ENVIRONMENTAL RISK MITIGATION MEASURES FOR SECOND GENERATION ANTICOAGULANT RODENTICIDES PROPOSED BY THE UK

Contents

1. Background

Anticoagulant rodenticides form the mainstay of chemical control of rodents within the EU. Under the EU Biocidal Products Directive (BPD) five second generation anticoagulant rodenticide (SGARs) active substances (brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen) have recently been reviewed under the EU review programme.

For each of these 5 SGAR active substances, it was agreed that they should be included on the Annex I "positive list", despite risks identified to humans, non-target animals and the environment, because of the public health benefits of their use and the lack of alternatives which are equally effective and carry less risk to the environment and humans.

The final decision regarding how and where SGARs could be used within individual EU Member States was delegated to the Member States themselves. It was agreed that:

> *"Member States will be able to make restrictions at the product authorisation stage on the use of rodenticides containing any of the 2nd generation anticoagulants, which can go further than the risk mitigation measures explicitly set out in Annex I of Directive 98/8/EC. Such measures could include specific restrictions on outdoor use, or even a ban on such use, if such restrictions appear appropriate for sound scientific reasons."*

As UK Competent Authority for biocides, HSE has carried out a risk assessment for the environmental effects of the five SGARs based on the Annex I risk assessments from the EU reviews (which considered use in and around buildings (EU, 2012)) and on data collected by the UK. This assessment (see accompanying document: HSE, 2012a) led to the following conclusions:

- Data on the SGAR active substances indicate that brodifacoum is the most persistent in the environment and has the highest innate toxicity to birds and mammals; difethialone and flocoumafen have a higher innate toxicity than either bromadiolone or difenacoum;

- All of the PEC/PNEC ratios[1] for primary[2] poisoning are greater than one, indicating unacceptable levels of risk, however it is not possible to rank the five SGARs in terms of risk;

- All of the PEC/PNEC ratios for secondary[3] poisoning are greater than one, indicating unacceptable levels of risk, however it is not possible to rank the five SGARs in terms of risk;

- With regard to the secondary poisoning risk to birds, predator feeding studies have been submitted which indicate that, depending on the feeding profile, all SGARs can cause mortality and sub-lethal effects. However, these risks were not considered quantitatively in the EU reviews. Luttik *et al* (1999) reviewed several of the studies and stated that ‘little can be deduced from these feeding studies about the relative toxicity of the compounds to barn owls, even when they are included in the same experiment’;

[1] PEC = predicted environmental concentration; PNEC = predicted no effect concentration. If the resulting ratio is greater than 1 then further refinement or risk mitigation are required to ensure that the risk is ‘acceptable’.
[2] Primary poisoning in this instance refers to the consumption of the bait itself.
[3] Secondary poisoning in this instance refers to the consumption of treated rats, mice and other rodents by predatory or scavenging birds and mammals.

- Limited UK data on the use of flocoumafen and brodifacoum outdoors are available (Appendix 5), which indicate that incidents of poisoning of non-target organisms can occur. In 1987, the UK's independent Advisory Committee on Pesticides (ACP) recommended that the use of products containing these active substances should be limited to indoor use only (ACP, 1987) under our national biocides and pesticides legislation, the Control of Pesticides Regulations (COPR). No equivalent data are available for either difethialone, bromadiolone or difenacoum;

- Data from the UK's Predatory Bird Monitoring Scheme (PBMS) indicate residues of the SGARs are found in a wide range of species, as well as in a large proportion of predatory birds. The source of the residues is unknown and the toxicological significance of the residues is not fully understood;

- Data from the UK's Wildlife Incident Investigation Scheme (WIIS) indicate that incidents involving four out of the five SGARs do occur[4]. The identified causes of these incidents range from correct use, abuse and misuse, whilst the causes of other incidents have not been identified. See Appendix 4 for further consideration of WIIS data. There are also concerns regarding under-reporting (Luttik et al, 1999; EFSA, 2009);

The accompanying UK environmental risk assessment (HSE, 2012a) concluded that as the PEC/PNEC ratios for use in and around buildings are greater than 1 on the basis of the available data, no 'safe use' can be identified for products containing second generation anticoagulant active substances. However, as PEC/PNEC ratios only provide an indication of whether the exposure can exceed the 'no effect concentration', they should not be interpreted as meaning that all of the active substances pose the same risk in terms of likelihood and frequency of impacts.

In order to rank these active substances in terms of potential impact, further information is necessary, for example on the metabolism of the active substance, excretion rates and binding strengths, as well as ecological data on predatory/scavenging birds and mammals. Field trial data would also be needed to provide an indication of whether the predicted risks are realised under field conditions and the likelihood and frequency of impacts. It is not proposed to request such information, however, in the absence of these data, it is not possible to accurately rank these active substances in terms of potential risk.

In view of the need to control infestations of commensal rodents for public health and the protection of infrastructure, and the importance of having efficacious rodenticides to achieve this, it is recognised that options might need to be considered which provide less than the maximum protection for non-target species and the environment, particularly where there are concerns for public health.

As the PEC/PNEC ratios are greater than one for all of the SGAR active substances, it is necessary to consider the role of risk mitigation measures and in particular the likely impact they will have on reducing the risks.

2. Aims and outcome

This document and the associated document (HSE, 2012a) discuss the risk of accidental poisoning of non-target wildlife by SGARs, the environmental risk mitigation measures identified in the EU risk mitigation document (EU, 2007) and the effect they have on reducing environmental risks. They propose a number of ways forward which the UK could

[4] No incidents have been reported for difethialone; as products containing this active substance have only been authorised in the UK since 2011, and for indoor use only.

adopt for SGAR product authorisation taking into account issues such as the need to control populations of resistant rodents and maintain public hygiene.

Please note that this document does *not* address risk mitigation measures to prevent the accidental poisoning of humans, which have been discussed in a separate document and stakeholder consultation (HSE, 2011a).

The two documents form the basis of a UK stakeholder engagement on environmental risk mitigation measures for SGARs. To this end they will be circulated to organisations representing the following stakeholders and interested parties, for dissemination and comment:

- rodenticide bait manufacturers
- organisations representing pest controllers in the private and public sectors
- organisations representing gamekeepers and farmers
- nature conservation and wildlife organisations

In addition the documents will be made available for comment via the HSE website.

Comments are invited via the Stakeholder Response Form word document associated with this document. All comments should be received by **2nd November 2012**.

A summary of the responses received will be made available shortly afterwards. Based on the responses there may be a need for further stakeholder engagement, and/or more targeted discussion.

The ultimate outcome of the process is to establish criteria for HSE as UK Competent Authority for the Biocidal Products Regulations and Biocidal Products (Northern Ireland) Regulations (BPR/BPRNI)[5] to assign risk mitigation measures for SGARs at product authorisation. Such risk mitigation measures would be specified as Conditions of Authorisation relating to use, to be communicated to SGAR users on product labels.

3. Risk mitigation measures

The European Commission outlined a range of possible risk mitigation measures to be considered by Member States in a European Commission Working Document (EU, 2007). These measures are considered below.

In considering the relevance of a risk mitigation measure, it is necessary to judge whether it will reduce the risk adequately and appropriately. From an environmental perspective, for a use to be considered acceptable under normal circumstances, the PEC/PNEC ratio should be 1 or less. If it is greater than 1, then risk mitigation measures can be used to reduce the risk, either qualitatively or quantitatively[6], so that the ratio is reduced to 1 or less. If this is not possible, then the decision to authorise a product and its associated use should be based on a risk benefit analysis.

[5] The EU Biocidal Products Directive (Directive 98/8) (BPD) is implemented in the UK by the Biocidal Products Regulations and Biocidal Products (Northern Ireland) Regulations. The BPD and BPR/BPRNI will be superseded by the EU Biocidal Products Regulations in 2013.

[6] Risk mitigation measures are measures that reduce the risk to acceptable levels whilst still ensuring the product can be used appropriately. A risk mitigation measure can reduce the risk quantitatively – for example, if a particular baiting technique was known to reduce the exposure to such a level that it no longer posed a risk (i.e. PEC/PNEC = 1 or less). Risk mitigation measures (for example – cleaning up dead/dying rodents, limiting use to certain areas, users etc.) can reduce the risk from a qualitative perspective, i.e. the effect cannot be quantitatively factored into the PEC/PNEC calculation, however the overall outcome is that the risk is 'acceptable'.

Some of the risk mitigation measures are set out below, together with an indication as to how, either qualitatively or quantitatively, they may reduce the risk.

3.1 Restriction of user type

Biocides legislation makes a distinction between users who are professionals and those who are non-professionals (i.e. amateurs)[7].

On the subject of restricting the user type of rodenticides as a risk mitigation measure, the Commission Risk Mitigation paper (EU, 2007) states:
"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.
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."

In accordance with the EU decision that individual EU Member States could set criteria for how and where SGARs could be used within their territory, some EU Member States have already adopted policies whereby anticoagulant rodenticides are restricted to professional users only.

HSE comments

HSE considers that the first sentence in the above section of the EU Risk Mitigation paper is supported by anecdotal evidence and a behavioural study of non-professional and professional users of non-agricultural pesticides (Edworthy et al, 2001). In this study it was

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[7] The EU Technical Notes for Guidance for Human Exposure (EU, 2008) considers professional users of biocidal products to be *"those coming into contact with a biocidal product as a consequence of their professional life. In general the professional user is subject to national worker protection legislation and has residual risk controlled through control measures, which although a last line of defence, may include the use of Personal Protective Equipment. However, some workers will have limited knowledge and skills to handle hazardous biocidal products – particularly if the use of biocidal products is not routinely required in their workplace (e.g. incidental use of slimicides, insecticides, irregular disinfection and use of products containing preservatives). The exposure conditions of these users might be similar to those of non-professional users. There are also specialised professional users, who will probably have expert knowledge and skill in handling hazardous biocidal products and their pattern of use will show greater frequency and/or duration of use (e.g. pest control operators)."*

In the EU Technical Notes for Guidance non-professional users are considered as *"consumers, i.e. a member of the general public who may primarily be exposed to biocides by using a consumer product. The consumer is unlikely to take informed measures to control exposure and to follow exactly the instructions for using the biocidal product. In addition, the non-professional pattern of use is expected to show a lower frequency and/or duration of use."*

In the UK professional users of biocidal products are considered to be those individuals who are required to use biocides as part of their work and who have received appropriate information, instruction and training. There is no requirement for formal accreditation.

shown that non-professional users were less likely than professionals to interpret correctly and carry out a set of safety instructions on product packaging, particularly if it was presented in an associated information sheet. HSE therefore agrees with the EU Risk Mitigation paper that non-professional users are less likely to properly implement risk mitigation measures than professionals.

However it is expected that environmental exposure following non-professional use of baits in the UK is a relatively minor proportion of overall environmental exposure, as non-professional control of rodents in the UK is focussed on the control of mice inside domestic premises, with baiting treatments against rats being limited.

Regarding practicability, prohibiting all non-professional use of SGARs would require a clear, enforceable definition of professional users to be communicated to all concerned.

There is recent evidence that, due to financial considerations and a reduction in local authority pest control budgets, householders with domestic rat infestations are increasingly likely to attempt rat control themselves rather than commission a professional pest controller (Sheffield City Council, 2011). It is therefore anticipated that if baits were not available to non-professionals, financial considerations would cause householders to delay action against rodent infestations or use ineffective treatments and so increase the risk to public hygiene.

Overall HSE agrees with the Commission risk mitigation paper (EU, 2007) and considers that while professional users should continue to form the mainstay of rodent control, it is not appropriate for the UK to prohibit all non-professional use of SGARs. There is further discussion of possible restrictions of non-professional use of SGARs in the following section (3.2).

3.2 Restriction of outdoor situation of use

The EU working group developing environmental emission scenarios identified four situations of rodenticide use for the purposes of environmental risk assessment in a guidance document (EU, 2003):

- sewerage systems
- in and around buildings
- open areas
- waste dumps/landfills

According to sections 2.3.4 and 2.4.4 of EU, 2003 secondary poisoning hazards are not relevant when the rodenticide is used in sewerage systems or in fully enclosed spaces where rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Further information on the scenarios and the expected primary and secondary poisoning hazard in the Emission Scenario Document is provided in Appendix 5.

The Commission Risk Mitigation paper (EU, 2007) proposes restricting situation of use as a risk mitigation measure and states:
"*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 in and around buildings*"[8].

[8] The EU Risk Mitigation Paper (EU, 2007) states "'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."

Five options are considered further below which represent a broad spectrum of options for restricting the area of use of SGARs in the UK.

HSE comments

The UK agrees that the principle of restricting outdoor use of SGARs should be explored as a risk mitigation measure for minimising the risk of primary and secondary poisoning of non-target species. It is recognised that this may have significant effects on the use of SGARs in the UK; surveys of rodenticide use in Great Britain under COPR show that a substantial proportion of rodenticide baits used by professionals are used in outdoor situations, either around buildings or away from buildings[9].

In the following section five options for restricting outdoor use of SGARs are described. An option of allowing unrestricted outdoor use of SGARs (i.e. around buildings, open areas and waste dumps/landfills) has not been considered due to the outcomes of the environmental risk assessments.

In discussing these options, it is important to consider the need to control infestations of commensal rodents for public health and protection of infrastructure, and the importance of efficacious rodenticides in this policy[10].

In discussing these options, some of the benefits and limitations of each option have been identified, although the list should not be taken as exhaustive.

Option 1 - Restrict SGAR use to indoors (including sewers)

One option is for SGAR use by both professionals and non-professionals to be restricted to indoor use only. If the UK were to adopt this option, then it is proposed that the definition of "indoor use" which has been applied to COPR rodenticide products be adopted, i.e.

"Situations where the bait is placed within a building or other enclosed structure and where the target is living or feeding predominantly within that building or structure; and behind closed doors. If rodents living outside a building can move freely to where the bait is laid within the building, such as bait in open barns or buildings and tamper-resistant bait stations placed in open areas, this is not classified as indoors. However, sewers or closed drains are considered to be 'indoor situations".'

Benefits

- Provides a high level of protection for non-target species, as it minimises the risk of primary and secondary poisoning.
- Decision making is transparent and consistent for all SGARs.
- The borderline between indoor and outdoor use is relatively easy for users and enforcement authorities to interpret.

Limitations

- This option would reduce the range of rodenticide active substances available for outdoor use. Currently, the SGAR active substances bromadiolone and difenacoum can be used outdoors in the UK (Appendix 2). Alternative chemical rodenticides (i.e. those that are

[9]Between 38% and 46% of bait is laid indoors or in sewers, between 34% and 49% of bait is laid outdoors around buildings and between 13% and 21% of bait is laid outdoors away from buildings. Further information is presented in Appendix 2.

not SGARs) which can be used outdoors are listed in Appendix 3, together with an indication of some of their limitations.

- Resistance to first generation anticoagulants has been reported in some areas of the country. Restriction of all SGARs to indoor use only would remove the ability to use effective anticoagulants against resistant populations in outdoor locations around buildings and waste dumps/landfill sites, with potential consequences for public hygiene.

Discussion

- The risk assessments in the Annex I assessment reports indicate that for all SGARs, the PEC/PNEC values are considerably greater than one and therefore indicate unacceptable environmental risks.
- Available field trial data for flocoumafen and brodifacoum indicate the potential for effects to be realised in the field. No equivalent field data have been submitted for the other SGAR active substances.
- Predatory bird studies are available for all five SGARs and these indicate that mortality can result following exposure to any of them.
- It can be argued that SGARs could be restricted to use indoors and in sewers, until additional data are made available to indicate that the risk in practice is lower than predicted from the PEC/PNEC values.

If this option was selected, the impact on rodent control would need to be considered in detail to fully appreciate its wider implications.

Option 2 - Restrict SGAR use to in and around buildings and sewers

A second alternative would be to limit the use of SGAR active substances to “in and around buildings”. It will be necessary to formulate a workable definition of use ‘in and around buildings’. While a current UK definition exists for “indoors” (see option 1), no similar definition has been agreed for “around buildings”.

Any such definition should be clear enough to allow users to understand where they can or cannot use a particular product, flexible enough as to not unduly restrict how and where a product can be used, but above all, the definition must be legally enforceable.

Factors which could be considered when proposing a definition include:

- That the infestation must be connected to a building
- That the infestation must be affecting the building, its occupants or contents
- Where the infestation is living and/or feeding
- Where treatments can take place
- How far from a building can an infestation be before it is not considered associated with the building

It is important that any definition arrived at cannot be interpreted in a way which would allow unrestricted ‘outdoor’ use, for example use in open areas.

The following definition is proposed:

“This product can be used to treat rodents in and around buildings where:

- ‘in buildings’ is as applied to rodenticides under COPR (see option 1)
- ‘around buildings’ is defined as *"where a rat population is living and/or feeding predominantly within 5 m of a building or other enclosed structure, and is having a significant impact on the building or its occupants. Bait stations or covered bait points should be placed around the perimeter of the building, and burrow baiting is permitted providing that it is within 5 m of the building. Baiting should not take place along hedgerows or in woodlands."*

Benefits

- Provides a wide range of SGARs for control of rodent infestations in and around buildings
- Decision making is transparent and consistent for all SGARs
- Concerns have been raised over some rodenticide uses away from buildings (such as on waste dumps/landfills and in game bird rearing areas) as a potential major route of contamination of non-target small mammals and predators. This option would remove the currently permitted use of bromadiolone and difenacoum in open areas, and would therefore decrease the exposure of non-target organisms in these areas of concern.
- Resistance to difenacoum and bromadiolone has been recorded in certain areas of the UK. It has been argued that limited outdoor use of flocoumafen, brodifacoum and difethialone may allow these populations to be better controlled. In addition, it has been argued that targeted use of flocoumafen, brodifacoum and difethialone may pose a lower overall environmental risk than the continued outdoor use of ineffective products containing either bromadiolone or difenacoum against resistant populations. How the use of these active substances outdoors would affect the overall risk to predatory/scavenging birds and mammals is uncertain.

Limitations

- This option would reduce the range of rodenticide active substances available for use in outdoor open areas and waste dumps/landfill sites, as bromadiolone and difenacoum were previously used outdoors with no such restrictions (Appendix 2). Alternative rodenticides and their limitations are summarised in Appendix 3. Overall it is feasible that with this option the ability to rapidly control rodent infestations in outdoor open areas and waste dumps/landfill sites could be hampered.
- The potential risk to non-target species from use of flocoumafen and brodifacoum will increase compared to the risk arising from their current use in the UK under COPR due to products containing these active substances currently being restricted to indoor use only. No field trial data are available on the potential impact of the use of difethialone in and around buildings, but the available ecotoxicological data suggest that the impact on non-target species could be in line with other SGARs.

Discussion

Rodent infestations in and around buildings can have significant implications for public health and the protection of infrastructure. Changing the restrictions on use to allow outdoor use around buildings for all SGARs will concentrate their use on those areas with the greatest apparent need for effective control of rodents. This option would attempt to balance the risks to non-target species with the benefits of effective SGAR use.

While this option does not provide the very high degree of environmental protection as Option 1 (in that access to the baits or to rodents which have consumed the bait is not restricted by the indoor situation), it does allow for chemical control of rodent populations living outdoors, including populations which are resistant to first generation anticoagulant rodenticides.

From an environmental point of view, restricting outdoor use to around buildings may reduce the risk to some non-target species of bird and non-target mammal, as some predatory birds (e.g. kestrels) tend not to forage or hunt around buildings; however other species (e.g. red kites and barn owls) will forage in close proximity of buildings.

The environmental impact ‘in and around buildings’ from the use of the 2 active substances currently permitted for use outdoors (bromadiolone and difenacoum) can be partly estimated from the available WIIS and PBMS data (Appendix 4) on the recorded incidents

following their use outdoors (Appendix 2). While the situation of use related to some of the incidents has not been determined, as well as some incidents being classified as misuse or abuse, it could be considered that the current level of incidents arising from correct use has previously been tolerated and could be considered to be an 'acceptable' level, given the benefits arising from the use of SGARs to control rodents.

If this option is accepted then the following should be noted:

- The risk assessments carried out as part of the EU review considered the 'in and around buildings' use scenario, and all of the resulting PEC/PNEC ratios were greater than 1.
- The exposure estimates in this use scenario, in terms of residues in treated rodents as well as the amount consumed by predatory/scavenging birds and mammals, are the same for 'in and around buildings' as it is for use in 'open areas'. The key difference between the two situations of use (i.e. in and around buildings and use in open areas) is the use of these areas by predatory/scavenging birds and mammals, i.e. whether one situation is used more by predatory/scavenging birds and mammals than the other.
- Without further data, it is not possible to predict the impact of this proposal in terms of likelihood or frequency of impacts on non-target species, or on the efficacy of rodent control. It involves both the restriction of use of difenacoum and bromadiolone from open area use, but permits the use of brodifacoum, flocoumafen and difethialone outdoors for the first time. As such, the availability of SGARs in open areas will be reduced, but the availability of different SGARs for use around buildings will be increased.

Option 3 – Restrict SGAR use to in and around buildings and sewers for professional users, and indoor use for non-professional users

This option is similar to Option 2, in that use of all 5 SGARs would be permitted in and around buildings (including use in sewers) by professional users, but use in open areas would not be permitted.

However, the use of SGARs by non-professional users would be restricted to indoor use only.

Benefits

These are the same as Option 2 for professional users.

For non-professional users, the indoor use only position might be more easily understood by non-professionals than a restriction of use to in and around buildings (as in Option 2). Additionally, as non-professional users are less likely to properly implement risk mitigation measures, this option limits the environmental risks arising from improper use by non-professional users**.**

Limitations

These are generally the same as Option 2, although an additional limitation would be the restriction of outdoor rat control by non-professionals to non-SGAR rodenticides. As HSE has no information on the extent of use of rodenticides by non-professionals, either indoors or outdoors in the UK, it is difficult to predict the impact of this part of the proposal on rat control or the overall risk to non-target species.

As the situations of use for professional (indoors and in and around buildings) and non-professional (indoors only) users would be different, there is potential for confusion among users and enforcement authorities.

Discussion

While there is a public hygiene “need” for rodenticide use around buildings, it is possible that non-professional users will find it difficult to distinguish between use around buildings from other outdoor use scenarios, such as open area use. Non-professional users comply less with risk mitigation measures to reduce the risk of the wildlife exposure (e.g. selection and use of appropriate bait boxes and stations, covered bait points or burrow-baiting, making frequent site visits, searching for rodent bodies and the removal and disposal of surplus bait).

Therefore one option is to restrict non-professional use of SGARs to indoor use only, but to permit professional use of SGARs in and around buildings and in sewer systems (as discussed under Option 2).

HSE has no data on the extent of outdoor use of SGARs by non-professionals in the UK, but it is thought that a substantial proportion of this use is for the control of mice inside domestic premises, which would continue under this option. However, the use of SGARs by householders to control rodents in domestic gardens and on compost heaps would not be permitted under this option. The extent to which this restriction would reduce the overall risk of primary and secondary poisoning of wildlife is not clear.

Option 4 - **Continue with the use areas/restrictions applied under COPR**

Under Great Britain's national legislation (COPR), difenacoum and bromadiolone were permitted for use both indoors and outdoors, while the environmental risks identified for brodifacoum and flocoumafen meant that these SGARs could only be used indoors.

When products containing difethialone were authorised in the UK, restrictions on use similar to those for brodifacoum and flocoumafen were applied.

If the precedent set under COPR is still viewed as appropriate, based on the overall dataset now available for all five SGARs, and on the basis of experience under COPR, one option would be to continue with the areas of use previously permitted for brodifacoum, flocoumafen, bromadiolone and difenacoum. On the basis of the information available on innate toxicity, it can be argued that difethialone should be treated in the same way as brodifacoum and flocoumafen.

Under this option, these areas of use would be continued.

Benefits

- Would maintain the current range of rodenticide active substances available for use outdoors, including locations around buildings, open areas and in waste dumps.
- The impact of this proposal on non-target species and public hygiene is known as this option presents a continuation of current UK policy.

Limitations

- Decision making less transparent than for other options as there is no rationale for treating these SGARs differently with regard to there potential risk to the environment.
- Reduces the potential range of SGARs available for outdoor use which has been raised as a significant concern particularly regarding the control of certain resistant rat populations.

Discussion

Since their introduction into the UK in 1975 and 1984 respectively, brodifacoum or flocoumafen products have been restricted to indoor use, except for a small number of time and location-limited outdoor approvals for experimental or emergency purposes. For flocoumafen and brodifacoum a range of studies were submitted to the UK ACP, including field studies. On the basis of the data provided, the ACP concluded that products containing these active substances posed an unacceptable risk to birds and mammals through primary and secondary poisoning. Although the view has been expressed that these field trials do not represent current best practice in rodent control and that most were conducted around farm buildings (hence not necessarily reflecting the full spectrum of where rodenticides could be used), they do indicate the potential impact that outdoor use of these rodenticides may have via both primary and secondary poisoning (ACP, 1987).

Since their introduction into the UK in 1975 and 1977 respectively, difenacoum and bromadiolone have been approved for UK use indoors, around buildings and in open areas. No field data were available to confirm whether the potential risks identified in the Annex I assessment reports are realised in practice.

For difethialone, no field trials are available to confirm whether the risks identified in the Annex I assessment report are realised in the field. A comparison of data on toxicity, metabolism, and persistence indicated that it was potentially similar to brodifacoum or flocoumafen.

Data on UK wildlife incidents from the WIIS scheme are presented in Appendix 4, which indicate that incidents have occurred with four of the SGARs. No incidents have been recorded with difethialone under WIIS as of June 2011, as products containing it were only granted authorisation in 2011. Whilst there may be issues regarding the exact classification of incidents into misuse or approved used etc, it is clear that the levels have been tolerated and hence could be deemed to be ‘acceptable’ given the need and hence benefit from the use of SGAR to control rats.

If this option is adopted, it is proposed that the uses of products containing SGARs are revisited in consultation with the rodenticide and pest control industry, in order to determine how difenacoum and bromadiolone products could be used while minimising the likely exposure of predatory/scavenging birds and mammals. The practicalities, appropriateness and adequacy of the risk mitigation measures should be considered fully to determine their likely impact on the risk. This process could result in a range of further risk mitigation measures and/or restrictions to ensure that the risk is kept as low as practically possible.

Option 5 – **For professional users continue the use areas/restrictions from COPR, for non-professional users restrict all SGARs to indoor use**

For professional users, this is the same as Option 4. For non-professional users, this is the same as the relevant part of Option 3.

Benefits and Limitations

The benefits and limitations discussed in the relevant sections of Options 3 and 4 also apply here.

- One possible limitation is a high potential for confusion among users and enforcement authorities.

Discussion

The discussions from the relevant sections of Options 3 and 4 also apply here.

3.2.1 Proposal for authorising SGARs to treat rodent populations in specific restricted outdoor locations

Recently concern has been raised by some local authorities and pest control operators over control failures believed to be due to rodenticide resistance. Each of the above five options proposes some restriction on the outdoor use of SGARs, and it is recognised that this might impair the control of some populations of rodents, with possible implications for public hygiene. Overall it is acknowledged that, whichever option is adopted, under certain circumstances there may be a strong justification to relax restrictions on the outdoor use of SGARs to treat problematic rodent infestations in specified location.

As a consequence, in 2011 the UK's ACP endorsed a procedure under COPR to permit the outdoor use of SGARs that are otherwise restricted to indoor use, notably brodifacoum and flocoumafen (HSE, 2011b). The first test of the new procedure, with 6 simultaneous applications, has identified significant problems, and a "lessons learned" exercise is being instigated with relevant interested parties. Nonetheless, it is still envisaged that such a procedure can developed; as COPR is in the process of being superseded, it is proposed that a similar procedure be set up under BPR/BPRNI to allow the use of SGARs to treat infestations at certain outdoor locations which would otherwise not be permitted. It is envisaged that this procedure would only be appropriate for controlling a small proportion of outdoor rodent infestations.

3.3 Restriction of bait formulation type and method of bait placement

3.3.1 Bait formulation type

The Commission's Risk Mitigation document (EU, 2007) makes reference to the role of bait formulation type and composition. These may affect the risk of primary poisoning in a number of ways:

- grain baits are thought to be relatively attractive to small mammals and certain birds (EU, 2003)
- in comparison wax block formulations may provide a lower risk of primary poisoning as they are thought to be relatively unattractive to birds and are relatively easily fixed to bait points, thus minimising the risk of bait transfer by rodents (Quy, 2001)
- the colour of a grain bait may affect its attractiveness to birds (EU, 2003)
- it is a requirement for anticoagulant rodenticides that a human taste deterrent, such as denatonium benzoate, is included in all baits. However the effect on the risk of primary and secondary poisoning of non-target species is not known.

HSE comments

While the use of certain formulation types, such as wax blocks, or specific bait colours, might reduce the potential for primary poisoning for some bird species under particular conditions, there is a lack of evidence that it would have an effect on primary poisoning of small mammals.

In addition, restricting the availability of different formulation types may impact negatively on the ability to control rodent infestations where the target rodents exhibit an aversion to certain bait formulations.

Therefore HSE does not propose any restrictions on particular bait formulation types or composition, as continuation of current UK policy.

3.3.2 Use of bait stations and covered/protected bait points

Regarding placement of baits, the Commission's Risk Mitigation paper (EU, 2007) proposed that *"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."*

HSE comments

Data obtained under the UK's PBMS provides evidence that SGAR residues transfer up the terrestrial food chain to non-target predatory/scavenging birds (notably barn owls, red kites and kestrels) and mammals. Residues in barn owls and kestrels in particular are thought to be due to predation on small live non-target mammals such as wood mice and voles, rather than predation on target rodents (rats or house mice). Therefore, reducing access to bait from non-target species such as wood mice and voles whilst at the same time maintaining adequate uptake of bait could play a role in minimising the risk of secondary poisoning of predators and scavengers, as well as minimising the risk of primary poisoning.

There is evidence that rats show aversion to consuming bait placed in manufactured plastic bait stations, compared with home-made bait stations (Buckle & Prescott, 2011; Quy 2010). However there is no evidence that small mammals such as mice and voles (Brakes & Smith, 2005) show aversion to consuming bait in a bait station, and it has been proposed that bait boxes may provide a refuge for small mammals, such that their use may inadvertently increase the secondary risk to predatory/scavenging birds as small mammals are a preferred food source for several of the species. No evidence is available to support this proposal.

Overall, although manufactured tamper-resistant bait boxes have an important role in preventing access of humans and other non-target species to bait, restricting all bait use to them may prolong the time taken to establish control over a rat infestation and increase the risk of primary and secondary poisoning of non-target species. Therefore HSE considers that users should be able to select from manufactured plastic bait stations, home-made bait boxes and covered bait points. The key issue is that bait should be placed in such a manner to ensure that non-target animals cannot gain access or access is restricted to a minimum. This represents a continuation of current UK policy.

It should be noted that this mitigation measure will potentially have some impact on secondary poisoning, i.e. if access to small rodents is prevented then the potential risk to birds that consume only small mammals (e.g. kestrels) should be reduced. The significance of bait boxes or bait placement in reducing the risk quantitatively is not known.

3.3.2 Use of burrow baiting

In a recent UK stakeholder engagement on human health risk mitigation measures, the British Pest Control Association (BPCA) raised the issue of burrow baiting: "It is widely accepted that the best means of avoiding bait shyness and improving the efficacy of

treatment is to deliver the rodenticide in a grain formulation directly to the burrow system of the rodent, providing all burrows are sealed after the treatment."

HSE comments

HSE agrees that in certain circumstances burrow baiting has been found to be an efficient method of bait placement, although the potential exists for bait to be spilled or pushed out of the burrow into the surrounding area, with the potential for primary poisoning. Therefore, subject to any restrictions in the outdoor situation of use (3.2) and where this technique is specifically named on the product label, it could be made a condition of use to revisit the site at specified intervals to monitor and if necessary clean up bait.

3.4 Restriction of maximum duration of baiting

In recent years there has been concern that the practices of permanent and proactive baiting (i.e. placing bait in areas where there isn't an active rodent infestation, with the intention of intercepting any immigrants into the area) may be contributing to the exposure of non-target species to SGARs. In particular there is concern that feeding of small non-target mammals such as voles and wood mice from permanent bait stations, contributes to the entry of SGARs into the food chain, and the presence of SGAR residues in predatory and scavenging birds.

In addition, there has been concern that permanent and proactive baiting can increase the pressure for populations of target rodents to development anticoagulant resistance. Guidance published by the UK Rodenticide Resistance Action Committee (RRAC, 2003) states "To avoid the development of resistance in susceptible rodent populations, do not use anticoagulant rodenticides as permanent baits routinely. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas."

In addition, guidance published by the pest control and rodenticide industries (BPCA, 2001; CRRU, 2012) states;
"*In most cases, any anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined and documented. If bait continues to be consumed without effect, a more potent anticoagulant should be considered. If bait take is poor, relative to the apparent size of the infestation, consideration should be given to re-siting the bait points and possibly changing to another bait base, as well as making other environment changes".*

HSE comments

In 2011 HSE engaged with stakeholders in the UK rodenticide and pest control sectors on the feasibility of making the 35-day recommended duration of baiting statutory in the UK, and thus bringing permanent baiting with SGARs to an end (HSE, 2011a).

Responders in the pest control industry provided the following justifications for permitting bait campaigns lasting longer than 35 days to continue:

- permanent baiting, particularly in the site perimeter, is often required under third party audited contracts between food processing/storage sites and pest controllers
- long-term baiting can control rodent reinfestation of a site, for example on a farm or where rats are entering an urban site from a break in a sewer awaiting repair
- long-term proactive baiting of locations such as food outlets and sewerage systems is reported to help prevent rodent infestations becoming well established
- longer-term baiting may be used to control an infestation of resistant rodents

Pest controllers responding to the consultation also expressed a view that rodent control should focus increasingly on integrated pest management approaches and where necessary reactive campaign baiting, rather than proactive permanent baiting. It was also proposed that any move to restrict permanent baiting should be accompanied by discussions with third party organisations setting and implementing audit standards in the food and farming industries.

In summary, it is considered that from the perspective of minimising the risk of exposure of wildlife and the pressure for the development of anticoagulant-resistant populations of target rodents**,** reactive bait campaigns of short duration, rather than permanent proactive baiting, represents best practice. However there are situations where baiting in excess of 35 days may be justified. Therefore it is proposed that the BPCA phrases:
"In most cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined and documented" be included on SGAR product labels (both professional and non-professional) after the EU Annex I phrase *"Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits".*

3.5 Specifying frequency of visiting bait points

It is agreed good practice for all users of SGARs to revisit bait points frequently in order to:

- Minimise primary risk – frequent visits should ensure that any bait that is split or dragged out of bait boxes is removed
- Minimise secondary risk – frequent visits should ensure that dead and dying rodents are removed and hence not consumed by predatory/scavenging birds and mammals.
- Monitor consumption of and if necessary replenish bait – if adequate levels of bait are maintained the efficacy of baiting will be maximised and the likelihood of target rodents consuming sub-lethal doses of bait reduced

In addition, it is accepted that good site management (i.e. cleaning up the site and removing refuges) is very important; however it is not known quantitatively how this could affect the risk/impact on non-target species.

Therefore it is a condition of Annex I inclusion that anticoagulant rodenticide products are labelled with the phrase:
"*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*".

However as "frequent intervals" is not defined, this could include visits separated by relatively long time intervals, which would potentially result in a high risk to non-target species. Therefore the option of setting a statutory minimum frequency for users to revisiting bait points should be explored.

The following issues are considered relevant:

A voluntary code for rodenticide use endorsed by the UK rodenticide and pest control industries states:
"*Never fail to inspect bait regularly. Where the risk assessment or treatment records show that multiple visits are required, then those should be made as frequently as is considered necessary. Daily inspection may be required in some circumstances"* (CRRU, 2012)

The "ideal" frequency of revisiting a bait point for a particular situation may depend on the target rodents; for a large infestation of mice feeding lightly from a number of sources, the

first revisit would be expected to be sooner than for a small infestation of Norway rats showing extreme neophobic behaviour.

Guidance on best practice for rat control (CSL, 2002) states:

- *"During anticoagulant treatments, some or all of the rats may ignore the bait completely or eat it without hesitation. During the first week of baiting, at least two visits may be required to see how the rats are reacting.*
- *If the rate of bait uptake is slow and control is not urgently required, a visit once a week thereafter may be sufficient to check that the baits are still fresh, search for dead rats and ensure that other animals have not found the bait.*
- *If bait uptake is rapid, the first rat dead or dying of anticoagulant poisoning may appear after about 4 days and then others in the population may succumb over the following days and continue doing so for several days after the last take of bait. While rats often die underground, many do not and thus a search for bodies must be carried out and any carcasses found should be disposed of safely to prevent predators and scavengers eating them. Hence, during the first 2 weeks, 5 or more visits may be necessary not only to maintain a constant supply of bait, but also to recover dead or dying rats. If all is well and bait take and rat signs are clearly decreasing, 1-2 visits per week may suffice thereafter, unless there are concerns about the safety of the baits, in which case extra visits should be made"*.

HSE comments

In 2011 HSE consulted with rodenticide suppliers and users on the feasibility of agreeing a minimum frequency of anticoagulant bait revisiting (HSE, 2011a). HSE proposed that the first follow up should be no later than 7 days after the initial application, and subsequent follow up visits should be no more than 14 days apart.

Responders in the pest control industry raised the following concerns with this proposal:

- there would be an increase in costs associated with more frequent visits of professional pest controllers, which would be passed on to the client. It was suggesting that cost increases would encourage clients to treat rodent infestations themselves, rather than engage a pest controller
- pest controllers treating domestic infestations may be unable to gain access to clients' properties at specified revisiting dates. No information was provided on potential issues accessing bait points in commercial premises and farms
- the pattern and frequency of revisits may vary with the method of baiting; for a pulsed baiting campaign with flocoumafen or brodifacoum the dosing schedule will be different from a saturation baiting campaign with difenacoum or bromadiolone.

Overall is recognised that due to variations in baiting practices and rodent behaviour as well as the practicalities of SGAR baiting in domestic, industrial, urban and rural settings it is not appropriate to set a compulsory minimum bait revisiting frequency which holds for all SGAR baits in all situations of use.

In summary, it is considered that from the perspective of ensuring that dead and dying rodents are not available to predators and scavengers daily revisiting represents best practice. However it is appreciated that this is not always feasible. Therefore HSE proposes that the CRRU code phrase *"Daily inspection may be required in some cases*" should be included on all SGAR product labels after the EU Annex I phrase *"Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished"*. Users should also comply with any instructions on revisiting bait specified for a particular SGAR product on the label.

4. Conclusions and proposed way forward for product authorisation under BPR/BPRNI

In summary, the BPD risk assessments for the five SGARs identified a very high concern for primary and secondary poisoning of non-target species via the terrestrial food chain.

Based on the available data HSE has concluded that it is not possible to clearly rank the active substances in terms of risk and, as such, there is an argument that all five SGARs should be treated in the same way.

As the PEC/PNEC ratios for the exposure scenarios for all 5 SGARs are greater than one, it is necessary to consider the role of risk mitigation measures and in particular the likely impact they will have on reducing the risk. It is also important to recognise the need to control infestations of commensal rodents (including resistant populations) for reasons of public health and the protection of infrastructure, and that options might therefore need to be considered which provide less than the maximum protection for non-target species and the environment to allow this public health goal to be achieved.

An assessment of the effectiveness of different rat baiting strategies on UK farms (Cowan, Quy and Lambert, 2003) concluded:
"New rodenticides are unlikely to be developed in the foreseeable future that will alleviate all public concerns about humaneness and non-target effects. In the meantime, current formulations will continue to be used until either resistance in the target species or restrictions on their use lead to product withdrawal. A more strategic application of rodenticides, along with other measures, has been suggested that takes account of the potential mobility of rats and the ability of populations to recover when resources are seemingly unlimited. If effective, the strategy should minimise re-application of rodenticides once established populations are brought under control, given that lowland agricultural environments in the UK will always be habitable by Norway rats. This should retain the effectiveness of rodenticides whilst also minimising potential adverse environmental consequences of their use".

Against this background, and based on the discussions detailed within this document, a number of conclusions have been drawn as a proposed way forward in the UK:

4.1 Restriction of user type

A case can be made from a public health viewpoint that non-professionals should be able to continue to use rodenticide baits for the control of mouse infestations and small rat infestations. Therefore HSE does not propose a "blanket restriction" on user type, and considers that where appropriate SGARs should be available to trained professional, non-specialised professional and non-professional users. It is considered that trade associations and other stakeholder organisations have an important role in increasing competence and understanding of non-specialised professional and non-professional users.

4.2 Restriction of outdoor situation of use

Since insufficient information is available to robustly rank baits based on the five SGARs for potency, and some outdoor use needs to be retained for reasons of maintaining public and animal hygiene, HSE proposes a preferred option whereby SGAR use is restricted to in and around buildings and in sewers (Option 2 in section 2.2). It is considered that this option would:

- help to address concerns that open area use of difenacoum and bromadiolone under COPR is a major contributor to the residues of those actives seen in wildlife carcasses
- permit SGARs (including those previously restricted to indoor use under COPR) to be used outdoors in a restricted and targeted way, i.e. in the situation of use where there is a high public hygiene "need", enabling the rapid control of resistant rodent populations
- allow householders to continue to bait for rodents in domestic gardens, a use which is considered unlikely to result in substantial exposure of wildlife.

4.3 Restriction of bait formulation type and method of bait placement

In order to maintain a wide range of bait types of bait types available for rodent control, HSE does not propose "across the board" restrictions on formulation type, composition.

Regarding bait placement it is proposed that the following phrases[11] are included on the labels of all SGAR bait products to ensure that non-target animals cannot gain access or access is restricted to a minimum:
"Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)
For use in areas that are inaccessible to infants, children, companion animals and non-target animals"

For a particular product users should comply with any specific instructions in the use of manufactured bait stations, home-made bait boxes, covered bait points and burrow baiting.

4.4 Restriction of maximum duration of baiting

In order to help minimise the risks of wildlife exposure and the pressure for the development of resistant populations of target rodents**,** it is proposed that the phrases
"In most cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined and documented"
be included on all SGAR product labels following the EU Annex I phrase
"Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits".

4.5 Frequency of revisiting bait points

Due to variations in baiting practices, rodent behaviour and the demands of baiting in different settings it is not considered appropriate to set a statutory minimum frequency for revisiting all SGAR bait points. However it is proposed that the phrase
"*Daily inspection may be required in some cases"*
should be included on all SGAR product labels following the EU Annex I phrase
"Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished".

For a particular product users should comply with any specific instructions on the frequency of revisiting bait points to replenish bait and/or collect rodent bodies.

[11] These are in addition to the EU Annex I phrase "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. "

5. Determining success

It is proposed that to help evaluate the success of the above proposed measures for mitigating the risk to non-target species, the PBMS and WIIS could be used, subject to satisfactory arrangements being made for the future funding of these schemes. For example, if the chosen proposal did reduce exposure to predatory/scavenging birds then it might be detected by a decrease in the number of birds containing SGAR residues as well as the actual concentrations found in individual birds. In carrying out this assessment consideration would need to be made for the recent improvements regarding the level of detection of SGAR residues in tissue.

The following sources could be monitored to provide some information on the maintenance of public health and rodent control:

- recorded cases of rodent borne infections such as leptospirosis[12]
- mouse and rat infestations in and around domestic properties recorded by the English House Condition Survey[13].

Chemicals Regulation Directorate
Health and Safety Executive
August 2012

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[12] Leptospirosis is reportable under RIDDOR and approximately 50 - 100 cases are confirmed in the UK each year by the Public Health Laboratory

[13] In 2007 2.07% of sampled occupied dwellings in England had mice inside; 3.04% had rats in the garden and 0.37% had rats inside.

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7. Abbreviations

ACP – Advisory Committee on Pesticides
BPCA - British Pest Control Association
BPD - Biocidal Products Directive
BPR/BPRNI – Biocidal Products Regulations and Biocidal Products (Northern Ireland) Regulations
COPR – Control of Pesticides Regulations
CRRU – Campaign for Responsible Rodenticide Use
PBMS – Predatory Bird Monitoring Scheme
PEC - Predicted Environmental Concentration
PNEC = Predicted No Effect Concentration
SGAR – Second Generation Anticoagulant Rodenticide
WIIS – Wildlife Incident Investigation Scheme

Appendix 1. Approval and use of rodenticide products in Great Britain: experience under COPR

Under COPR 385 rodenticide products were approved for use in Great Britain against rats and/or mice. 34% were 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 products approved for non-professional (amateur) use	Number of products approved for professional use
First generation anticoagulants		
Warfarin	0	13
Coumatetralyl	2	5
Chlorophacinone	0	4
Second generation anticoagulants		
Difenacoum	123	106
Bromadiolone	102	98
Brodifacoum	18	38
Flocoumafen	0	3
Difethialone	0	0
Other active substances		
Carbon dioxide*	0	2
Alpha chloralose	5	3
Powdered corn cob	6	3

The policy for approving SGAR products under COPR has been that:

1. Brodifacoum and flocoumafen products (both professional and non-professional) may only be approved for use indoors (including in sewers)
2. Difenacoum and bromadiolone products (both professional and non-professional) may be approved for use indoors, around buildings, in open areas and in refuse dumps.
3. All SGAR products must carry the following label phrases in order to mitigate the risk to the environment:

- *Prevent access to bait*/gel*/dust* by children, birds and non-target animals particularly dogs, cats, pigs and poultry.*
- *Harmful to wildlife.*
- *Wild mammals and birds may be at greater risk if this product is not used in accordance with the label.*
- *[Non-professional products] Search for and remove rodent bodies at frequent* intervals during treatment. Collect and dispose of the remains of bait and any remaining rodent bodies after treatment. All waste should be double-bagged using bin liners or similar before disposal in a bin with a secure lid to prevent accidental poisoning of dogs, cats, birds, foxes and other wildlife or by contacting either a specialist contractor or the Local Authority where waste bins are not provided. Do not dispose of in any other way. (*Intervals will vary depending on product used; see manufacturer's guidelines).*
- *[Professional products] Search for and remove rodent bodies at frequent* intervals during treatment (unless used in sewers). Collect and dispose of the remains of bait and any remaining rodent bodies after treatment (unless used in sewers). You must ensure that you comply with legislation regarding the correct disposal of waste. For further guidance, contact the Environment Agency or your local Scottish Environment Protection Agency (SEPA) office. (*Intervals will vary depending on formulation and treatment regime; therefore the user should refer to and comply with the manufacturer's guidelines).*

Appendix 2. Professional use of rodenticides in Great Britain: experience under COPR

There are some statistics on the usage of rodenticides by professional users in Great Britain from 10 to 15 years ago. It is expected that since these surveys were carried out, the proportion of SGARs used will have increased. HSE is not aware of statistics on the usage of rodenticide in the UK by non-professionals.

Data on rodenticide usage by professional pest controllers working for local authorities in Britain are available for 2001 (Dawson & Garthwaite, 2004; Tables 2 and 3). 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; Table 4), 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%).

In a survey of rodenticide usage in British farms growing grassland and fodder crops during 1997 (Garthwaite et al, 1999; Table 5), 82% of the 869 farms sampled reported using rodenticides to controls rats and/or mice. In 83% of cases bait was applied by farmers themselves, rather than by contractors (17%).

Table 2. Local authority use of rodenticides in industrial and domestic situations in 2001.

	Situation of use			
	Indoors	Sewers	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	202,997	31636	173,155	105,568
All actives - % of total bait used indoors and outdoors	40	6	34	21
Individual actives - % of all bait used in situation of use				
Bromadiolone	25	7	36	36
Difenacoum	36	<1	40	51
Warfarin	6	9	8	8
Coumatetralyl	<1	1	2	3
Chlorophacinone	<1	0	12	<1
Brodifacoum	15	82		
Flocoumafen	2	23		
Powdered corn cob	<1		<1	<1

Total bait used indoors, outdoors and in sewers was 513,357 kg (Dawson & Garthwaite, 2004).

Table 3. Local authority use of rodenticides in agricultural situations in 2001.

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	39,834	35,355	21,263
All actives - % of total bait used indoors and	41	37	22

outdoors			
Individual actives - % of all bait used in situation of use			
Bromadiolone	57	68	55
Difenacoum	17	23	33
Warfarin	3	40	5
Coumatetralyl	<1	<1	<1
Chlorophacinone	4	3	5
Brodifacoum	14		
Flocoumafen	1		

Total bait used indoors and outdoors was 96,452 kg (Dawson & Garthwaite, 2004).

Table 4. All professional use of rodenticides on arable farms in 2000.

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	641,333	826,605	210,668
All actives - % of total bait used indoors and outdoors	38	49	13
Individual actives - % of all bait used in situation of use			
Bromadiolone	32	31	8
Difenacoum	35	39	16
Warfarin	<1	1	<1
Coumatetralyl	3	2	1
Chlorophacinone	24	33	74
Brodifacoum	<1		
Flocoumafen	<1		
Sodium cyanide		<1	<1
Aluminium phosphide		<1	<1

Total bait used indoors and outdoors was 1,678,607 kg (Dawson, Bankes & Garthwaite, 2003).

Table 5. All professional use of rodenticides on farms growing grassland and fodder crops in 1997.

	Situation of use		
	Indoors	Outdoors around buildings	Outdoors away from buildings
All actives - kg bait used	139,344	152,534	52,130
All actives - % of total bait used indoors and outdoors	40	44	15
Individual actives - % of all bait used in situation of use			
Bromadiolone	37	39	33
Difenacoum	41	42	23

Warfarin	2	2	<1
Coumatetralyl	2	1	<1
Chlorophacinone	12	15	43
Brodifacoum	1		
Flocoumafen	<1		
Sodium cyanide		<1	<1
Aluminium phosphide		<1	<1

Total bait used indoors and outdoors was 349,170 kg (Garthwaite, de'Ath & Thomas, 1999).

Appendix 3. Alternative rodenticide active substances to SGARs

Table 6. List of substances with comments and limitations

Active substance	Comments and limitations
First generation anticoagulants (warfarin, coumatetralyl, chlorophacinone)	In some areas of the UK rodent resistance to these agents is widespread.
Gassing agents (hydrogen cyanide, aluminium phosphide)	Only suitable for use by trained professionals in open areas. Poison antidotes not available.
Alphachloralose	Efficacy only demonstrated for indoor use against mice
Powdered corn cob	Efficacy yet to be demonstrated
Vitamin D agents (Calciferol, cholecalciferol)	Although efficacious not currently supported under BPD review programme, would require full assessment as a new active
Bromethalin	Not currently supported under BPD review programme, would require full assessment as a new active

Appendix 4. Summary of Wildlife Incident Investigation Scheme (WIIS) data on SGARs

Table 7. WIIS data from 1997 to June 2011, "group by" category search

Active substance	approved use	abuse	misuse	unspecified	Total	%
brodifacoum		5	8	11	24	9
bromadiolone	4	12	25	37	78	30
difenacoum	1	23	35	28	87	34
flocoumafen			2	1	3	1
mixture of rodenticides	1	1	32	32	66	26
Total	6	41	102	109	258	100
%	2	16	40	42		

Table 8. WIIS data from 1984 to date, (note some 2007 data missing)

Active substance	approved use	abuse	misuse	unspecified	Total	%
brodifacoum	10	6	21	20	57	14
bromadiolone	15	17	50	67	149	37
difenacoum	13	34	55	56	158	39
flocoumafen			2	1	3	1
mixture			18	19	37	9
Total	38	57	146	163	404	100
%	9	14	36	40		

These data have been obtained from the Food and Environment Research Agency. Table 7 is a summary of all the incidents assigned to the four SGAR from 1997 to 2011. This summary may include some "for information only" type incidents where there were no analyses carried out. It will not include any incidents attributed to other categories, where some very low level of anticoagulant residue was found and not considered to be linked to the cause of death. The "mixture of rodenticides" category may include mixtures of first and second generation rodenticides, although it is likely to be mainly second generation.

In Table 8 data from 1984 onwards is presented. In this dataset there may be some double counting in that an incident involving more than one rodenticide may be included twice. It should be noted that there are some incidents from 2007 missing from this dataset. In addition, there were at least 30 incidents with background anticoagulant residues, but many of these incidents will have been missed out from the data. However, the overall trends between the data are similar – although there are more "mixture of rodenticide" incidents in 1997 onwards data and less approved use incidents.

The categorisation of incidents in to approved, abuse, misuse and unspecified is difficult and there is sometime uncertainty in the classification, especially between misuse and approved use. It is also likely that the unspecified category consists of a mixture of misuse and approved use incidents. Despite the difficulty in confidently attributing each incident, it is clear that there have been several incidents involving all rodenticides.

In considering these data the concerns of Luttik *et al* (1999) and EFSA (2009) regarding the potential for under reporting should be noted.

Luttik *et al* (1999) compared a subset of these data covering the period 1985-96 with the usage over the same period. They concluded that there had been 8 incidents that were attributable to rodenticide poisoning over that period. These 8 incidents were considered to be due to the approved use, however due to the delayed toxicity of SGAR it is difficult to be specific about the source, therefore the 8 incidents considered in detail may have been due to misuse as well as approved use. The analysis by Luttik *et al* (1999) indicated that there were 4, 0.2, 0.2 and 0 incidents per 1000 tonne of bait for brodifacoum, bromadiolone, difenacoum and flocoumafen respectively. Caution is needed in interpreting these data as the number of incidents per active substance is small.

Appendix 5. Information on environmental exposure scenarios provided in the PT 14 Emission Scenario Document (EU, 2003)

Scenario	General comments	Primary poisoning hazard	Secondary poisoning hazard
2.3 Sewer system	The brown rat [Rattus norvegicus – Norway rat] is the only mammal that can live in sewers. Depending on the structure of the sewer and the food content in the sewers the rats may often or rarely move to the surface in search for food.	There is no primary poisoning hazard to mammals or birds because no other mammals (or birds) are living or occurring in sewers.	The secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. However, according to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.
2.4 In and around buildings	A 10 meter zone around the farm building is considered the most frequented zone for the rodents. Mice typically forage in the immediate vicinity and the rats make longer foraging trips outside the location along hedgerows and the like. Brown rats exhibit thigmotactic behaviour (i.e. contact with a vertical surface)	Regarding the possible primary hazard to non-target animals, only birds and mammals of the same size as the target rodents, i.e. rats and mice, may be able to enter the bait stations.	Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Predators among mammals and birds may occur inside buildings or they may hunt in the immediate vicinity of buildings, e.g. parks and gardens. Scavengers may also search for food close to buildings.
2.5 Open areas	This scenario covers control of rats and water voles in open areas such as around farmland, parks and golf courses where the aim is to prevent “nuisance” from burrows or “soil heaps” or due to public hygiene reasons. Rodenticides are also used to reduce impacts on game rearing or outside food stores (potato/sugar beet clams).	The bait may also attract other vertebrates and small birds. The situation in the open area scenarios is basically similar to what is mentioned for commensal rodents above regarding the risk of primary poisoning.	Secondary poisoning hazard may occur in the open area scenario but it is not assumed to be a problem after gassing. Predators among mammals and birds may occur in the immediate vicinity of buildings, e.g. parks and gardens or further away. When moving around the rats may be caught by raptors and scavengers may find dead rats.
2.6 Waste dumps/landfills	This scenario covers control of rats and disposal of rats in waste dumps and landfills where the exposure is assumed to be higher than that described in the open area scenario. In some instances, applications of rodenticides to refuse dumps take place. Mostly the use is limited to occasions of population outbreaks of rats. Often the rodenticides are deployed around the perimeter of the dump, more than in the disposal area itself.	Concerning the risk of primary poisoning the situation is regarded similar to that described above for vole control in the open areas.	The secondary poisoning hazard applies to predators among mammals and birds and scavengers and thus the situation is comparable to that described above for commensal rodents in the open areas; however, there might be more predators around a landfill than in the open areas e.g. seagulls, crows, etc.