



This paper was provided to the Joint Committee for decision/discussion or information. Please refer to the minutes of the meeting for Committee's position on the paper.

To view other Joint Committee papers and minutes visit <http://www.jncc.gov.uk/page-2671>

To find out more about JNCC visit <http://www.jncc.gov.uk/page-1729>

JOINT NATURE CONSERVATION COMMITTEE

DETERMINING WHICH CHEMICALS MAY HAVE SIGNIFICANT IMPACTS ON BIODIVERSITY: AN OUTLINE FRAMEWORK

Paper by Helen Baker, Jennifer Best and Lawrence Way

1. Background

- 1.1 Thousands of kinds of chemicals are used daily for a very wide range of purposes. Many of these are released into the environment as the result of normal regulated use, or through failure to comply with regulations. The result is exposure of biodiversity, as a component of the environment, to potential diffuse or point source pollutants.
- 1.2 Protection of human and animal health are primary drivers for regulating chemicals, but pollution remains a major potential threat to biodiversity, and the regulations include (to varying degrees) an assessment of the risk to the environment. The regulatory arrangements are complex and operate at EU and member state levels, but, in essence, there are separate processes based around the uses of chemicals e.g. Plant Protection Products, Biocidal Products, Veterinary Medicines, Personal Care Products, Pharmaceuticals, and general (industrial) chemicals. In the cases where there are direct releases to the environment (with the exception of veterinary medicines) Natural England, as the Joint Committee's Lead Agency, provides advice as part of the risk assessment and approvals processes to the relevant competent authorities.
- 1.3 General chemicals are currently poorly regulated, with an estimated 30,000 chemicals in use that have not yet had any environmental risk assessment. This gap is being addressed by the EU 'Registration, Evaluation and Authorisation of Chemicals' (REACH) Regulation that came into force in June this year. This will require manufactures to register their chemicals and carry out a risk assessment process including an environmental risk assessment. The UK competent authority for REACH is the Health and Safety Executive. However, this process will take until 2020 to complete.
- 1.4 Superficially, we could consider the regulatory processes in place sufficient to be protective of biodiversity where these processes include an environmental risk assessment. We are engaged and provide advice on the individual assessments and the processes for prioritisation.

- 1.5 There are several reasons, however, why chemicals may pass into use through the regulatory processes and still pose major risks to biodiversity such as population effects or disruptions to ecosystem functioning:
- i. the testing carried out in support of risk assessments is based largely on short term exposure to a few test organisms under controlled laboratory conditions. Such testing may not detect long term effects of low doses or may not reflect the actual behaviour of the chemical in the environment and hence how the organisms would be exposed in the natural environment;
 - ii. regulatory testing is also usually carried out for each individual chemical separately. Although formulations (multi-actives) may be tested for pesticides, this is more usual in higher tier tests. However, even this does not account for the cocktails of chemicals that are found in environment;
 - iii. scientific knowledge of the properties of some chemicals and how they interact in the environment is still limited;
 - iv. the regulated use may not in practice prevent unwanted release of chemicals with a known significant impact into the environment;
 - v. un-regulated use is significant and either not recognised or the mechanisms to pick it up are not sufficient;
 - vi. environmental, human health and other benefits are balanced when considering regulation, so benefits for human safety may be considered against potential environmental impact, especially where no alternatives are available (as is done for flame retardants - reducing human mortality -vs- long term environmental impact);
 - vii. there will, for the next decade or so, be a very large number of general chemicals that have not been through an environmental risk assessment.
- 1.6 It is not possible for the biodiversity sector to take on the task of running more extensive risk assessments based on laboratory and other testing.
- 1.7 Paper JNCC 07 N08 (September 2007) introduced work underway to develop a more strategic approach to detecting the biodiversity impacts of chemicals. The paper set out the case for why a biodiversity focussed risk assessment process, to supplement the standard risk assessment processes for chemicals approval, is needed and identified the development of a framework approach as a means to achieve this.
- 1.8 As JNCC 07 N08 described, a key application of the framework is to formulate advice to the regulatory processes. However, another important application is to identify and set priorities for conservation-led research and

monitoring, where it is clear that no existing process will deliver the required evidence.

- 1.9 This paper outlines a framework, which has been tested by considering its application to five chemicals from differing classes and with differing levels of knowledge on biodiversity effects. The framework requires further development, but sufficient work has been done to allow assessment of whether it can improve our detection of and response to the possible threats to biodiversity of chemicals.
- 1.10 The framework is being developed through the JNCC Wildlife & Pollution contract with Centre for Ecology and Hydrology.

2. **The outline framework**

- 2.1 The proposed outline framework (Annex 1) is a two-stage process that builds on the existing risk assessment process required to achieve approval for the use of a new chemical or a change in the use of an already approved chemical. The most significant difference is the use of monitoring and research information from the physical environment and free-living biota, which is not used as part of the standard approvals process. The way in which the framework is used will depend on whether the chemical is completely new, whether related chemicals are already in use, or whether it has some previous usage (including outside of the UK); this will influence the level of monitoring and research information available.
- 2.2 When a chemical is approved for use, or a change in use, it can then be assessed through the framework.

Stage one: Applying chemical and usage data

- 2.3 Stage one incorporates the outcomes of the existing regulatory risk assessment process for a chemical, which relies on knowledge both of the inherent properties of the chemical (hazard assessment) and its scale and timing of use. The chemical properties assessed are:
 - i. persistence in the environment, either in the approved form or as a degradation product;
 - ii. whether it is likely to be available to affect biota (its exposure potential);
 - iii. bioaccumulation characteristics, i.e. whether it is likely or known to accumulate in biota;
 - iv. toxicity.
- 2.4 Within this regulatory process, judgements on the potential impacts on biota rely almost exclusively on laboratory studies and scale of use judgements are fairly restricted, considering timing of use and, depending on the regulatory

mechanism, quite a limited consideration of where and how much the product will be used.

- 2.5 Our proposed framework adds to this stage by a more comprehensive assessment of the proposed scale of use of the chemical¹; both the volume of the chemical in use and the actual distribution and scale of areas affected by use. Enhancing the usage assessment is important to judge risk as, for example, the intended use may be limited to certain application times in the year, but bioaccumulated chemicals will be available at other times also.
- 2.6 The end of stage one is a judgement of risk to biodiversity based on chemical properties and scale of use, and for convenience we are calling this a 'Qualitative Environmental Risk Assessment' (QERA).

Stage two: Applying monitoring and research data

- 2.7 Stage two relies on the use of monitoring data and research findings to evaluate whether the QERA is robust in its assessment of potential impact on biodiversity or should be modified. The assessment of potential exposure and impacts in biota is further developed using a combination of information from both regulatory chemicals monitoring and other types of monitoring information:
- i. presence of chemicals in physical media from regulatory monitoring (sampling in air, water and sediments);
 - ii. evidence of chemicals-related mortality in wildlife from regulatory compliance monitoring (Wildlife Incident Investigation Scheme);
 - iii. presence of chemicals in biota and possible effects (*inter alia* Predatory Bird Monitoring Scheme, EA Otter Project, Cetacean Strandings Investigation Programme);
 - iv. evidence of possible population level effects from chemicals, drawing on the range of surveillance data that are available from national schemes, for example trends in abundance or distribution of populations, breeding success and survivorship;
 - v. results from research on effects of chemicals in free-living organisms.
- 2.8 Stage two results in a biodiversity-linked assessment which for convenience we are calling: a Qualitative Biodiversity Risk Assessment (QBRA). The level of information available for any of the steps described will be variable, especially in relation to biota monitoring and research. However, a judgement on a precautionary approach to evaluation of the QERA, in response to insufficient data, would be made at this stage.

¹ This is in line with the way in which the EU Registration, Evaluation and Authorisation of Chemicals (REACH) programme of retrospective chemicals assessment will operate.

- 2.9 The final step in the approach is to prescribe actions, including prioritisation, on the basis of the final assessment of level of concern. The grading of risk from 'not of concern' through to 'major concern' allows us to be more consistent in how we respond to risk from chemicals to biodiversity.
- 2.10 For chemicals of 'major concern for biodiversity' and for which there is sufficient scientific evidence, the priority action would be an immediate and direct input into the regulatory process. Where scientific evidence is more limited for these chemicals and for chemicals of medium concern, then advice to government on change in policy and possibly to industry on best practice would be among the priority actions. In addition, other actions might include adapting surveillance to improve detection of effects in biota, conducting targeted research using archived and/or fresh animal tissues, or analysing existing monitoring data in new ways to highlight possible correlative evidence.
- 2.11 A further step needed for the framework is to include an alerting mechanism that will stimulate a fresh review of an approved chemical if there are significant changes in its use (e.g. scale) or in evidence of its properties or biodiversity impacts. This part of the framework requires additional development to establish criteria for triggering a review and assigning priority to that review.

3. **Testing the framework**

- 3.1 To test whether the framework would work for a wide range of classes of chemicals, we undertook analysis of four different approved chemicals; two rodenticides (difenacoum and brodifacoum), a plant protection product and veterinary medicine (cypermethrin) and an industrial chemical (Decabromodiphenyl ether (decaBDE) - a brominated flame retardant). We also reviewed a formerly widely used and much studied chemical that is now banned, DDT, to see whether the framework would perform well.
- 3.2 The framework requires detailed compilation of evidence and an example of an assessment of risk using it is provided in Annex 2. The test results in summary level are provided below for each chemical. The goal is that the framework should have, in each case, provided some clear level of risk for chemicals where preliminary evidence or concern suggested possible risk. The framework should have made it possible to decide an appropriate level of action.
- 3.3 ***Decabromodiphenyl ether (decaBDE)***
A flame retardant used to reduce fire risk in many products. A chemical with high human safety benefits, but its persistence has raised concern that it may have long term environmental and biodiversity affects. The framework provides a way of quantifying this concern.

Stage 1: The approvals process identified that decaBDE is a highly persistent brominated flame retardant, being neither readily nor inherently biodegradable. The potential for uptake and

accumulation of the substance by fish and other aquatic and terrestrial organisms appears to be low and toxicity is also low. Our framework adds exposure information which in this case shows high volumes of use in the EU as a whole.

Stage 2: Research and sampling shows that decaBDE has been found at low concentrations in fish, marine mammals and predatory birds' eggs (those of bird-eating Peregrine Falcons and fish-eating Common Terns). These findings appear to contradict the conventional wisdom that molecules such as decaBDE are too large to pass through biological membranes and should not accumulate in organisms.

QBRA: Unknown

Action: Plan a follow up review after the finalisation of the European 'existing substance review' to see if usage in UK can be found from existing sources and to see if research has advanced knowledge of its toxicity.

3.4 ***Brodifacoum***

A rodenticide known to affect rodent predators, restricted to indoor use, but it is very effective, and so there is market pressure to widen its use and advanced steps in Europe to approve this. The framework provides a way of judging whether existing use is a problem for biodiversity, and provides the foundation for judging any change in use. (A full version of the application of the framework for Brodifacoum is provided in Annex 2).

Stage 1: The approvals process identified that Brodifacoum is relatively persistent in soil and water, and in exposed animal tissues, particularly the liver. Anticoagulant rodenticides are very toxic, disrupting the normal blood-clotting mechanisms, resulting in increased bleeding tendency and, eventually, profuse haemorrhage. Brodifacoum is currently restricted to indoor only use in the UK due to its potency. The framework confirms the volume of usage and hence exposure to biodiversity beyond the target rodents is limited but widespread.

Stage 2: Review of research and sampling sources shows that poisoning of wildlife by brodifacoum is listed in most annual reports from the Wildlife Incident Investigation Scheme. Tissue analysis shows sub-lethal exposure of small numbers of individuals (typically less than 10% of individuals tested) of various bird and mammal species nationally Predatory Bird Monitoring Scheme (PBMS; CEH), which may in part due to its indoor only use which results in lower usage. Population monitoring of species that prey on rodents shows a mixed picture, some increasing, some with moderate declines but no casual links to poisoning.

QBRA: Medium Concern (limited release, but high toxicity and persistence in tissues).

Action: The main action is to continue to advocate responsible use of the rodenticide which minimises risk to biodiversity. If the current regulatory process in Europe changes use (this is being considered) the first step will need to be a re-evaluation of risk.

3.5 *Difenacoum*

This rodenticide is one of the market leaders, used in public health, agricultural and domestic situations. The approved use includes measures to minimise its availability to non-target biodiversity. The framework can assess whether the scale of risk indicates this is working.

Stage 1: Difenacoum is a second-generation anti-coagulant rodenticide approved for indoor and outdoor use in the UK. Difenacoum is relatively persistent in soil and water, but also persists in exposed animal tissues, particularly the liver. Anticoagulant rodenticides are very toxic, disrupting the normal blood-clotting mechanisms, resulting in increased bleeding tendency and, eventually, profuse haemorrhage.

Stage 2: Poisoning of wildlife by difenacoum is listed in most annual reports from the Wildlife Incident Investigation Scheme. Sub-lethal exposure of large numbers of individuals (typically up to 20-30% of individuals tested) of various bird and mammal species nationally (PBMS; CEH).

QBRA: Medium Concern (widespread release and high toxicity, but lower persistence in tissues).

Action: Continue to work with industry to ensure good practice minimises actual exposure of the chemical to rodent predators. Review if usage changes.

3.6 *Cypermethrin*

Cypermethrin is a synthetic pyrethroid insecticide approved as a plant protection product and a veterinary medicine. The conservation community noticed its impact on freshwaters (e.g. major cause of white-clawed crayfish deaths) due to its use as sheep dip. This practice has subsequently been suspended. The framework can be used to see what level of risk there is now.

Stage 1: Cypermethrin is neither persistent nor bioaccumulative, but is extremely toxic to aquatic invertebrates and toxic to a range of vertebrate species. Usage is widespread being used in arable, horticulture and as a sheep dip (currently suspended). The tonnage used for horticultural applications is not high.

Stage 2: To date, impacts from sheep dip have been investigated more extensively than those from the plant protection use. In 2007, a

pollution reduction programme was put in place for sheep dips primarily to address impacts from cypermethrin. In 2006, sheep dips caused more than one third of Environmental Quality Standard (EQS) failures in England and Wales; 64 caused by cypermethrin and 19 caused by diazinon. This was an increase from 22 in 2005, in part due to the increased targeted sampling carried out by the EA as part of the pollution reduction programme and although cypermethrin was withdrawn in March 2006, farmers were allowed to use up stocks. EQS failures downstream of wool scourers are also a yearly occurrence in spite of substantial chemical monitoring of wool pre-scouring. Monitoring of aquatic invertebrate communities has shown that pollution incidents involving cypermethrin have caused damage to rivers often miles downstream from the point at which the pollution occurred. A number of recent incidents have also resulted in white-clawed crayfish kills. Invertebrate monitoring at these sites has also shown that communities can be impacted for years after the incident. Impacts from agricultural use are not well known; issues relating to sheep dip use have been of higher priority, but now that this usage is controlled the Environment Agency is prioritising research on identifying impacts from agricultural uses.

QBRA: Medium Concern (limited release (due to marketing suspension for sheep dip), high toxicity).

Action: The main action is to continue to work with the Environment Agency to advise Government and Industry on reducing risks to biodiversity from sheep dip application as the suspension is lifted. The agricultural impacts need further research.

3.7 **DDT**

If DDT were a new chemical today the regulatory approvals process would probably allow its use, but with restrictions to prevent it entering water systems. Approvals testing (stage 1) would show that DDT and its metabolites and degradation products are extremely persistent but relatively immobile in soil. They would also find that DDT is of low to moderate toxicity to mammals, birds, earthworms and bees, but extremely toxic to aquatic organisms. However, due to its binding to soil, the movement to soil and water would probably be considered to be low, and management to reduce DDT entering water courses would reduce risks to aquatic organisms. Therefore, using this information, DDT would have been of minor to medium concern dependent on volume of use. As usage data (from the 1960s) was not available to this study, but we know that DDT was widely used in agriculture at that time it is suggested that DDT would have been of medium concern. However, there would have been insufficient information for concluding stage 2 of the framework approach and so the QBRA for DDT is likely to have been "Unknown". It's probable that given what was known about the persistence, bio-availability, and bioaccumulation characteristics of DDT that a precautionary approach would have been adopted and subsequent recommended actions would have included at least monitoring for residue

appearance in wildlife (i.e. through a tissue scheme). The DDT story has significantly changed our perspective on chemicals in the environment, and was the primary driver behind development of the risk assessment process. It especially highlighted that a range of evidence needs to be considered, including sub-lethal effects, in researching the effects of chemicals. Whilst, the recommendation to monitor for DDT in wildlife might have resulted in relatively limited scope of study in the 1960s, it is because of DDT that the scope of recommended study today would be broader.

4. Further development needs

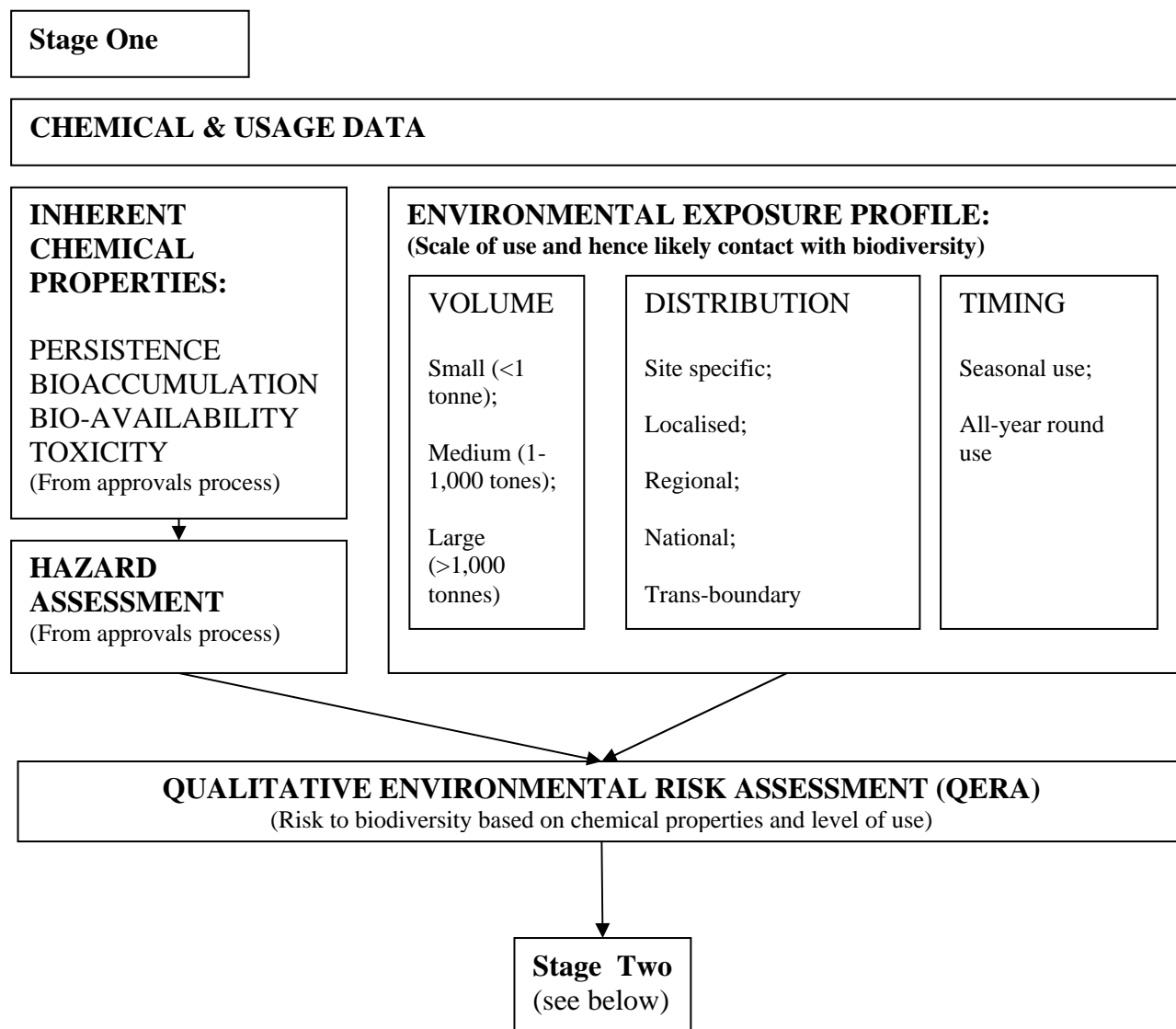
- 4.1 We believe that the framework will have significant benefits, providing a clear, simple and robust method for the agencies, through the Lead Agency, to assess and prioritise responses to chemicals that are of concern for biodiversity. However, there are several parts of the outline framework that require further development before it would be suitable for operational use.
- 4.2 Additional guidance, or an expert forum, will be required for interpreting the signals from population monitoring. Expert groups exist within the country agencies, but there may be merits in broadening the available expertise to include input from surveillance partners and other stakeholders. One option is to integrate provision of advice into existing surveillance contracts.
- 4.3 The process of assigning a concern level to the QBRA requires explanatory notes and additional guidance, especially in relation to insufficiency of data and application of the precautionary principle.
- 4.4 The alerting process for review of already approved chemicals needs development, with selection of criteria for triggering an alert and for setting priorities.
- 4.5 All of the above development steps are feasible, but will require some new resources, both in Lead Agency and JNCC staff time and some additional funds for commissioning inputs from expert partners (CEH); we anticipate the funding resource to be relatively small (c. 10K) and so recommend that this is done in 2008/09.
- 4.6 Alongside the development of the full framework we will need to consider how it might operate in practice and develop a project plan, which will also then allow us to estimate the operational cost of the framework approach. This will need to tackle questions about how its operation might be funded, who will undertake the assessments, what volume of review should be undertaken in each year (also depends on understanding how long a review would take) and how the outcomes should be published. Broader prioritisation of the chemicals on which to undertake the framework analysis will be informed by the regulatory risk assessment process, assessments done as part of the REACH initiative (which runs to 2020), and current understanding of the potential risks to biodiversity from assessments and reviews done to date (e.g. the UK Chemical Stakeholders Forum review, Predatory Bird Monitoring Scheme review, etc).

5. **Monitoring needs in support of the framework**

- 5.1 The framework integrates the use of monitoring data with other data, but as with all assessment processes there is the question of what kind of monitoring provides the most cost effective way of detecting impacts.
- 5.2 The suite of schemes designed to detect the presence of chemicals in biota, and their possible effects, are typically based on annual collection of tissue samples and annual analysis and publication of results. Most rely on some form of volunteer effort, for example the submission of carcasses, to run in a cost effective way. The tissue banks archived by these schemes are an incredibly valuable resource for targeted research and the success of the framework hinges on these tissue banks being maintained and added to on a regular basis. An alternative to annual analysis of tissues for any given chemical is periodic analysis of archived tissues collected from a discrete and relatively short period of time, cycling these to allow for repeat assessments over the long-term where this is identified as being the appropriate response. However, we have not done a cost-benefit analysis of the various alternatives for analysing tissues to provide advice as part of the framework analysis, but the schemes could be encouraged to undertake such an assessment. However, there remains a need to support both regular tissue archiving and a level of regular analysis.
- 5.3 Setting the use of population monitoring data into the framework provides a clearer role for these data and will help develop a wider network of experts who can input into framework implementation. The explicit link should help make greater use of population monitoring data and also provide valuable feedback for improving the surveillance suite, or in identifying the need for undertaking short-term enhancements to increase knowledge of certain demographic parameters.

ANNEX 1

An outline framework for determining which chemicals may have significant impacts on biodiversity.



Stage Two

MONITORING & RESEARCH DATA

EXPOSURE PROFILING

REGULATORY DRIVEN MONITORING – CHEMICALS

(i.e. is the chemical turning up in the environment)

PHYSICAL MEDIA

- Air (CEH);
- Freshwater (EA/SEPA);
- Freshwater sediments (EA/SEPA);
- Marine waters (CEFAS/SEPA/FRS);
- Marine sediments (CEFAS/SEPA/FRS).

BIOTA (POST-APPROVAL)

Wildlife Incident Investigation Scheme (PSD/CSL/SASA)

BIOTA MONITORING FOR CHEMICAL EXPOSURE

(i.e. is the chemical turning up in biodiversity)

- Otter Monitoring (EA);
- WIIS (PSD/CSL/SASA);
- Predatory Bird Monitoring Scheme (CEH);
- Cetacean Strandings;
- Seals;
- Marine biomarkers

POPULATION EFFECTS PROFILING

POPULATION MONITORING (BIODIVERSITY)

(i.e. is the biodiversity likely to be affected declining, and do we know why)

- Bird population trends (BTO/WWT/RSPB/JNCC/GCT);
- Bird survival indices (BTO/JNCC/GCT);
- Bird productivity indices (BTO/WWT/JNCC/GCT);
- Fisheries data (EA/CEFAS/FRS);
- Distribution changes (except birds) (BRC);
- Marine mammal populations (SMRU/Seawatch);
- Other biodiversity monitoring

RESEARCH

INDIVIDUAL EFFECTS PROFILING

(i.e. scanning research literature for relevant findings)

IN-FIELD EFFECTS STUDIES ON FREE-LIVING ORGANISMS

ADDED TO QUALITATIVE ENVIRONMENTAL RISK ASSESSMENT

QUALITATIVE BIODIVERSITY RISK ASSESSMENT (QBRA)

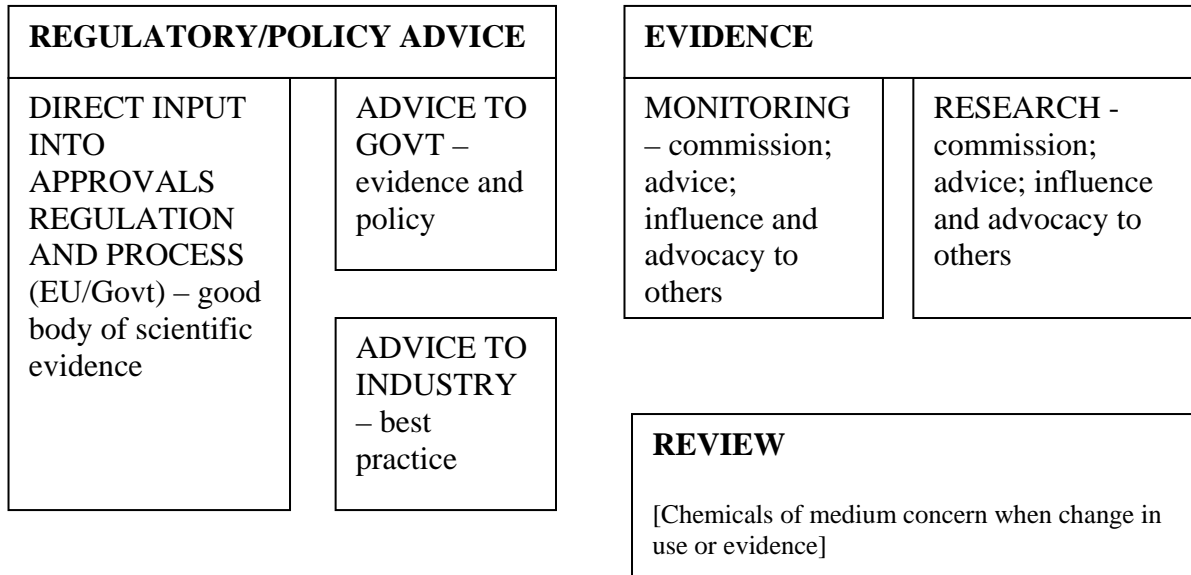
(Risk to biodiversity based on chemical properties, usage, and evidence actual behaviour in the environment)

INDICATIVE LEVELS OF CONCERN

- NOT OF CONCERN – no release, none toxic;
- MINOR CONCERN – limited release, low toxicity;
- MEDIUM CONCERN – limited release and high toxicity, or widespread release and low toxicity;
- MAJOR CONCERN – widespread release and high toxicity;
- UNKNOWN – insufficient data

ACTIONS (see below)

ACTIONS



ANNEX 2

A draft chemical profile based on the outline framework for determining which chemicals may have significant impacts on biodiversity: Brodifacoum

	BRODIFACOUM
CHEMICAL PROFILE	
Physiochemical & Toxicological Properties	
Persistent?	Yes - Brodifacoum relatively persistent in soil (DT50 - 77-1332 days) and water. Rapidly broken down by sunlight in aqueous solutions - EHC 175. However more importantly persist within exposed animal tissues, particularly the liver. Elimination is bi-phasic with an initial DT ₅₀ of 14 days in possums but with noappreciable further decline after 256 days (Eason <i>et al. New Zealand Journal of Agricultural Research</i> 39 , 397-400). DT ₅₀ in rat liver estimated to be 130days (Eason et al. <i>Ecotoxicology</i> 11 35-48).
Bioavailable/Bioaccumualtaive?	Yes - 'Anticoagulant rodenticide compounds are readily absorbed from the gastrointestinal tract...' EHC 175
Toxic?	Very to vertebrates - 'Anticoagulant rodenticides disrupt the normal blood-clotting mechanisms, resulting in increased bleeding tendency and, eventually, profuse haemorrhage' EHC 175 Acute-single dose LD50 for rat is 0.26 mg/kg Highly toxic to fish.
Scale of Use	
Small (<1 tonne per year)	Approx. 0.003 tonnes of active ingredient per year on arable and fodder farms and municipal use. RESTRICTED TO INDOOR USE ONLY IN BRITAIN. However, use by private pest control officers and other agricultural practices (e.g. intensive pig and poultry rearing but no figures available)
Medium	
Large (>1000 tonnes per year)	
Environmental Distribution	
Site specific	
Localised	
Regional	
National	Use is national
Trans-boundary	Brodifacoum is relative immobile in the ambient environment and so trans-boundary movement is unlikely, unless carried as residues by migratory animals
Temporal Profile	
Seasonal	
Year-round	Used all year round
EXPOSURE PROFILING (Sources of Information/Managing Organisation)	
Physical Media	There isn't any information on residue levels in physical media.
Air (CEH)	
Fresh Water (EA)	
Fresh Water Sediments (EA)	
Marine Waters (EA/Cefas)	
Marine Sediments (EA/Cefas)	
Deposition (CEH)	
Soil (CEH)	

Biological Media	
Otters Monitoring (EA)	No monitoring for rodenticides. Brodifacoum has been detected in an otter, apparently result of pesticide abuse (WIIS 2003 report)
WIIS (CSL)	Some poisoning of wildlife by brodifacoum listed in WIIS reports in most years
PBMS (CEH)	Long-term monitoring of barn owls (1982-) and kestrels (2001-) and small numbers of red kites. Single studies on tawny owl and buzzard provide information on species exposed (extent and severity), temporal and spatial trends
Cetacean Monitoring (IoZ?)	N/A
Seals (IoZ NHM?)	N/A
Red Kites (IoZ)	Analysed through PBMS and WIIS (see above)
Marine biomarkers (CEFAS)	N/A
Scientific Papers	Information on exposure published from above studies and elsewhere indicating exposure of wide range of non-target mammals and birds
INDIVIDUAL EFFECTS PROFILING These are specifically effects on free-living organisms rather than laboratory tests (see Toxicity section).	Sub-lethal exposure of relatively small numbers (typically <10% of animals tested) of individuals of various bird and mammal species nationally (see PBMS)
	Lethal exposure detected in small numbers of non-target vertebrates nationally (see WIIS and PBMS)
	Suggested evidence that anticoagulant rodenticides may have effects on Ca metabolism in experimental animals (see EHC 175) but no evidence in wildlife (eg., Knopper et al. <i>Bull. Environ. Contam. Toxicol.</i> 78 249-251) but few studies.
POPULATION EFFECTS PROFILING	
Bird Population trends (BTO)	Some population declines concurrent with introduction/increased use but no evidence of causal links and relatively low level of exposure (see above)
Bird Reproductive Indices (BTO)	N/A
Fisheries data	N/A
Distribution - except birds (TMP, BRC, VWT, EA, etc)	Polecat (predator of target species with history of exposure) population expanding.
Pop trends - marine mammals (SMRU; SeaWatch)	N/A
Game bags	Other predators of non-target small mammals with history of exposure to rodenticides: decline in weasel game bag records and lack of increase in stoat game bag records (despite increase in rabbit numbers) concurrent with brodifacoum use. No evidence of causal links and low level of exposure
QUALITATIVE BIODIVERSITY RISK ASSESSMENT (PRIORITISATION)	
NOT OF CURRENT CONCERN	
MINOR CONCERN Geographically/ temporally limited exposure and/or impacts.	
MEDIUM CONCERN Geographically/ temporally limited exposure, but impacts shown. Widespread exposure but no/limited impacts.	Yes; because of toxicity and persistence, and residues occurring in wildlife, but limited use and current restriction to indoor use. When non-approved use outdoors, has resulted in non-target mortalities.

<p>MAJOR CONCERN Widespread exposure and impacts and/or Impact on high valued species. May include indirect effects on other species or "ecosystem services"</p>	
<p>UNKNOWN Too little data to assess.</p>	
<p>What factors would amend this assessment?</p>	
<p>Changes in usage magnitude and/or pattern of chemical?</p>	<p>Yes. Could occur due to changes in regulations which would allow use outdoors. Would be expected to lead to significant rise in wildlife mortality incidents due to very high potency</p>
<p>Change in prey base/habitat use by susceptible organism?</p>	<p>Yes. Change in prey base to increase intake by predators of target and non-target prey species could occur if preferred alternative prey declined. Would only be likely if concurrent with change to outdoor use</p>
<p>Other (specify)</p>	<p>(i) Severity and duration of anticoagulation increased if individual has previously been exposed to difenacoum (Findley in prep). Change to outdoor use of brodifacoum would likely result in exposure of individuals that already contain difenacoum residues, and this may enhance resultant mortalities. (ii) increased resistance to other anticoagulants may lead to increase in use of brodifacoum and/or license for outdoor use (iii) development of brodifacoum resistance in target prey would also increase likely risk of secondary poisoning in predators</p>
<p>RESULTING ACTIONS</p>	
<p>Detailed Quantitative Risk Assessment National or International Scale</p>	<p>Currently reviewed under Biocides Directive. Review again via framework analysis if significant change in use.</p>
<p>Disseminate Datasets Available to regulators and wider community</p>	<p>Datasets available through PBMS and WIIS</p>
<p>Advice to Stakeholders e.g. to regulators, industry etc. Relating to potential effects and mitigation measures.</p>	<p>Advice to ACP provided using data from WIIS and PBMS Industry-led initiative for safe use of rodenticides (CRRU--- http://www.thinkwildlife.org.uk/crru-code.php) dependent on PBMS and WIIS information and on PBMS monitoring</p>
<p>Scientific Publications</p>	<p>Yes from above monitoring and other studies</p>
<p>Chemical Monitoring Schemes Needed Site specific..... Regional (county or country)..... National International programmes..... </p>	<p>YES—only means for detecting changes in frequency and magnitude of exposure and mortalities if exposure scenarios change. Already in place (PBMS and WIIS).</p>
<p>Specific Targeted Research</p>	<p>Needed to assess risk from co-exposure to other anticoagulants</p>