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RISK MITIGATION MEASURES FOR ANTICOAGULANTS USED AS RODENTICIDES

Several anticoagulants used as rodenticides are currently under evaluation within the review programme established by Directive 98/8/EC concerning the placing on the market of biocidal products.

All these substances are highly toxic. They are also non-selective, and can pose a high risk of primary and secondary poisoning to non-target animals and children. In addition, resistance to some of these substances has been reported.

Most Rapporteur Member States (RMS) for these anticoagulants suggested specific mitigation measures to address these risks. However, although all Member States agree that anticoagulants require special precautions when used, they did not necessarily agree on the risk mitigation measures to be taken.

In addition, some Member States suggested that these measures could be harmonised at EU level through specific provisions in the Annex I inclusions, others that they could be deferred to product authorisation level.

This paper outlines a common approach for both Annex I inclusion and products authorisations.

It was however recognised, during the extensive discussions, which took place during the drafting of this paper, that:

- The choice of the most appropriate risk mitigation measures is closely linked to the design, pack size, area of use, category of users, conditions of use, composition of the final product. The choice of specific risk mitigations measures should therefore be deferred to product authorisation stage when all the details of the products to be placed on the market are available. The objective of the Annex I inclusion should thus be to identify general risk mitigation measures, which can apply to all products, as well as specific risks/hazards to be addressed at product authorisation.
- The conditions under which a Member State during Mutual Recognition could adopt different risk mitigation measures to reflect for example a specific resistance pattern or the fact that it has a body of trained professionals, which could use products more safely, should be clarified in the context of the revision of the Directive.
- The case of 2nd generation anticoagulant substances might have to be reviewed again after Annex I inclusion as some of these substances are candidates for the

process of comparative assessment. This can however only be performed after all alternatives have been evaluated and products assessed, as only then sufficient knowledge of whether the alternatives pose significantly less risk to health or to the environment will be available.

- In view of such a review, it would be useful for data to be made available from Member States and industry on resistance development, pets and wildlife incidences and occurrence of residues of anticoagulants in the wildlife.

Risk mitigation measures for anticoagulants used as rodenticides

Anticoagulants used as rodenticides are highly toxic substances. They are also non-selective, and can pose a high risk of primary and secondary poisoning to non-target animals and children. Operator safety may also be at risk if unattended. In addition, resistance to some of these substances has been reported. Last but not least, many of these substances are also classified as PBT¹ substances.

A number of suggestions to mitigate these risks are listed below.

Category of users

It was proposed to restrict the use of the anticoagulants to professionals only.

The primary reason given is that the restriction to professional use only is necessary to ensure that appropriate measures are taken to avoid the development of widespread resistance to the anticoagulant. It is also expected that professionals will be more likely to apply a number of risk mitigation measures (e.g. proper and secure placing of baits, recovery of unused baits, collection and proper disposal of dead rodents, etc) thus limiting the risk of primary and secondary poisoning. In general, such a restriction would be intended to increase the safety of use of the product, especially when the anticoagulant is a PBT substance.

However, restricting the use of a given anticoagulant to professionals has also important drawbacks. It would in particular reduce the availability of these substances and consequently make amateur use more difficult, which may thus in turn hamper fight against rodents, mice in particular. In addition, if all current amateur uses of a given anticoagulant had in future to be only undertaken by professionals throughout the EU, the extensive infrastructure of professional pest management that such decision would make necessary does not yet exist.

Another recognised problem is linked to the interpretation of the term 'professional'. As indicated in the Emission scenario document for biocides used as Rodenticides ², this term is used in order to *emphasise that the general public is not allowed to use a certain substance*. It is however not *clear and distinct*. It only indicates that *'professionals' are assumed to have a minimum of knowledge of the substance they are handling by training or education whereas non-professionals (or the general public) are assumed to have little or no knowledge of the substances*. In the different countries the meaning of professional use may vary. For instance, the interpretation may be that the product is only to be used by pest control operators who have taken a special course on this matter. In some countries, caretakers, farmers or the staff of the pest control companies are considered professionals whereas other countries authorise professional users and some

¹ Persistent, Bioaccumulative and Toxic.

² Available at http://ecb.jrc.it/Documents/Biocides/ENVIRONMENTAL_EMISSION_SCENARIOS/PT_14_Rodenticides.pdf

compounds are allowed to be used only by professional firms, i.e. authorised/licensed people.

Besides, there is no evidence that the use of anticoagulants by amateurs has resulted in the development of resistance in rodents. In addition, other risk mitigation measures, such as restricted areas of use, detailed instructions for use, specific product design or limited pack size, are also very efficient to limit the potential risks of certain substances, thus allowing their sale to the general public.

It is important to note as well that the anticoagulant rodenticides products placed on the market would not be classified as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2, as the concentration of their active substances are much lower than the limits triggering such classification.

In conclusion, it does not appear proportionate, on the basis of current knowledge, to restrict all uses of a given anticoagulant substance to professionals only. In fact, in most cases, through a combination of appropriate risk mitigation measures, such as the ones described below, some products can be made available to the general public. Only, when no combination of these measures can adequately limit the risks linked to the use of anticoagulant rodenticides, should such use be restricted to professionals only.

In addition, to avoid possible diverging interpretations, when reference is made to 'professionals', the term is meant to cover pest control operators as well as farmers, whilst 'professionals trained to use the product' refers to pest control operators or to other professionals (e.g. farmers) having received an appropriate training. In addition, 'amateur use' clearly refers to users who are not professionals and are unlikely to have received any specific training in the use of anticoagulant rodenticides.

Lastly, regarding those anticoagulants, which are PBT substances, it is recognised that risk-mitigation measures must be taken, to limit the risk of secondary poisoning in particular. It is however difficult to identify at the level of the Annex I inclusion, which measures would be the most appropriate, as these would depend upon the design, pack size, area of use of the final product. Although appropriate risk mitigations measures must be taken, this can only be decided at product authorisation level. Thus, when appropriate, the following specific provision could be inserted for those PBT anticoagulants that will be included in Annex I of Directive 98/8/EC:

In view of the fact that the active substance is a PBT substance appropriate risk mitigation measures must be taken to protect the environment.

Area of use

Firstly, when the use of an anticoagulant presents such a risk of primary and secondary poisoning that the area of use must be as confined as much as possible, the authorised use could be limited to use in and around buildings³ or to indoor use only.

Specific provisions on the area of use could be combined with other provisions, in particular with those on the category of users and on the product design, to effectively limit the risk of primary or secondary poisoning. It may for instance be possible to restrict the outdoor use of a given anticoagulant to professionals only, whilst the amateur use of the same anticoagulant in a ready-to-use product may be restricted to indoor use.

Composition

Provisions on the composition of the product may also be useful to reduce the risk of primary and secondary poisoning.

As these substances are highly toxic, it is appropriate to indicate for the most potent ones, and certainly for the PBT ones, a maximum concentration, above which they can not be incorporated in products. Thus, when appropriate, the following specific provision could be inserted for those anticoagulants that will be included in Annex I of Directive 98/8/EC:

Products other than premixes for professional use shall not contain more than X % w/w of the active substance.

or

Products, which contain more than X % w/w of the active substance, shall only be placed on the market for use by professionals trained to use them.

Also, the inclusion of a bittering agent in formulations at appropriate concentrations may reduce accidental ingestion, from children in particular. Similarly, the inclusion of a blue dye renders the product unattractive to non-target animals like birds. Besides, in case of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

Therefore, anticoagulant substances should only be used in combination with a bittering agent and a dye and the following specific provision should be inserted for those anticoagulants that will be included in annex I of Directive 98/8/EC:

Products shall contain an aversive agent and a dye.

It is also recognised that the addition of aromas (e.g. vanilla, chocolate, hazelnut), certainly increase the risk of accidental ingestion by children, whilst the overall impact of such addition on the attractiveness of the bait for rodents remains to be demonstrated. Products shall therefore not contain additional aromas/flavours, which are attractive to humans.

³ 'In and around buildings' shall be understood as the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer system or ships but not in waste dumps or open areas such as farmlands, parks or golf courses.

Formulation

In certain circumstances, the formulation of the product (e.g. non-dusting formulation) may help to reduce the risk for the operator.

Similarly, when products are ready-to-use (i.e. when no further dilution or mixing is required), the risk for the operator would also be reduced.

Packaging

The packaging of the product also plays a role and can be used to reduce primary, as well as secondary, exposure of humans and non-target animals. For example, specific product design can make baits less accessible, in particular to birds, domestic animals as well as children, and can thus reduce the risk of exposure. Specific product design may also help to increase operator safety and thus better protect professional users from repeated exposure. Therefore, where appropriate, the placing on the market should be restricted to certain specific product design.

Although bait boxes are in most cases not a part of the packaging of the bait or product design but a device sold separately, they may nonetheless be useful to prevent access by other animals/humans. Again, where appropriate, the product information could include an instruction that the product may only be used in bait boxes. However, it is also recognised that there are many satisfactory ways to prevent access to bait by non-target animals and the use of tamper-resistant bait boxes is but one of them. Effective rodent pest management is facilitated when tamper-resistant bait boxes are unnecessary, for example in locked buildings, with no public access and no access to non-target animals, in wall and ceiling voids and in sewers. Also, the relatively high cost of these stations may deter users from placing adequate and enough baiting points, thus affecting treatment efficacy and duration.

Pack size

The size of the package placed on the market should be proportionate to the duration of the treatment and appropriate to the pattern of use of particular user groups.

The sale and/or supply of larger pack sizes should be restricted to professionals, whilst amateur users, who preferably should only control small rodent infestations in limited areas, should only be able to purchase small pack sizes. The latter would in particular apply to products against mice, in order to avoid their use against rats, when the efficacy against rats has not been demonstrated.

Labelling

Article 20(3) stipulates that biocidal products shall be labelled in accordance with the provisions of Directive 1999/45/EC⁴ relating to the classification, packaging and labelling of dangerous preparations.

However, Directive 1999/45/EEC may not allow a sufficient description of the special risks which may arise during the use of biocidal products, anticoagulant rodenticides in particular. Therefore, the standard phrases suggested below should allow a sufficient

⁴ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

description of the special risks, which may arise during the use of anticoagulant rodenticides, and the safety precautions, which should be taken⁵.

Thus, in addition to the elements already listed in Article 20(3), all packaging of anticoagulant rodenticides is to show the safety precautions for the protection of humans, animals or the environment, in the form of the following standard phrases:

- Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.
- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
- Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits⁶.
- Remove all baits after treatment and dispose of them in accordance with local requirements.
- Keep out of the reach of children.

This last safety precaution should always be carried on the label of the products, whilst the others could be carried out elsewhere on the packaging or on an accompanying leaflet together with the other directions for use and disposal of the product required by article 20(3) of Directive 98/8/EC.

In addition, for products to be used in public areas, when tamper-resistant bait stations are not used, the following safety precaution shall be carried on the label of the products or elsewhere on the packaging or accompanying leaflet:

- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Codes of Good Practices

Careful management of anticoagulant rodenticides is essential to minimise the opportunity of exposure to non-target species whilst maximising impact in target rodents.

⁵ This is by analogy to what has been done in the PPP area, where Commission Directive 2003/82/EC of 11 September 2003 amending Council Directive 91/414/EEC as regards standard phrases for special risks and safety precautions for plant-protection products establishes specific safety precautions for rodenticides. These are:

- The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.
- Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.
- Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.

⁶ This safety precaution would however not apply to products licensed for household use against mice; as it would otherwise make impossible the protection of empty houses against mice infestation.

Therefore, in addition to product labelling and instructions for use, several good practice documents and training courses are now available to professional users.

Appendix

Model Annex I entry for anticoagulant substances used as rodenticides

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions*
		EC No: CAS No:					14	<p>In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> (1) The nominal concentration of the active substance in products other than premixes for professional use shall not contain more than X mg/kg of the active substance. Or (as appropriate) Products, which nominal concentration of the active substance is more than X mg/kg, shall only be placed on the market for use by professionals trained to use them. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

* For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: <http://ec.europa.eu/comm/environment/biocides/index.htm> “