Justification for the renewal of the approvals for the anticoagulant rodenticides brodifacoum, bromadiolone, chlorophacinone, coumatetralyl, difenacoum, difethialone, flocoumafen and warfarin

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The UK Rodenticide Resistance Action Group (RRAG)

RRAG is a UK-based group consisting of representatives from Universities, government agencies and all sectors of the pest control industry, with expertise in rodenticide resistance. (http://www.bpca.org.uk/pages/index.cfm?page_id=53&title=rrag).

Current Steering Group:

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Trade Association Representatives:

Dee Ward-Thompson	BPCA
Iain Turner	NPTA

Opinion

It is the opinion of the UK Rodenticide Resistance Action Group that all currently-available anticoagulant rodenticide active substances are essential in the EU for the control of pest rodent infestations. It is the further opinion of the RRAG that the second-generation anticoagulants brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen are all essential in the fight to combat the increasing severity and spread of anticoagulant resistance in the UK, and more widely in Europe. In particular the three active substances, brodifacoum, difethialone and flocoumafen, that are known to be effective against all currently-known anticoagulant resistance mutations, in both Norway rats (*Rattus norvegicus*) and house mice (*Mus musculus*), are of paramount importance in the protection of human and animal health and well-being. None of the alternatives discussed below are sufficiently cost-effective to provide complete alternatives to the above-mentioned active substances

Discussion and supporting information

Rodent control is essential, and in many cases a legal requirement, to prevent disease transmission, consumption and contamination of food and feedingstuffs, structural damage and to remove social abhorrence. Currently, the anticoagulant rodenticides (also referred to as AVKs) are the dominant and most effective substances for rodent control. Therefore, the current AVK active substances approved for PT 14 will continue to be essential for efficient and effective rodent control in order to maintain good public hygiene and protect public health.

The original evaluations for first approval at EU level recognised the need of the AVKs. The corresponding Assessment Reports for the AVKs acknowledged this when they concluded that:

According to the Annex I inclusion criteria referred to in Article 10 of the Directive and TNsG on Annex I inclusion, AVKs should not be included in Annex I. However, in the decision making also benefits of using the active substance in the biocidal products have to be considered (Paragraph 96 in Annex VI of the Directive). It is concluded that AVKs are needed as rodenticides for human hygiene and public health reasons. In this exceptional case the benefit should take precedence over the risks and AVKs should be included in Annex I.

[The text above is a generalised extract based on the conclusions of the Assessment Reports of the AVKs]

All of the AVKs meet one of the exclusion criteria under Article 5(1) of the Biocidal Products Regulation (BPR), which prohibits their approval unless one or more of the derogations provided for in Article 5(2) are met. It is our conclusion that two of the derogation conditions are met, namely:

Art 5(2)(b) - it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment;

Art 5(2)(c) - not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

A comprehensive report from independent experts (Risk Mitigation Measures for Anticoagulant Rodenticides as Biocidal Products (RMM)), commissioned by DG Environment, has been published 'with the aim of identifying the best practice available and whenever possible to define a harmonised strategy at the EU level' which 'will certainly contribute to the responsible and sustainable use of anticoagulants rodenticides, reducing the risks posed to human health, animal health and the environment by these products.' The independent RMM report identifies the features of an ideal rodenticide and then concludes that 'It will be difficult to find a rodenticide that can meet more of the above features than the anticoagulant rodenticides' and also that 'alternatives to AVKs are limited today.'

Although there are a number of alternative chemical rodenticides approved under the BPR, none offer the utility and efficacy provided by the AVKs as acknowledged by the experts in the RMM report.

These are described below:

Alphachloralose

This substance is only used for mouse control indoors and is not approved for the control of rats.

Aluminium phosphide

This fumigant is used only by specially-trained professional pest control technicians. It cannot be used in proximity to buildings because it works by the evolution of a toxic gas which cannot be fully controlled when it has been produced. Although valuable in some circumstances, this property makes aluminium phosphide inappropriate for most rodent control situations in the built environment.

Hydrogen cyanide

Like the previous active substance, this is used only by specially-trained and equipped professionals as a fumigant in hermetically-closed structures.

Carbon dioxide

Once again, this substance is currently restricted for use only against mice indoors. It is dispensed using a special automatic application device which is appropriate only in limited practical use situations.

Powdered corn cob

In comparison with other PT 14 active substances, powdered corn is relatively new to the market. Practical experience of its use is limited and information from published literature on its efficacy is scarce.

As a result of these limitations, the vast majority of rodent control operations in the EU are conducted using the anticoagulant rodenticides, and will be so for the foreseeable future. The anticoagulants are widely used because they are generally efficacious, practical in use and, in comparison with the acute rodenticides that preceded them, have valuable safety characteristics.

There are some alternative techniques to anticoagulant rodenticides for the management of rodent infestations, although none of these are considered to be as cost-effective and efficient as the use of an efficacious rodenticide. These alternatives fall into two broad categories; those aimed at killing rodents (e.g. traps, glue-/sticky-boards) and those that aim to restrict either their population size (habitat modification) or access of populations to vulnerable areas (repellents and proofing/exclusion). They provide useful complementary techniques to the use of anticoagulant rodenticides for controlling rodents but are not considered to be replacements for them.

Rodent Trapping

Traps, either spring traps or break-back traps, designed to capture and kill rodents are useful in some circumstances. However, their effective and humane use requires a high degree of skill and when necessary they should be set in tunnels to avoid adverse impacts on non-target wildlife, pets and children. They may not kill cleanly and therefore should be checked daily so that animals captured, but not killed, may be humanely despatched. Such traps may be effective in situations

where infestations are small but are unlikely to be cost effective against large and dispersed rodent infestations. Live-capture traps have the advantage that, if they are checked frequently, captured non-target animals can be released unharmed. Some authorities recommend that these traps are checked twice daily. Captured target animals must be despatched humanely, because in some Member States it is illegal to translocate and release them. Once again, these traps may provide effective control of small infestations, particularly of mice.

Glue Boards

Glue- or sticky-boards are available in some countries but are illegal in other countries. They may provide effective control in some circumstances. Like traps, they may capture non-target animals and birds and must be checked at least twice daily. Untrained users of glue-traps are unlikely to know how to despatch humanely the rodents caught on the adhesive surface.

Habitat modification

Rodents require food, harbourage and, in the case of rats, water in order to establish troublesome infestations. Such infestations will either not establish at all, or will be limited in size, if any of these requirements is denied. Habitat modification alone will not control an existing infestation and may move an infestation elsewhere. It is often used as a preventative measure when control has been achieved using a chemical control method.

Repellents

There are currently no chemical repellents for rodent control approved under the Biocidal Products regulation. It is considered that there is no convincing scientific evidence to indicate that ultra sound and electromagnetic devices are effective.

Rodent Proofing

Preventing the access of rodents to vulnerable buildings by proofing is an important requirement in sustainable rodent control but it will not control an existing infestation. Proofing is particularly difficult to implement and maintain in respect of house mouse infestations.

In conclusion, very little has changed since February 2010 – when the last AVKs were included in Annex I of the Biocidal Products Directive – and July 2015 – the date of their renewal submissions under the BPR. The conclusions of the original assessments remain valid, and the continued lack of credible alternative active substances to control rodent pests and protect public health means that the AVKs continue to be essential for efficient and effective rodent control, as recognised by the experts in the RMM report.