

Draft rodenticide proposals published

For nearly ten years pesticide manufacturers have been battling with the new requirements of the Biocidal Products Directive. Now it is the turn of the pest control servicing companies to begin to see the effect that it will have on the industry

In September 2006, the withdrawal of products will begin and some old favourites will disappear. These are the products based on active ingredients which nobody agreed to support through the new rigorous approvals process.

Next year will see the withdrawal of products whose active ingredients were originally to be supported but where the notifier has afterwards decided not to proceed with the submission of new data.

The Biocidal Products Directive

For those who are not aware of how it will work, the BPD process can be divided into two. First will come the listing of an active ingredient on Annex 1 of the BPD. To achieve this, manufacturers must submit a data package on a representative product, which is assessed by a single Rapporteur State, who then makes recommendations to the European Chemicals Bureau, representing all 25 Member States.

When the ECB agrees that the active ingredient in the product can be listed on Annex 1 of Council Directive 98/8/EC, known to us as the BPD, it will lay down the parameters under which competent authorities in each country can give their subsequent approvals.

After the active ingredients are listed, formulators in each country will then be able to reapply for approvals, switching from their existing national scheme, such as COPR in the UK, to the new approvals under the BPD. This will be necessary because approvals under existing national schemes will be withdrawn two years after the first listing of the relevant active ingredient in Annex 1.

Further withdrawals can be expected at this time, as approval holders are faced with both the need to get letters of access from the owners of successful data packages and the extra fees required to switch from a current national approval to one given under the BPD. Present indications are that not all existing approval holders will get access to data packages and that the fees will be in the region of £20,000 per formulated product.

It must be understood that manufacturers have no moral or legal duty to support pesticides through the new regulatory process if the costs outweigh the benefits. Some current products simply do not justify a fee of £20k plus the cost of preparing a new data package which could be another £10k – £20k on top of that.

The products most affected will not be the main branded products because their manufacturers will have already spent hundreds of thousands of pounds to get their actives through the BPD and the secondary fee is relatively small.

Formulators operating in several European countries will no doubt reduce the number of different products they produce, focusing on the formulations which they can sell best throughout the EU. This is because these formulators will need to recover the extra costs from several markets and not just one and the harmonisation of approvals across the EU will make this easier.

It is the local formulators and distributors who will find the fees most difficult to justify, since they must recover the extra costs from a single market. Most of these formulators will have several own label products, which will compound their problems.

Current position

At the moment, we are in the first period when manufacturers of rodenticides and timber treatment products are waiting for their active ingredients to be listed in Annex 1. Data packages were submitted in 2004 and the first draft recommendations (warfarin and warfarin sodium) were published last October. Draft recommendations on other rodenticides have followed later in 2005 and in 2006.

Insecticide active ingredients are next on the list and data packages are currently being submitted and assessed.

It should be remembered that these are merely draft recommendations and these may be amended as a result of the consultation process which has followed their publication. Further changes may also come during the final assessments which will involve a committee made up of representatives from all 25 Member States.

What the recommendations published so far show are the possible trends and the apparent difference in approach between north and south regulators.

So what are the published draft recommendations so far?

i) Warfarin

Only data from a task force, which includes Killgerm, was submitted.

The Rapporteur State was Ireland and they recommended in August 2005 that warfarin should be allowed as a rodenticide in the form of a wax block bait or grain bait. They therefore proposed that warfarin be included in Annex I of Council Directive 98/8/EC and that the inclusion be conditional on a minimum purity of 92 %.

- Difenacoum baits should not be placed where food, feeding-stuffs or drinking water could be contaminated
- In case no standard safety phrases are required on the product label, adequate safety instructions should be provided in the use instructions
- Difenacoum should not be used in an area where resistance to second generation anticoagulants is suspected
- The labelling of the biocidal product should contain guidance on resistance management
- Difenacoum baits should not be deployed permanently
- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be dimensioned according to the size of the infestation
- A complete elimination of rodents should be achieved
- The authorisation holder shall report any observed resistance incidents to the Competent Authorities
- The authorisation holder shall submit monitoring data every fifth year to demonstrate that the proposed normal use of difenacoum has not caused any adverse effects on the non-target vertebrates
- Only tamper-resistant bait boxes should be used. If possible the baits should be secured in the bait boxes so that rodents cannot remove the bait from the bait box
- The unconsumed baits should be collected after the end of the campaign and disposed of as hazardous waste
- Dead rodents found during or after the campaign should regularly be disposed of so that they do not become available for any animals, or contaminate soil and water. Incineration is a recommended way of disposal
- The package should contain the following specific safety precautions using the standard phrases defined in Directive 91/414/EEC:
- The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents
- Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned
- Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips

Coumatetryl

Only data from Bayer Environmental Science was submitted.

The Rapporteur State was Denmark and they recommended in September 2005 that coumatetryl is included in Annex I of the Directive 98/8/EC, subject to the following:

- a) The active substance coumatetryl, as manufactured, shall have a minimum purity of 98% w/w.
- b) The identity and maximum content of impurities
- c) Products containing coumatetryl may be used for the control of rats (*Rattus rattus* and *Rattus norvegicus*)
- d) Biocidal products containing coumatetryl must be authorised only for use by professionals (pest control operators)
- e) Biocidal products containing coumatetryl must be authorised in a way that ensures the use of products to be protected (e.g. bait stations, enclosed boxes designed to be "tamper-proof") such that exposure to humans and animals, primary as well as secondary exposure, is minimised as much as possible



- f) Risk mitigations like the use of a non-dusting formulations, e.g. a paste and the addition of a bittering agent to the biocidal product, should be prerequisites for authorisation.

Chlorphacinone

Only data from Liphatech was submitted.

The Rapporteur State was Spain and they recommended in September 2005 that chlorphacinone is included in Annex I of the Directive 98/8/EC, subject to the following specific provisions:

- a) The active substance, chlorphacinone, as manufactured, should have a minimum purity of >97.8% w/w
- b) The identity and maximum content of impurities
- c) Products containing chlorphacinone may be used to control rats (*Rattus norvegicus*) and mice (*Mus musculus*)
- d) Biocidal product containing chlorphacinone must be authorised in a way that ensures the use of the products to be protected such as the exposure to humans and animals, primary as well as secondary exposure, is minimised as much as possible
- e) Biocidal products containing chlorphacinone (block baits and grain baits) could be authorised for use by professionals and non-professionals.
- f) The addition of a bittering agent to the biocidal product should be prerequisite for authorisation
- g) Considering the high risk for non-target terrestrial vertebrates the authorisation of each formulation should include specific risk mitigation measures for avoiding or minimising the exposure to birds and non-target mammals and the assessment of the primary and secondary risks expected after the adoption of these risk mitigation measures.

Further recommendations are that:

- The organisms to be controlled by using products containing chlorphacinone was restricted to *Rattus norvegicus* (block and grain baits) and *Mus musculus* (grain baits). The applicant did not submit efficacy data for other species.
- The results on human health risk assessment of the representative products (blocks and grain baits) concluded that these can be used by professional and non-professional users.
- However, the representative product, tracking powder, due to the risk identified in the indirect exposure as a result of use, makes this type of product unacceptable.

Brodifacoum

Only data so far submitted by Syngenta has been accepted. At the time of writing, no other recommendations on data supplied by others have been published.

The Rapporteur State was Italy and they recommended in

March 2006 that brodifacoum is included in Annex I of the Directive 98/8/EC.

Further comments are that:

- Because of the high toxicity of the brodifacoum-based commercial products, even at very low dosages (0.005% a.i.), the use of commercial products should be restricted to professional uses.
- Although the product is ready-to-use and the general public is not exposed to the active substance, the use of the rodenticidal product by non-professional users should be discouraged.
- Documentation on effectiveness of brodifacoum against target organisms is well conducted, according to the standard methods for efficacy testing of biocidal products and active substances (rodenticides) presently available in Europe. Results are satisfying and reliable. Nevertheless as all bioassays have been carried out on the field or in semi-field scenarios, they cannot be considered as exhaustive. At least two laboratory tests, a no-choice and a choice test, should be carried out in order to better assess the effectiveness (100% mortality in no-choice) and the acceptability/palatability in choice test.
- No risk is anticipated for manufacturers, formulators, non-professional users and for secondary exposed humans
- There is an acceptable level of risk to the professional user from acute exposures to brodifacoum.
- Predictably there is a potentially very high risk of primary poisoning to exposed non-target vertebrates, birds and mammals
- A theoretical very high risk of secondary poisoning of mammals and birds is shown using the assumptions and scenarios laid down in the guidance documents (TGD and ESD)
- In order to include the active substance in Annex I of BPD, restrictions of use should be taken into consideration (e.g. to professional personnel for outdoor uses and indoor use for amateur products).
- The risk to non-target birds and mammals can be reduced by limiting their access to the bait. This can be attained through the use of bait stations or protected devices (e.g. boxes)

- The use of bait stations might reduce the primary poisoning hazard of non-target animals if they are robust enough (tamper-resistant) and the access to the bait compartment is designed to be no larger than necessary (to exclude mammals larger than adults of the target species).
- However, in some situations smaller mammals might still be at risk, as they can enter bait stations. Furthermore, experimental evidence has been reported that rats often remove bait particles from boxes and leave them when other animals might find them
- In order to mitigate the risk emerged the applicant proposed a revised label. The revised phrases relating to disposal of excess bait and removal of rodent bodies, in particular: "after treatment (except when used in sewers) all remains of bait and any rodent bodies must be removed, bagged and stored in rigid lidded containers; and disposed of safely via the domestic waste stream".
- Risk would not be sufficiently mitigated from the proposed revised (for amateur and professional products) as removal of remains baits doesn't mitigate the risk emerging from primary poisoning since a normal rodent control campaign is expected to last up to 35 days, a long period during which non-target species are likely to gain access to baits.
- About the removal of carcasses and rodent bodies, this operation is not always possible, especially in the case of application around buildings and in open areas. In fact, since the death is delayed for several days after exposure to the anticoagulant, the target species might die far from the application site
- The safe use of active substance is highly dependent on the application type of formulated products. In fact, as small pellets and whole grain are highly attractive to birds, this kind of application should pose high risks especially for the open areas scenario, while wax block formulation appear to decrease the attractiveness to the birds and so reduce the possibility of poisoning incidents.

Published draft recommendations are still awaited for bromadiolone and flocoumafen.

Full details of the draft recommendations are available from the ECB website on http://forum.europa.eu.int/Public/irc/env/bio_reports/library?l=/p_t_rodenticides&vm=detail&d&sb=Title



Brodifacoum products will remain on the market subject to conditions