UK ANTICOAGULANT RODENTICIDE PRODUCT AUTHORISATION AND THE CRRU STEWARDSHIP SCHEME

Information document, January 2015

PURPOSE OF THIS DOCUMENT

- 1. This document lays out HSE plans and timescales for the authorisation of second generation anticoagulant rodenticides (SGARs) in light of the development of a 'stewardship scheme' by suppliers and representatives of rodenticide users, coordinated by the Campaign for Responsible Rodenticide Use (CRRU), with a view to securing responsible use of these products.
- 2. The principle of developing a voluntary stewardship scheme has been agreed between HSE, Defra, and Public Health England, the devolved administrations, and Departments and Agencies with principle policy responsibilities for this area.
- 3. In order to meet our statutory obligations HSE is proceeding to authorise some rodenticide products on the basis set out in this paper. Stakeholders are welcome to provide views on this plan and the timescales. Although this document refers primarily to SGARs, we would envisage that the principles will also apply to first generation anticoagulant rodenticides (FGARs) since the issues being addressed are fundamentally the same.
- 4. The stewardship scheme being proposed by CRRU is the product of extensive discussions with the interested parties. HSE does however remain open to constructive input and suggestions for improvement.
- 5. This information paper has been circulated to inform key stakeholders of HSE's plan to authorise SGAR products under stewardship as developed by CRRU. Comments on HSE's approach or the proposed stewardship scheme will be considered at any time, but are in particular invited before the end of January 2015. Comments can be sent to chemicalsconsultation@hse.gsi.gov.uk.

SECTION 1

RODENT CONTROL AND ANTICOAGULANT RODENTICIDES

Summary

- 6. Chemical rodent poisons or 'rodenticides' are legally considered to be 'biocides' with active ingredients incorporated into 'biocidal products'. Important safeguards ensure that biocides can be used without causing significant harm to people, the environment, or non-target animals.
- 7. The EU Biocidal Products Regulation (BPR) sets the standards for assessment and authorisation of biocidal products. HSE is the UK Competent Authority for BPR and leads UK policy on biocides.
- 8. As Competent Authority HSE has a legal duty to authorise the supply/use of biocidal products (including rodenticides) only where risks can be managed or where the benefits of use outweigh the risks. If the risks are too great for example to the environment then HSE cannot legally authorise a product to be sold/used.

- 9. All 'anticoagulant' rodenticides fail environmental risk assessment for use outdoors in relation to primary and secondary poisoning. However, despite carrying greater risk than would normally be acceptable, outdoor use of anticoagulant rodenticides is sometimes necessary. Without anticoagulant rodenticides it would be very difficult to control many pest rodent populations.
- 10. In order for HSE to have the legal power to authorise rodenticides for use outdoors we must be assured that risks will be managed as effectively as possible and balanced with the need to control rodents.
- 11. In practical terms the risks associated with anticoagulant rodenticides may result more from how, rather than where, they are used.
- 12. Non-professional users (amateurs, e.g. householders) use smaller quantities of rodenticide. Thus, anticoagulant rodenticide products can be and are authorised for amateur use outdoors (around buildings only) subject to controls on pack size and other conditions to help control risk.
- 13. Professional outdoor use of anticoagulant rodenticides however is much more extensive and uses higher volumes. Some typical examples of professional use include pest control technicians; gamekeepers who use rodenticides at work; and use in the farming industry of rodenticides to protect food and infrastructure and prevent disease. In order for HSE to legally authorise anticoagulant rodenticide products for professional use outdoors, including in open areas, it is necessary for industry to demonstrate that such use will be safe and responsible.
- 14. In April 2013 HSE asked industry coordinated by the CRRU to explore ways to improve and spread good practice and self-police professional use of SGARs via an industry-led, voluntary 'stewardship' scheme.
- 15. Since then CRRU has been working with the industry to develop a stewardship proposal which will credibly lead to improved competence in SGAR use so that these products can be authorised for professional use outdoors. On the 19th September 2014 CRRU submitted their final updated proposals noting that the agriculture sector is not fully developed (see paragraphs 60-63).
- 16. HSE consider that, although some aspects require further work, the CRRU proposal is on the whole credible. HSE are therefore proceeding with authorisation of SGAR products for professional use outdoors.

Background: the need for anticoagulant rodenticides

- 17. Pest rodents can threaten public and animal health and infrastructure, for example in sewers, waste management, and urban environments. Controlling problem rodents is socially and economically important and is sometimes required by law e.g. for food hygiene.
- 18. The main three rodent species in the UK that come into conflict with humans are the house mouse and the brown and the black rats.
- 19. An important aspect of rodent control is the number of rodents which a particular area is able to support the 'carrying capacity' of that environment. Any given area will be able to support a given number of rats based on the availability of resources i.e. food, water and 'harbourage' (shelter).
- 20. Limiting access to any one of these resources reduces the carrying capacity, while increasing the availability of one resource increases the carrying capacity. For example if food is the limiting factor in an area then increasing the amount of food

available will increase the number of rats present up to the point where something else (a lack of water or harbourage) becomes the limiting factor.

- 21. Rodent species have a naturally very high breeding rate in theory, in ideal conditions, one breeding pair could result in 15,000 descendants within a year. Because of their exceptionally high breeding potential, in suitable conditions, a rodent population can very quickly breed back to the environment carrying capacity.
- 22. Ideally the way to fully combat an existing infestation is therefore to make the objective complete eradication, or to reduce populations to a more acceptable level, and to ensure the carrying capacity of the environment is minimised in order that other rodents do not simply move in to take advantage of the resources which become available.
- 23. The aim of any effective rodent control programme is therefore to discourage initial or repeat infestation by a range of measures to make the environment more hostile to rodents and less able to support them, and to eradicate any existing rodent infestation. This wide-ranging approach is known as Integrated Pest Management (IPM).
- 24. A wide range of rodent control measures exist to form a part of an IPM strategy. Each has advantages and disadvantages including effectiveness, suitability for different situations, relative humaneness, and risks to non-target animals or humans. A combination of methods is usually needed to prevent or effectively remove a rodent infestation.

Non-chemical rodent control

25. Protective measures to discourage infestation include (for example):

- proofing measures to exclude rodents from buildings (mesh over openings, metal kickboards on doors to discourage rats gnawing through them, barriers over drainpipes, etc.)
- making the environment less rodent friendly (clearing away ground cover to leave exposed areas around buildings, as rats avoid crossing open areas which leave them more open to predators), and
- removing sources of food, water and harbourage to reduce the carrying capacity of the environment.
- 26. Non-chemical methods to control an infestation include trapping ('breakback' traps, live capture traps, sticky traps), shooting, use of dogs and cats, etc.
- 27. Traps need to be checked regularly under animal welfare legislation both to release any non-target animals which may have been caught and to dispatch trapped target animals.
- 28. Shooting is self-evidently useful only for visible rats. The use of dogs and cats have limited effectiveness if rats are able to escape.
- 29. These methods are generally useful for small, isolated infestations. Pest controllers generally do not use these techniques for a large infestation because the resources needed to achieve acceptable control levels are very high, they are slow, and they cannot realistically achieve the same results as chemical control.

Chemical rodent control

- 30. Chemical control methods, including fumigants and baits, tend to require relatively less effort. Fumigants can be used against rats in certain situations and require a high level of competence and certification for purchase and use. If applied correctly, baits have the advantage that rather than having to seek out the target, the target seeks out the treatment.
- 31. Ideally, a rodenticide should possess a number of features, including that the onset of toxicity should be slow to avoid bait shyness, it should be lethal in normal amounts of food, it should be palatable to rodents and there should be no variation in susceptibility across ages, sex or strain. Products containing anticoagulant rodenticides can be formulated to meet these features but resistance to the active ingredient is a significant problem.
- 32. All anticoagulant rodenticide products rely on the same mode of action interfering with vitamin K metabolism to disrupt the blood clotting process. Some rats in a population will however have mutation(s) making them less susceptible to the effects of anticoagulant compounds. This confers a significant competitive advantage for survival of that portion of the rodent population where anticoagulant rodenticides are in use.
- 33. Because these rodents are more likely to survive exposure to the anticoagulant and pass on this resistance to their descendants, use of anticoagulant rodenticides effectively selects rodents with this mutation for survival and breeding. Their high breeding rate then enables the rodent population to rapidly become resistant to further treatment. This problem is exacerbated by use of anticoagulant rodenticides in large quantities or where they are not needed.

First Generation Anticoagulant Rodenticides (FGARs)

- 34. Warfarin was the first anticoagulant developed, quickly followed by chlorophacinone, diphacinone and coumatetralyl. These are the 'first generation anticoagulant rodenticides' (FGARs). In the early 60s massive use of FGARs was considered an opportunity to reduce or even eradicate rat populations from many areas.
- 35. FGAR resistance was first reported in Scotland in 1958 and was followed by similar reports elsewhere in Europe and the US. As FGAR resistance spread new, more powerful, anticoagulants were developed to deal with it the 'second generation' anticoagulant rodenticides (SGARs).

Second Generation Anticoagulant Rodenticides (SGARs)

- 36. There are large areas of the country with no recorded rodent resistance, where FGARs will work. There are also areas with FGAR resistance where SGARs will work.
- 37. Resistance to anticoagulant rodenticides has continued to develop. Some geographical areas now have rodent populations resistant both to FGARs and to the SGARs permitted for outdoor use (difenacoum and bromadiolone), leading to areas where chemical control with anticoagulant rodenticides is currently ineffective.
- 38. Use of three SGAR compounds brodifacoum, flocoumafen and difethialone has only been permitted indoors in the UK because of their relatively higher toxicity. The same high toxicity led to these compounds being marketed as 'single feed

rodenticides' as it is (theoretically) possible for a rodent to pick up a lethal dose in a single feed.

- 39. However, as they work through the same biological mechanism, the timescale for controlling an infestation is not particularly shorter for a SGAR than it is for a FGAR.
- 40. Greater use of SGARs makes it more likely that resistance will develop in time and so it is counterproductive to use SGARs where they are not entirely necessary or in an uncontrolled manner.

Amateur (non-professional) use of ARs

- 41. Although poisoned rodents may move in and out of buildings, indoor use of ARs carries relatively low risk to non-target species and the environment as its use is by its nature confined. Indoor use of anticoagulant rodenticides is generally permissible for both amateur and professionals.
- 42. A significant number of SGAR-containing products are currently authorised for amateur use both indoors and 'in and around buildings' (i.e. one of the outdoor use areas).
- 43. Such amateur use of anticoagulant rodenticide products in and around buildings carries lower risk than professional use as it is less extensive, uses relatively small quantities of AR-containing product in limited pack sizes with specific use conditions.
- 44. This allows the public to deal with small initial rodent infestations in a proportionate manner and so reduces risks to public health by preventing escalation of infestations and controlling rodent population size. It also means that the amateur user does not need to wait for the services of a professional pest controller and can deal with the infestation quickly and at minimal cost.
- 45. Therefore, in view of the relatively low environmental risk and for the reasons outlined above, HSE considers that authorisation of amateur use anticoagulant rodenticide products should be retained for 'in and around building' use without the need for stewardship.

Professional use of ARs

- 46. All outdoor use of anticoagulant rodenticide products (including 'in and around buildings') by professionals carries a significant risk that they will enter the wildlife food chain either when non-target animals consume poison directly ('primary' poisoning) or when predators take an animal which has done so ('secondary' poisoning).
- 47. It is not possible to prevent entirely either the movement of poisoned target rodents or access to poison by smaller non-target species (such as wood mice and voles) which are then taken by other wildlife. It is therefore not possible to eliminate risks to the environment resulting from outdoor use of SGARs. Although some professional outdoor use has been permitted in the past for some anticoagulant rodenticide products, modern scientific evaluation has concluded that anticoagulant rodenticides should not be used outdoors by professionals because of these environmental risks.
- 48. Recent evidence from monitoring of predatory birds and other sentinel species in some locations has shown increasing levels of SGARs in tissue samples, indicating that uptake in these species has already occurred and is increasing, providing supportive evidence of the risk assessment conclusions regarding frequent and high volume use of SGAR-containing products by professionals.

'Stewardship'

- 49. Without anticoagulant rodenticides it would be very difficult to control many rodent populations. Despite carrying greater risk than would normally be acceptable, outdoor use of SGAR-containing products by professionals is sometimes necessary as part of an integrated pest management programme. The pack-size limits and use conditions set on products supplied for amateur use, while minimising environmental risks, make them less useful for large-scale rodent control and minimising environmental risks.
- 50. In order for HSE to have the legal power to continue to authorise rodenticides for use outdoors (including in 'open spaces' away from buildings) we must be assured that risks will be managed as effectively as possible and balanced with the need to control rodents.
- 51. As an interim position HSE has been authorising sale of some SGAR-containing products for professional use 'in and around buildings' where exposure risks for non-target animals are thought to be lower, and because there are concerns about the impacts on public health due to uncontrolled rodent infestations.
- 52. A few older SGAR products are still available for professional use in open spaces/countryside in the UK but approval of these products will expire over the next few years and currently could not be renewed in light of the contemporary assessment of environmental risks. Currently no SGAR-containing products are authorised under BPR for outdoor professional use in waste dumps and open areas.
- 53. However, this position cannot be maintained long-term. It prevents use of SGARcontaining products in the open, and so restricts the ability of professionals such as farmers, gamekeepers, park rangers, and waste site operators to effectively control pest rodent populations.
- 54. In practical terms HSE consider that risks from primary and secondary poisoning associated with SGAR-containing product use arise more from <u>how</u> they are used (application methods, appropriate volumes, no long term use, used only where necessary, etc. and good practices for site management, carcase removal etc.) rather than <u>where</u> they are used. Where industry can demonstrate active 'stewardship' for safe and responsible professional use that controls the environmental risks, HSE can legally authorise SGAR products for use outdoors, including in open areas.
- 55. The demonstration of active stewardship for safe and responsible professional use of SGARs will be provided by industry-led monitoring, ranging from information on uptake of training, knowledge surveys, to the monitoring of SGAR residues in predatory birds. The monitoring results will be provided regularly to HSE. Should HSE not be assured that the risks of using SGARS are being managed and that alternative prevention and control methods for rodent infestation are being appropriately undertaken, Government will act accordingly, for example by increasing restrictions or revoking product authorisations.

The timetable for development and implementation of Stewardship

56. The need and demand for outdoor use of SGARs, coupled with concerns both about mounting anticoagulant rodenticide resistance and residues in wildlife, led HSE to ask industry in April 2013 to explore ways to improve and self-police SGARs via an industry-led, voluntary 'stewardship' scheme.

- 57. Since then HSE has been working with stakeholders, co-ordinated by the Campaign for Responsible Rodenticide Use (CRRU), to develop an industry-led stewardship proposal that will credibly lead to improved competence in SGAR use, so that SGAR products can continue to be authorised.
- 58. CRRU presented their first stewardship proposal to a government oversight group comprising interested Departments and Agencies in March 2014. CRRU were asked to revise their proposal to give greater detail on how they would change user behaviour and demonstrate commitment to responsible use and monitoring, which is essential in order to make informed decisions about the impact of continued outdoor professional use of anticoagulant rodenticides, and gauge the effectiveness, of the stewardship scheme in mitigating risks.
- 59. CRRU made a revised proposal in June 2014. The government oversight group agreed that the revised proposal, while improved, was still not sufficiently well-developed or wholly credible. The government oversight group asked CRRU to present an agreed and credible industry stewardship proposal by the end of July 2014.
- 60. On the 19th September, after further discussion with HSE, CRRU submitted their updated proposals noting that the proposal for the agriculture sector was not fully developed.

The agriculture sector

- 61. The agricultural sector needs to control rodents primarily for food hygiene but also to reduce food and feed spoilage and protect infrastructure, etc. Agricultural quality assurance schemes such as the 'Red Tractor' also often require a certain level of rodent control.
- 62. While the agriculture sector have participated in CRRU's work to develop stewardship, in July representatives from that sector expressed concern that the stewardship approach needs to be pragmatic or proportionate to the needs of farmers.
- 63. NFU have agreed to work with CRRU, supported by HSE, to propose a proportionate and pragmatic way in which users in the agriculture sector can gain demonstrable competence in use of anticoagulant rodenticides outdoors, in accordance with stewardship standards by February 2015. NFU have signalled that they expect quality assurance schemes will play a significant role in this.

Government views

- 64. The government oversight group consider that the CRRU proposal requires further work in order for the proposed stewardship scheme to offer the necessary assurance that user competence will improve and that risks to non-target animals will be addressed, particularly as regards the agriculture sector.
- 65. Nevertheless, in the view of government the CRRU proposal is fundamentally sound and demonstrates adequate commitment from industry. HSE are therefore able to proceed with authorisation of products, as described in the next section of this paper.
- 66. HSE will continue to work with CRRU to develop the stewardship concept as an effective and proportionate means to secure the necessary competence in professional use of anticoagulant rodenticides across industry.

67. At a late stage in the preparation of this Information Document the government announced that it would build on the 'Accountability for Regulator Impact' scheme by updating the guidance to cover government sponsored voluntary regulation. Working with other government departments HSE will consider and apply the guidance, when available, to SGAR stewardship as appropriate.

SECTION 2

HSE PLAN FOR SGAR PRODUCT AUTHORISATION UNDER STEWARDSHIP

- 68. HSE intend to authorise anticoagulant rodenticides for sale and professional use under the terms of the proposed industry stewardship scheme, adherence to which will be set as a condition of authorisation, including a requirement that labels bear the phrase 'For supply to and use only by professional users holding certification demonstrating that they have been trained according to the UK second generation anticoagulant rodenticide (SGAR) stewardship programme requirements.'
- 69. In practice this means that for those areas of use covered by stewardship the professional user will need evidence of their competence to use the product in order to purchase it and the supplier will need to confirm that the customer has provided this evidence prior to sale.
- 70. To introduce authorisation under stewardship, the timeline is as follows:

The aim is that all pending product authorisations currently with HSE will be completed by 31 January 2015 to enable the statutory deadlines to be met for these products where appropriate.

- 31 Jan 2015 From this date, any applications for new biocidal product authorisations, or to amend existing authorisations for SGARs can include outdoor use under stewardship with a clear indication of the intended use pattern: 'in and around buildings', 'waste dumps', 'open areas', or any combination of these. It should be noted that, although stewardship may enable authorisation to be granted to mitigate risks of primary and secondary poisoning, the application may still fail for other environmental compartments in these use scenarios.
- 1 June 2015 deadline for all existing authorisation holders to apply for outdoor use under stewardship. Note that this includes those currently granted authorisation for use 'in and around buildings'. Requests to extend existing authorisations to other outdoor areas under stewardship will not be granted if they fail the risk assessment for_other environmental compartments.
- 1 November 2015 deadline for ceasing making available on the market for those rodenticide products where existing authorisation holders have not applied for authorisation under stewardship for professional outdoor use by 1 June 2015
- 1 June 2016 deadline for ceasing use of anticoagulant rodenticide products for professional outdoor use where this has not been applied for under stewardship.

Authorisation plan

- 71. HSE must process the SGAR applications that have been on hold pending the development of stewardship proposals by 31 January 2015.
- 72. The authorisation process is not straightforward because applications for authorisation vary and products are progressing through transitional periods from being regulated via Control of Pesticides Regulation (COPR) approval, then Certificates of Exemption (CoE) and then Biocidal Products Directive/Regulation (BPD/R) authorisation, with the need to reflect phase out periods during transition.
- 73. Application of COPR to a given active substance is 'switched off' at the 'date of inclusion' of that active substance into the BPD/R framework.
- 74. Certificates of Exemption (CoEs) were required to bridge the gap between COPR 'switching off' and authorisation being issued under BPD. As long as HSE had received an application by the time of the date of approval of the active substance(s) under the BPD/BPR then a CoE has been issued permitting products previously approved under COPR to stay on the market.
- 75. If and when BPD/R authorisation is granted HSE will also grant a further 'phase out CoE' which allows for up to 180 days for supply and 365 days for use of the original product from the date of the BPD/R authorisation decision.
- 76. Currently there are some products authorised under BPR which may or may not still have corresponding products with valid phase out CoEs. Some products are still awaiting their BPR authorisation and will have CoEs. There are no longer any products approved under COPR.

Immediate authorisations

- 77. HSE will complete pending authorisations (for bromadiolone, brodifacoum and flocoumafen products) in advance of and without linking to stewardship, unless the applicant indicates that they wish to have stewardship conditions applied to their products at this time (a letter requesting confirmation of applicants' preferred option will be sent at the same time as the distribution of this paper). Note that if authorisation is granted without stewardship conditions then the expectation is that the applicant will need to apply for professional use under stewardship by the 1 June 2015 deadline, with appropriate fees applied, in order to retain their authorisation beyond that date.
- 78. This approach will mean that all applications <u>so far received</u> by HSE under BPD/R will have been treated in the same way without reference to stewardship. This is an important matter of regulatory consistency, and also allows finalisation of the outstanding UK-led applications.
- 79. In line with HSE's obligations to progress applications as swiftly as possible authorisations where the UK lead will be prioritised, followed by 'mutual recognition' authorisations, with the aim that <u>all</u> pending applications will be processed by the end of January 2015.
- 80. HSE has received the following applications for product authorisation under the Biocidal Products Directive/Regulation:

SGAR active substance	Number of product authorisation applications received (UK lead + MR)	Current status of products		
		Control of Pesticides Regulation (COPR)	Certificates of Exemption (CoE)	Biocidal Products Regulation (BPR)
Difethialone	11 + 0	Not previously used in UK, never approved under COPR	None Not required as never approved under COPR	All authorised and renewed to August 2020 <i>Indoor use only</i> Amendment application required to change area of use
Brodifacoum	25 + 23	Previously approved for use indoors only	All under CoE	3 products authorised so far <i>Indoor only</i> (authorisation applications only for indoor use on mice)
Flocoumafen	0 + 4	Previously approved for use indoors only	All under CoE	None authorised as yet
Difenacoum	156 + 19	Previously approved for use in and out doors	All expired (including phase outs) No longer any products available for use in open areas	All authorised and renewed to August 2020 <i>In and around</i> <i>buildings</i>
Bromadiolone	99 + 42	Previously approved for use in and out doors	Some under CoE, some under phase out CoE, some no longer under any CoE Last product will be available to buy and use in open areas, 180 and 365 days, respectively, after BPR authorisation decision	Some authorised In and around buildings Others (1 UK lead+24MR) not yet authorised

MR = Mutual Recognition (another Member State conducts the first EU authorisation)

- 81. Difethialone products are already restricted to 'indoor only' use as these were authorised before the results of the risk assessment across all five SGARs showed that the science did not support different restrictions. However, as a matter of consistency, 'in and around buildings' use not linked to stewardship can be made available to applicants for these products, if requested prior to the January 2015 deadline although ultimately stewardship conditions would apply.
- 82. All other SGAR products authorised outside the terms of stewardship will be restricted to use 'in and around buildings' following previous decisions that this use area is essential to address public health concerns regarding rodent infestation.

Bromadiolone

- 83. Some products have already been authorised under BPD/R for use 'in and around buildings'. The remainder will therefore, as a matter of consistency, also be authorised for use 'in and around buildings' where this has been applied for.
- 84. Unless applicants choose to apply for use in open areas (etc), the issue of the decreasing availability of products will not be addressed in the short term. Use in 'open areas' and 'waste dumps' will not be allowed until the authorisation can be linked to stewardship. Note that the products will not be authorised for use under stewardship if they fail the risk assessment for other environmental compartments since the stewardship scheme applies only to the issue of primary and secondary poisoning.
- 85. In the short term this will allow the continued use of bromadiolone products 'in and around buildings' by those not yet trained and certified according to stewardship standards, although this use will no longer be permitted as of 1 June 2016.

Flocoumafen and/or brodifacoum

- 86. Several brodifacoum products have been authorised for indoor use only as per the applications.
- 87. The approach described at paragraph 81 will ensure that all products will be treated consistently and in line with scientific assessment. BPR authorisations will therefore relax the previous COPR restrictions on use, extending authorisation to use 'in and around buildings' compared to indoors only.
- 88. This might result in some short-term outdoor use of previously indoor-only SGARs without a link to stewardship. However, the expectation is that applicants for these products will apply by 1 June 2015 deadline for authorisation for professional use outdoors under stewardship to retain their authorisations (applicants may apply for stewardship earlier if they wish).
- 89. The scientific evidence does not however support the use of differing restrictions across the SGARs, and in order to be consistent HSE must recognise that the position adopted in authorisations already issued should be made available to those applicants who might wish to market for 'in and around building' use.
- 90. We further note that the ability to use these products around buildings may be beneficial to control in locations where resistance to difenacoum and bromadiolone has been demonstrated.
- 91. Use of any SGAR product outdoors around buildings or in open areas outside the terms of stewardship will no longer be permitted after 1 June 2016.

Authorisation under stewardship

- 92. The 1 June 2016 deadline is intended to allow for the formation of a stewardshiptrained and competent user base.
- 93. Under the terms of stewardship suppliers holding existing product authorisations and wishing to extend supply of SGAR-containing products for use in other outside areas (e.g. waste dumps and/or open areas) will need to apply for a 'major amendment' to their existing authorisation and pay the appropriate fee. At that point the authorisations will be linked to stewardship. Note that if the product fails the environmental risk assessment for other compartments not linked to primary or secondary poisoning then the authorisation will be restricted accordingly.
- 94. If no change in 'area of use' to that already authorised is applied for then these will be dealt with as an administrative change and will be charged accordingly.
- 95. Prior to the 1 June 2015 deadline, when requesting a change, applicants will be required to link their authorisation for outdoor use to stewardship, which would make possible the use in open areas (if applied for) subject to the outcome of the assessment for other environmental risks. NB Authorisation holders have indicated to HSE that they will not apply for open area

NB Authorisation holders have indicated to HSE that they will not apply for open area (etc) use for products containing difethialone, brodifacoum or flocoumafen.

- 96. Once authorisations are changed, a phase out will apply to existing stock (180 days for supply and an additional 180 days for use).
- 97. By this method all professional-use anticoagulant rodenticide biocidal products intended for outdoor use will eventually be linked to stewardship including 'first generation' active substances, and even where use only 'around buildings' is envisaged.
- 98. HSE, Defra, Public Health England, Natural England and the devolved administrations comprising a Government Oversight Group will monitor the impact of the introduction of the stewardship scheme (e.g. reviewing feedback from CRRU and data from the independent predatory bird monitoring scheme) as will CRRU who will oversee the sectors' performance.

SECTION 3

CRRU Stewardship Proposal

Please see separate document, attached.