

# Human health risk mitigation measures for anticoagulant rodenticide baits. Draft proposals for BPR product authorisation in the UK



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## 1. Introduction

Under the EU Biocidal Products Directive (BPD) the reviews of eight anticoagulant active substances have been completed under Product Type 14 (rodenticides). Difenacoum and difethialone are included on Annex 1 and coumatetralyl, warfarin, chlorophacinone, bromadiolone, brodifacoum and flocoumafen have been voted onto Annex I, with inclusion dates ranging from July 2011 to February 2012.

The use of products by both professionals and non-professionals (amateurs) was evaluated for all eight active substances. No unacceptable risks were identified following primary human exposure to either group. However, an unacceptable risk for infants ingesting bait was identified when secondary (bystander) human exposure scenarios were considered (EU, 2011). Despite the identified risk, Annex I inclusion has been granted for these substances because of their public health benefits.

Although all Member States agreed that the eight anticoagulant rodenticides require precautions when used, they did not agree on the risk mitigation measures to be taken. Consequently, a Risk Mitigation paper was agreed at the 24<sup>th</sup> CA meeting (EU, 2007) which distinguished between measures to be taken into account at EU-level through restrictions in the Annex I entry decision and **deferred** measures that can be taken into account during product authorisation at national level:

- All packaging of anticoagulant rodenticides is required to show safety precautions for the protection of humans, animals or the environment, in the form of standard phrases.
- Ready-to-use products shall not contain more than X% w/w of the active substance, or products which contain more than X mg/kg of the active substance shall only be placed on the market for use by professionals trained to use them.
- Products shall contain an aversive agent and where appropriate, a dye.
- Products shall not be used as a tracking powder.
- **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 package size and laying down obligations to use tamper resistant and secure bait boxes."**

## 2. Aim of this paper

As the use of non-anticoagulant rodenticides in the EU declines, anticoagulant baits are considered increasingly important in the UK's strategy for rodent control and the maintenance of public hygiene. The aim of this paper is to establish a transparent and consistent UK approach to the authorisation of anticoagulant rodenticide products in terms of the deferred risk mitigation measures listed in (4) above (i.e. restriction to professional use, an upper limit to pack sizes and restriction to bait station use). This approach needs to balance measures that protect infants from accidental poisoning with the potential public health issues that arise from lack of effective control of rodents.

NB This document does not address risk mitigation measures which might be proposed by the UK to protect **non-target animals and the environment**. Any such environmental risk mitigation measures, such as restrictions on outdoor use, will be in addition to the human health risk mitigation measures proposed here.

## 3. Bait stations, covered bait points and efficacy

In locations accessible to children and other bystanders, two approaches are routinely used to prevent secondary human exposure to baits:

a) placing baits in covered or protected bait points. In domestic premises bait trays should, for example, be placed behind heavy furniture or under kitchen units. Around buildings bait blocks or bait trays should be tethered inside or under materials found on site such as pieces of drainpipe, slate, board or corrugated iron.

b) placing baits in commercially available, tamper-resistant bait stations (either factory-filled or refillable). These are considered to give a higher level of protection to bait toxicity for bystanders than covered bait points.

There is evidence that commercially available bait stations may be less efficacious than covered bait points in controlling rats. In a recent study of Norway rats in the UK, approximately eight times less bait was consumed from plastic commercially available bait boxes than from covered wooden bait trays (Buckle & Prescott, 2011). There is no clear evidence that mice are less likely to feed from bait in manufactured bait stations than covered bait points.

HSE considers that for problematic infestations, particularly of rats, restricting baits to use in commercially available manufactured, prefilled bait stations may prolong the time taken to establish control over an infestation and increase the potential for anticoagulant resistance to develop and the potential for humans to be exposed to rodent-borne diseases.

#### **4. Professional and non-professional use**

All anticoagulant rodenticides are required to carry precautionary phrases on the label to mitigate the risk of secondary human exposure. These include:

- "Keep out of reach of children" and
- "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".

Anecdotal evidence and a behavioural study of non-professional users and professional users of non-agricultural pesticides (Edworthy et al, 2001) suggest that non-professional users are less likely than professionals to correctly interpret a set of safety instructions on product packaging, particularly if it is presented in an associated information sheet. Regarding the carrying out of safety instructions, there is evidence from an Australian study that incidents of children exposed to rodenticides tended to involve bait laid by non-professionals (Annex D). Incidents of children accessing bait laid by professionals, or accessing bait from the package were found to be less frequent.

#### **5. Bait pack sizes**

The Risk Mitigation paper discussed at the 24th CA meeting (EU, 2007) proposed that the size of a bait pack 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 UK view is that a **bait pack for sale to non-professionals** should be of a size **appropriate for controlling a single rodent infestation**.

## **6. Risks of human poisoning from secondary (bystander) exposure**

For each of the Annex I representative products, the outcome of the human health risk assessments was that in all cases the Acceptable Exposure Level (AEL) value was much smaller than the predicted exposure from accidental poisoning of infants (EU, 2011). Because the identified risks were all deemed to be similar, the UK CA does not consider it warranted to propose different human health risk mitigation measures for bait products due to differences in active substance.

Moreover, for the following reasons the EU risk assessments for the scenario of accidental poisoning in infants are considered relatively conservative.

- Acceptable Exposure Levels (AELs) were derived from short-term repeat dose studies such as teratogenicity studies, whereas the accidental poisoning scenario relates to a single exposure event. Anticoagulants are cleared relatively slowly from the body and AEL values derived from single exposure data are expected to be several times higher than AEL values derived from repeated dose studies.
- An extra assessment factor of either 3 or 10 was used in the derivation of the AEL values to reflect the severity of the effects caused by these substances (haemorrhaging leading to death).

The view that the risk factors are conservative is supported by incident data from the UK, Australia and the USA (Annexes C and D).

The Risk Mitigation paper discussed at the 24th CA meeting (EU, 2007) considered that the addition of aromas (e.g. vanilla, chocolate, hazelnut) are likely to increase the risk of accidental ingestion by children. However, given that the risk assessments for Annex I Inclusion are viewed as conservative, the UK CA considers it not warranted to include additional factors in the risk assessment of individual bait products to allow for the effects of sweet or pleasant aromas and flavourings.

## **7. Risk mitigation options**

In the following paragraphs a hierarchy of risk mitigation options is presented, with predicted implications for human exposure, efficacy and economic viability/cost of rodent control. The risk to the environment has not been considered for any of the options.

### **Option A – Restrict all use to professionals only**

**Bait placement could be in bait stations, covered bait points or uncovered in locations inaccessible to bystanders. Baits such as grain/granular/pellet baits to be supplied loose in packs with scoops/measuring devices for filling rat or mouse bait points**

*Human exposure:* This option is expected to provide a high degree of protection of human exposure to stored and laid bait, as professional users are expected to follow instructions on the product label regarding stored bait and security of bait points.

*Efficacy:* Expected to be high due to professionals being experienced in the selection and effective placing of baits.

*Cost of rodent control* The cost of controlling a small rodent infestation in domestic premises would be high if non-professional use products were removed from the market. Also, a proportion of householders would be likely to call in pest controllers later rather than sooner, and this would be likely to result in an infestation being more difficult to treat.

*Overall:* This option provides a high degree of protection, but at high cost. However if all current non-professional uses of anticoagulants had to be undertaken by professionals, rodent control would be adversely affected at least in the short term, as there would be insufficient professional pest controllers.

Options B, C, D, E and F are proposed for non-professionals, with the level of protection against human exposure decreasing from B to F.

### **Option B – Non-professional baits to be supplied and used in factory-filled (non-refillable) tamper-resistant bait stations.**

*Human exposure:* High protection from exposure to laid bait and stored bait, as children and users could only come into contact with bait if it is dislodged from the bait station (e.g. by shaking or following partial consumption by rodents).

*Efficacy:* For problematic rat infestations efficacy may be low due to the aversive effect of commercial bait stations. In addition, loose baits such as grain and pellet baits may be less attractive to rodents as they would need to be held in the bait station in the form of a sachet or packet.

*Cost of rodent control:* High cost option, as manufacturers pass on the cost of including a single use bait station with each bait pack to non-professional users. The economic viability of non-

professional factory-filled rat bait stations is questionable as the bait stations are larger, therefore more costly to produce. Individual product packs would either be suitable for mice or for rats, but not both.

*Overall:* This option provides a high degree of protection but the costs involved may make this option non-viable, especially for rat control.

**Option C – Non-professional baits to be used in refillable tamper-resistant bait stations and supplied as inner packs or units, each containing bait for one bait point (either rat or mouse).**

Inner packs or units could be:

- Sachets of grain/granules/pellets to be cut/torn open by the user and emptied into a bait point
- Wax blocks
- Place packs or sachets of grain/granules/pellets/paste bait (either perforated or non-perforated), to be laid intact at the bait point
- Bait-filled "TV dinner" type trays with removable film lids

Bait could be supplied in a pack containing multiple inner packs or units, subject to the maximum pack restriction. In the event of children accessing stored bait it is considered less likely that the child would access more than one inner pack or unit, therefore exposures would be limited. This option would also minimise user exposure as the user is not required to weigh/measure the quantity of bait, and would help ensure that non-professional users apply the correct amount of bait for the target species.

*Human exposure:* High protection from exposure to laid bait, intermediate protection from exposure to stored bait.

*Efficacy:* For problematic rat infestations may be low due to the aversive effect of commercial bait stations.

*Cost of rodent control:* Moderate. Non-professionals would be required to buy bait stations and bait in small pre-measured units (such as sachets) rather than loose in tubs or boxes. An individual product pack would either be suitable for mice or for rats, but not both.

*Overall:* Provides protection from exposure to stored and laid bait and economically a better option than B.

**Option D - Non-professional baits to be used in refillable tamper-resistant bait stations, and supplied loose in refill packs.**

This differs from option C in that bait in a bait station refill pack will not be prepacked into amounts for use in single bait points.

*Human exposure:* High protection from exposure to laid bait, lower protection from exposure to stored bait.

*Efficacy:* For problematic rat infestations may be low due to the aversive effect of commercial bait stations.

*Cost:* Moderate. Non-professionals would be required to buy bait stations. Less costly than option C as loose bait is cheaper than prepacked in small packs. However, unlike options B, C and E, individual product packs could be suitable for both mice and rats.

*Overall:* Although the protection from laid bait and cost implications are similar to C, provides a lower degree of protection to stored bait.

**Option E – Non-professional baits to be used in covered bait points, with bait to be supplied as inner packs or units, each containing bait for one bait point (either rat or mouse) (as in option C)**

*Human exposure:* Low protection from exposure to laid bait, intermediate protection from exposure to stored bait.

*Efficacy:* Generally high.

*Cost:* Low. Non-professionals would not be required to buy bait stations. An individual product pack would either be suitable for mice or for rats, but not both.

*Overall:* Offers some protection from laid and stored bait. Good in terms of efficacy and cost.

**Option F – Non-professional baits to be used in covered bait points, with bait to be supplied in bulk packs**

*Human exposure:* Low protection from exposure to laid bait, low protection from exposure to stored bait.

*Efficacy:* Generally high.

*Cost:* Low. Non-professionals would not be required to buy bait stations. Less costly than option E as loose bait is cheaper than in small packs. Unlike options B, C, and E, individual product packs could be suitable for both mice and rats.

*Overall:* Offers the lowest overall protection against bait exposure, and is the lowest cost option.

## **8. Proposals for comment**

a) In summary, the BPD risk assessments for anticoagulants identified a concern for accidental poisoning of infants. These risk assessments are considered conservative, and case reports have shown that when accidental child poisonings do occur they are associated with good recovery rates and no deaths. From a purely technical perspective, Options A, B and C provide the highest degree of protection for humans (in particular infants) from the toxic hazards of rodenticide baits. However there are public hygiene and socioeconomic considerations which require a less stringent control regime be considered.

b) It is central to UK policy for rodent control that professionals continue to use anticoagulant bait products against mice and rats. On the basis of evidence that professional users understand and carry out the label instructions for biocidal products, it is proposed that, subject to any other conditions on the Annex I listing, professional users should be allowed to continue to use their experience and training to store and apply a rodenticide bait securely and safely. Therefore it is proposed that **professionals** should be able to buy packs of loose bait and be able to apply bait in **tamper-resistant bait stations, covered bait points** or in locations inaccessible to bystanders **uncovered** (for example in open trays in sewers). This represents a continuation of the current UK policy for professional use under COPR.

c) HSE considers it appropriate that **non-professionals** should be able to continue to buy and use bait products for **mice or rats**. If mouse control were to become completely reliant on professional operators then this could cause a delay in treatment of household infestations due to cost and so increase the associated risks to public hygiene.

In comparison it is recognised that rat infestations can be more difficult to control and more destructive, and HSE considers that the mainstay of rat control should be professional. However it is considered that the limited use of rat products by non-professionals may be advantageous e.g. for controlling one or two rats in a garden shed. Regarding human health risk mitigation measures for non-professional products, as rat bait points contain more bait than



mouse bait points (typically 20 to 200 g for rats compared to 3 to 40 g bait for mice), secondary human exposure is potentially greater for bait laid for rats than for mice. Therefore different options are recommended for non-professional rat and mouse bait products.

d) **For non-professional use against mice**, it is proposed that products provide a level of protection equivalent to or greater than **Option E**. The requirement for bait to be included in factory-filled inner packs or units containing a fixed bait amount would reduce the likelihood of a non-professional applying more than the required amount of bait. Limiting the pack sizes according to the duration of the treatment and appropriate to the use pattern should also reduce the likelihood of misuse. In combination with other measures, such as clear label instructions, this measure is intended to make mouse products simple for non-professionals to use.

e) **For non-professional use against rats**, it is proposed that products provide a level of protection equivalent to or greater than **Option C**. In view of the potentially high exposure from rat bait points and the view that non-professionals may not always site bait in inaccessible locations, a key risk mitigation measure should be a restriction to tamper-resistant bait stations. Although this option may be associated with an increase in product costs, it may encourage householders to involve pest controllers when finding a rat infestation, particularly a larger one.

f) Regarding **pack size**, on the assumption that rodents consume at most 20% of their body weight per day it can be estimated that during a 15 day treatment of a moderately sized infestation of twenty mice (body weight 20 g) 1.2 kg bait would be consumed. Similarly during a 15 day treatment of a very small infestation of two rats (body weight 250 g) 1.5 kg bait would be consumed. These estimates are similar in magnitude to those reported for controlling small/medium mouse and rat infestations in anticoagulant baits field trials. Therefore it is proposed that **individual packs for non-professional use should not exceed 1.5 kg**.

Chemicals Regulation Directorate,  
Health and Safety Executive  
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## Annex A. Approval of rodenticide products in the UK: experience under COPR

As shown in Table 1, under COPR 385 rodenticide products have been Approved for use in the UK for use against rats and/or mice. 34% have been Approved for professional use only, 29% for non-professional use only and 37% for both non-professional and professional use.

**Table 1. Rodenticide products approved under COPR.**

Active substance	Number of non-professional products approved	Number of professional products approved
<b>FIRST GENERATION ANTICOAGULANTS</b>		
Warfarin	0	13
Coumatetralyl	2	5
Chlorophacinone	0	4
<b>SECOND GENERATION ANTICOAGULANTS</b>		
Difenacoum	123*	106*
Bromadiolone	102	98
Brodifacoum	18	38
Flocoumafen	0	3
Difethialone	0	0
<b>OTHER RODENTICIDE ACTIVE SUBSTANCES</b>		
Carbon dioxide*	0	2
Alpha chloralose	5	3
Powdered corn cob	6	3

\*Products in transition between COPR and BPR

### Current COPR policy regarding usage area for rodenticide approval under COPR

1. Mandatory risk mitigation measures for rodenticides approved under COPR include:

- precautionary phrases on product labels
- the inclusion of a warning dye
- the inclusion of the aversive agent denatonium benzoate.

2. For coumatetralyl, warfarin, chlorophacinone, difenacoum and bromadiolone products have been approved for application in either covered bait points, refillable bait stations and factory filled bait stations, although the latter are not the norm for COPR Approved products based on these active substances. Maximum bait pack sizes are 10 kg for non-professional products and 25 kg for professional products, and there is no requirement for inner packs.

Overall, the policy for coumatetralyl, warfarin, chlorophacinone, difenacoum and bromadiolone under COPR corresponds to option F for both rats and mice.

3. For brodifacoum and flocoumafen current UK policy is that:

- Non-professional use products are restricted to factory-filled bait stations containing at most 22 g of bait, for use against mice only.
- Professional use products are Approved for use against rats and/or mice, for application in bait trays, covered bait points and bait stations as well as in the form of a contact gel. The maximum pack size for professional brodifacoum products is 25 kg.
- No products (either non-professional or professional) have been Approved for outdoor use, due to environmental concerns.

Overall the policy for brodifacoum and flocoumafen under COPR corresponds to option A for rats and option B for mice.

4. Difethialone has not been assessed under COPR and no products have been Approved.

### **Annex B. Usage of Rodenticides in the UK: experience under COPR**

There are some statistics on the usage of rodenticides by professional users in Great Britain from 10 to 15 years ago. Since these surveys no new active substances have appeared on the market, but some non-anticoagulant actives have disappeared from the market (notably zinc phosphide, sodium cyanide, calciferol and cholecalciferol). It is expected that since these surveys were carried out, the proportion of second generation anticoagulants used will have increased due to the spread of resistance to first generation anticoagulants.

Information on rodenticide usage by professional pest controllers working for local authorities in Britain is available for 2001 (Dawson & Garthwaite, 2004). The most commonly used actives were bromadiolone (38%) and difenacoum (37%) followed by brodifacoum (11%) and warfarin (8%). 68% of bait was applied in commercial bait stations with bait also being applied in home-made bait stations (18%) under tiles (8%), in sewer benches (2%), on bait trays (1%), in holes (1%) and in the open (1%).

In a survey of rodenticide usage in British arable farms during 2000 (Dawson et al, 2003), 89% of the 766 farms sampled reported using rodenticides to control rats and/or mice. In 81% of cases bait was applied by farmers themselves, rather than by contractors (19%). The most heavily used active substances were difenacoum (38%) and bromadiolone (33%), followed by chlorophacinone (11%), brodifacoum (4%) and coumatetralyl (4%).

In a survey of rodenticide usage in British farms growing grassland and fodder crops during 1997 (Garthwaite et al, 1999), 82% of the 869 farms sampled reported using rodenticides to control rats and/or mice. In 83% of cases bait was applied by farmers themselves, rather than

by contractors (17%). The most heavily used active substances were difenacoum (45%) and bromadiolone (26%), followed by coumatetralyl (6%) and chlorophacinone (4%).

HSE is not aware of statistics on the current usage of rodenticide in the UK by non-professionals.

### **Annex C. Incident data on child poisonings from the UK**

Between 2004 and 2007 259 cases of children (aged < or = 12 years) being exposed to rodenticide products were reported to the National Poisons Information Service in the UK (Adams et al, 2009).

- In 119 cases exposure occurred after application of the product (e.g. after laying bait).
- In two cases medical teams found blood clotting time to be elevated.
- There were no deaths and no children were admitted to intensive care or had significant complications.
- The most common active substances implicated were bromadiolone (94 cases) and difenacoum (60 cases).

This study supports the view that although there has been widespread use of anticoagulant baits in the UK over the last 25 years by both non-professionals and professionals, incidents of accidental child poisoning are relatively rare and when they have occurred have been associated with a benign outcome.

### **Annex D. Incident data on child poisoning from outside the EU**

There is some information from outside the EU on the circumstances and outcome of accidental ingestion of rodenticide baits by children.

Incidents of accidental rodenticide exposure in the USA are routinely collated by Poison Control Centers (EPA, 1999). In a survey from 1993 to 1996, 48691 cases of unintentional residential exposure to anticoagulant rodenticides were reported for the under 6 age group; this figure represented 93.8% of the cases for all ages. Of these 48691 cases, 683 (1.4%) were symptomatic; in approximately 0.3% of cases the clotting time was prolonged and in approximately 0.1% of cases bleeding was reported. In 66% of symptomatic cases the baits were based on brodifacoum, the most widely used rodenticide in the USA. It is unclear whether baits in these incidents contained bittering agents or warning dyes as these are not compulsory in the USA.

This survey supports a view that while serious human health consequences of anticoagulant rodenticide ingestion may follow deliberate and repeated suicide attempts by adults, most cases of accidental ingestion of anticoagulant rodenticides occur in childhood and result in a benign outcome (EPA, 2006; Katona & Wason, 1989; Ingels et al, 2002).

In the 1990s an Australian survey investigated the circumstances of 115 cases of accidental ingestion of rodenticides by children (Parsons et al, 1996). In 9 cases (8%) the child accessed the rodenticide from the package, whereas in 103 cases (90%) the child obtained the rodenticide from the site of placement. The person responsible for placing the rodenticide was more likely to be the child's carer (77 cases i.e. 67%) than a professional pest controller (9 cases i.e. 8%). In 71 cases (69%), the parent or guardian thought the site of placement was unlikely to be accessed by the child. This study provides some evidence that non-professional users of rodenticide baits are less able than professional pest controllers to assess whether a bait location is inaccessible to children.

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