022*** (Traps & AVK Rodenticides)
Attachment 4: ***CEPA Holding Statement_Mar2023*** (EU-BPC Opinion implications)

The issue

CEPA is an observer in the **EU-BPC** process and intervened to question the trajectory that was emerging during 2022. However, ***misinformation from trap manufacturers***, the ***insistence of a very large EU country*** and apparent ***"inertia" on the part of a silent majority of national delegates*** led to the unjustified conclusion that traps are a viable alternative to use of AVK Rodenticides for control of mice indoors in all situations.

The EU-BPC's formal Opinion on this was sent to the **European Commission** in February 2023, which, as a result, may subsequently decide to ban anticoagulant (AVK) rodenticides for remedying indoor infestations of mice, meaning these essential tools would no longer be available to professional environmental public health protection companies for such purposes as of July 2024.

Before the Commission can act, it must hear the views of the **Standing Committee on Biocidal Products that represents the EU27 governments**. Neither the EU-BPC opinion nor the views of the Standing Committee are binding on the Commission but will be taken seriously and may influence the Commission's decision significantly. Full background information follows. Kindly review this so that you are fully aware of the situation.

Background Information

The key EU bodies dealing with Biocidal Products

The **EU Biocidal Products Committee (EU-BPC)** [1] is composed of government experts from the EU27 countries, the European Economic Area countries (Norway, Iceland and Liechtenstein), and Switzerland, and is chaired by the **European Chemicals Agency (ECHA).** It prepares the formal "***opinions***" of ECHA in relation to a number of processes (*see endnote* [i]) related to the management of the **EU Biocidal Products Regulation (EU-BPR)**[2], notably opinions on the approval (and review of approval) of active substances.

These opinions are sent to the **EU Standing Committee on biocidal products ("the Standing Committee")** and the **European Commission**. The Standing Committee is composed of representatives of the official government bodies at national level (one or more) that are responsible for overseeing the use of biocidal products on their territory. These are mostly environment ministries or agencies but, in some cases, also organisations working with financial, health or labour issues. In practice, the members of the EU-BPC often work for one or other competent authority, so there is a certain interdependence between the two committees.

While the Standing Committee can advise the EU executive, the final decision on what action to take under the EU-BPR rules following an EU-BPC opinion are taken by the European Commission.

The decisions taken in Brussels under the EU-BPR on whether an active substance is allowed or not apply directly in all the EU member states without need for any national legislation to make them law.

Substitute products under the EU-BPR (and relevance for anticoagulant rodenticides)

One of the objectives of the EU-BPR is to **identify substances of particular concern** to public health or the environment and to ensure that these substances are phased-out and replaced by more suitable alternatives over time.

AVK rodenticides have been identified as such but have been exempted from restriction under the EU-BPR because there are no viable alternatives. **The current exemption runs until July 2024**.

AVK rodenticides are thus currently classed as **candidates for substitution** (often simply referred to as "substitute products") when used in certain products/applications (*see endnote* [ii]). This means that the EU (via the EU-BPR and ECHA) will look out for alternatives to these active ingredients and carry out comparative assessments to determine existence/viability of "safer" products.

Once such a safer alternative is identified and the Commission is informed, the next stage is for the Commission to decide whether or not to proceed to ban the use of the "substitute product" in the reference application(s). Once banned, products containing the active substances can no longer be placed on the market or used for the specific application concerned.

The exemption for AVK rodenticides has been renewed once (valid until July 2024) and the EU is currently going through comparative assessment of them in order to determine whether the exemption should be renewed for another five years or allowed to expire, which is equivalent to a ban.

[1] *The BPC secretariat is managed by the European Chemicals Agency, based in Helsinki*
[2] *Regulation EU N° 528/2012 on biocidal products*

What happened in the EU-BPC last year

Last year, the EU-BPC reviewed whether mechanical traps could be considered as a viable alternative to anti-coagulant rodenticides in various applications.

CEPA is registered as an observer at the EU-BPC and contributed to all stages of the consultations, notably with written submissions to the EU-BPC in January and October 2022 last year (see ***Attachments 1 and 2***).

A minority of Member State representatives pushed for mechanical traps to be classified as a viable alternative. A single study carried out in a single country in a single context (initiated and provided to the EU-BPC by a single trap manufacturer) was cited as justification for this.

Following a very unsatisfactory discussion during the September meeting, CEPA wrote to the EU-BPC protesting the way the matter was being considered and asking to be allowed to make a formal presentation to the committee and this was agreed. ECHA also invited Biocides for Europe (the European manufacturers association) and an individual company that manufactures traps to present.

Following the interventions by CEPA and by Biocides for Europe, two or three countries expressed doubt about taking any decision without more extensive scientific evidence. However, most of the delegates remained silent, almost uninterested in the debate. The trap manufacturer observers repeatedly characterised traps as "IPM products", a clearly misleading term as there is no such thing – IPM is an approach not an item.

The 23 November conclusion and its implications

As a result of the apparent apathy in this "hybrid" in-person/online meeting, the EU-BPC then adopted more or less by default the formal conclusion that mechanical traps are suitable alternatives to anti-coagulant rodenticides for indoor control of mice, for inclusion in its "***Opinion on the comparative assessment for the second renewal of all anticoagulant or anti-vitamin K (AVK) rodenticides in the EU***".

At the same time, the committee concluded that their effectiveness was uncertain for other uses and target animals (like rats).

On 29 November, the EU-BPC secretariat published a statement on the ECHA website entitled "***Rodent traps can be effective at controlling house mice infestations***" (see ***Attachment 3***). It explicitly states that the EU-BPC had "one test available" to it, suggesting that the ECHA secretariat may be "uncomfortable" with the process in this case[3].

As AVK Rodenticides are categorised as "substitute" products, the establishment of a recognised alternative by the EU could lead the way to a quasi-automatic ban, meaning that, in the future, pest managers would be prevented from using AVK rodenticides for indoor mouse control, even in the event of a complex infestation where traps would be neither effective and/or feasible in practice.

Where do we stand in the process

The EU-BPC secretariat finally transmitted the formal report containing the Opinion on traps and AVK rodenticides to the Standing Committee and to the Commission in February 2023 (much later than originally announced). The report confirmed the conclusion that rodent traps are an effective remedy for indoor infestations of mice (in all situations). In so doing, the opinion contains significant inconsistencies and errors.

CEPA sent a holding statement to all members of the Standing Committee (see ***Attachment 4***) and to the Commission objecting to the conclusion contained in the Opinion and the way it was reached.

[3] This is even more evident if you listen to the podcast on the same page.

Based on the Opinion, the Commission must now formally decide whether to let the current exemption lapse (thus banning AVK rodenticides for dealing with indoor infestations of mice) or put forward a further five-year exemption. This is done in practice by preparing a formal and legally binding Commission Decision. A draft of this Decision will be shared with the Standing Committee for its views. The Commission has indicated in writing that it has started preparing the draft Decision but without specifying what precisely it will state.

The views of the Standing Committee are not binding on the Commission but, given that the Standing Committee formally represent the EU27 governments, any advice it gives will be taken seriously by the EU executive.

The next meeting of the Standing Committee is scheduled at the end of June 2023. Although it is not yet clear whether the Commission draft decision will be available then, it would be prudent to assume that it will. If not, then it would certainly be presented in the autumn.

The "built-in" bureaucratic inertia in this procedure is such that, without high-level political intervention (from the Commission leadership under pressure from member state governments and stakeholders), this process will result in an unwelcome ban that will put public health at serious risk.

Conclusion

The EU-BPC opinion now presents the real threat that AVK rodenticides will be banned after July 2024, making it impossible for professional environmental public health protection companies to do their job effectively in many situations, putting people and businesses at risk.

While there is no doubt that traps are valuable tools in the professional pest manager's toolbox – and their use is expanding – there are many indoor infestation situations where they will not be an effective enough remedy against mice to solve the problem and adequately protect hygiene and public health. Furthermore, the assessment has not taken account of the technical and economic feasibility in practice of large-scale use of traps for complex infestations.

These facts have been overlooked by the EU-BPC, at least in part because of the provision of inadequate and at times misleading information by trap manufacturers.

On the other hand, **the scientific (& ethical) validity of the EU-BPC opinion is highly questionable** because it has been taken on the basis of a single, very narrow study of rodent traps promoted by a single company which has a direct commercial interest in selling more of its own traps, something that might be expected if AVK rodenticides are banned for all mouse infestations indoors. It would be unthinkable that a chemical product would be authorised on the same unscientific basis.

To ensure that the Commission renews the exemption, CEPA and its customer base, whose safety or business interests will be negatively impacted in future by the removal of anticoagulant rodenticides, must now address this situation with the European Commission, relevant government agencies across the EU27 (and other countries involved) and engage all relevant stakeholders in sounding the alarm.

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ENDNOTES:

[i] *The EU Biocidal Products Regulation (EU-BPR) processes involving opinions from the EU-Biocidal Products Committee (EU-BPC) are as follows:*

- *Applications for approval and renewal of approval of active substances*
- *Review of approval of active substances*
- *Applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 of the EU-BPR and review of the inclusion of such active substances in Annex I*
- *Identification of active substances which are candidates for substitution*
- *Applications for Union authorisation of biocidal products and for renewal, cancellation and amendment of Union authorisations, except where the applications are for administrative changes*
- *Scientific and technical matters concerning mutual recognition between Member States in accordance with Article 38 of the EU-BPR*
- *At the request of the Commission or of the Member States, the EU-BPC is also responsible for preparing opinions on any other question that may arise from the operation of the EU-BPR relating to risks to human or animal health or the environment, or to technical guidance*

[ii] *The criteria for determining a candidate for substitution are based on the intrinsic hazardous properties in combination with the use. An active substance will be considered as a candidate for substitution if any of the following criteria are met:*

- *It meets at least one of the exclusion criteria:*
  - *carcinogen, mutagen, reprotoxic substance categories 1A or 1B according to the EU CLP Regulation*
  - *endocrine disruptor*
  - *persistent, bioaccumulative and toxic (PBT) substance*
  - *very persistent and very bioaccumulative (vPvB) substance*
- *It is classified as a respiratory sensitizer*
- *Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use*
- *It meets two of the criteria to be considered as PBT*
- *It causes concerns for human or animal health and for the environment even with very restrictive risk management measures*
- *It contains a significant proportion of non-active isomers or impurities*