



Efficacy Guideline 211

Home and Garden Products

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Introduction

Efficacy requirements for home garden products are similar to those for professional products. Evidence is required to support control claims and to support the crop safety of the product to both treated and subsequently planted crops/plants.

Where similar professional use products are already approved for identical or related crop uses, it will often be possible (assuming data access and use of an equivalent dose) to extrapolate the evidence of efficacy previously considered to the amateur use product. The need for additional evidence is thus reduced or eliminated. A bridging argument must however be included for this in the Biological Assessment Dossier.

In many cases where approval is sought for a home garden product, a professional product will already be approved. Details in relation to the extrapolation of evidence from professional to amateur use products are therefore considered first in this document (Section 1). Data required in the absence of any such extrapolation are considered subsequently (Section 2).

Bridging of evidence of efficacy from professional use products

It will often be possible (assuming appropriate data access) to at least partly support the efficacy of amateur use products by supplying in the Biological Assessment Dossier a bridging argument comparing the proposed uses of the amateur use product with those already approved for a similar professional product.

Effects on following crops are usually unaffected by formulation type. Therefore, for the majority of home garden products, a case based on an extrapolation of evidence of safety to following crops from that previously considered for approved professional products applied at equivalent or higher active ingredient doses would usually be acceptable.

Evidence supplied to support the efficacy of a product can be in the form of a reasoned case, with data provided where necessary. Such an argument must however take into account the possible differences listed below.

Formulation differences

Differences in co-formulants can have a marked effect on the efficacy of a product. Therefore, when proposing to extrapolate evidence from a professional product to an amateur use product, the effects on efficacy of any co-formulation differences present between the two products (particularly those relating to main solvents and surfactants) must be adequately addressed, with, unless differences are minor, bridging data supplied for this. More detailed guidance with respect to the importance of formulation differences is included in EPPO Guideline PP1/307 'Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products' and in Efficacy guideline 105 'UK Efficacy guidance on PPP formulation changes, and use of EPPO 1/307'

Differences in method of application

Differences with respect to the method of application (eg conventional hydraulic field sprayer, knapsack, or hand sprayer, compared with use of watering can or weed wiper) will result in differences in the dilution of the product applied and may also affect its distribution and coverage in the crop. These differences may in turn affect the efficacy of the product. In particular, differences in surfactant dilution resulting from knapsack or hand sprayer use (where a spray volume of typically 500 litres/ha is applied) compared with that from watering can use (with spray volumes of the order of 4000 litres/ha) have been shown to reduce the effectiveness of certain herbicide products.

Equivalence of dose applied

The dose applied by the proposed home garden product must be related to that applied by the approved professional product and any differences addressed with respect to the effectiveness and crop safety of the proposed product.

Where the dose on the approved professional and the proposed home garden product labels are both given in identical terms, a dose comparison will be immediately obvious. However, this is not always the case. Dose of an amateur spray applied product may be stated in terms of a specified concentration applied to plants 'up to run off' or as 'several short spray bursts', and dose for an amateur pelleted bait formulation in terms of the distance between individual broadcasted pellets. Stated dosages for the equivalent professional use products may however be given simply in terms of amount of product per unit area. Therefore, in the latter situations, it will be necessary for further information to be included in the Biological Assessment Dossier relating the previous approved professional use dose with that now proposed for amateur use.

Equivalence of situation of use

For many control claims, control in a professional agricultural/horticultural situation can be directly extrapolated to control in an amateur home garden situation. However, for no additional evidence to be required, it is important that both crop use and target 'pests' are equivalent in the two situations.

Frequently, a wider and more general crop use is proposed in the home garden situation than that previously approved for professional use. Where this is the case, the crop safety and effectiveness of the product in the broader range of proposed crop uses must be adequately addressed.

Garden lawns

Whilst evidence of efficacy from use of a product in grassland may be useful in supporting the efficacy of a similar product in garden lawns, because of the increased importance of lack of adverse visual effects to lawns, and due to the possible presence in garden lawns of fine leaved fescues and bent grasses which may be particularly susceptible to damage, some additional evidence would be required to confirm adequate crop safety in such situations. Also, for herbicide products, due to differences in weed competition in the two situations (the lawn situation often being less

competitive), some confirmatory weed control data from use in lawns would usually be required.

A more satisfactory extrapolation to support herbicide use in garden lawns would be that from professional use in amenity turf (eg bowling and golf greens), for which, due to an equivalent weed control situation and an equivalent crop safety requirement, no further evidence of control and of safety to grass would be required. For herbicide or growth regulator use, the possibility of adverse phytotoxic effects from use of cuttings from treated grass as a mulch or compost must also be addressed.

Trees and shrubs

Control in the home garden of weeds around trees and shrubs represents a relatively low plant competition situation. Because of this, it would not be appropriate to support such a claim solely on the basis of an extrapolation of evidence of control previously considered and approved for a similar professional product in a competitive 'in crop' situation. Evidence of weed control from use of an equivalent professional product in a non-crop or non-competitive crop (eg top fruit, onions) situation, could however be used in support of such control claims, with a reasoned argument or further data submitted to support the lack of adverse phytotoxic effects to the surrounding trees and shrubs.

Slugs

For bait formulated slug killers for general use in the home garden, no additional evidence for control of the assessed slug species in other crops would be required for approval, providing evidence previously considered in support of control claims for the professional product included use in crops which are particularly susceptible to slug damage (eg lettuce, double low oilseed rape). However, given the importance of garden slugs (ie *Arion hortensis* and *A. distinctus*) in the home garden situation, for this extrapolation to be possible, at least some of the previously considered evidence of control must relate to use against these species of slugs. Alternatively, additional control data from use of the product against garden slugs should be submitted with the home garden product application. Given the wide crop use possible in the home garden situation, some further confirmatory evidence of crop safety from use of product in a limited range of representative crops may also be required.

Note: The above details include some examples of particular situations which must be taken account of when developing use of a professional product in the Home Garden. For information on other situations encountered or for further comment on suggested trials programmes to meet these requirements contact HSE's Efficacy Section.

Standard efficacy requirements in the absence of bridging arguments from other products

'Pest' control

Details of replicated effectiveness trials are required, with the product applied as proposed in representative situations of use. The number of reported trials required to support an individual claim will vary depending on the quality of the trials, the need to

demonstrate product efficacy over a range of environmental conditions, and the extent and nature of other supported related claims.

Assuming no information is available from similar already approved professional products, for an individual major claim HSE would usually require supporting results from a minimum of six good trials conducted with the product. Where the extent of data builds up a knowledge of the spectrum of efficacy of the product, fewer trials for subsequent claims may be acceptable. For control of minor pests or diseases or of less competitive weeds, evidence from a minimum of three good trials would usually be required to support an approval.

To demonstrate adequate efficacy over the range of environmental conditions likely to be encountered, trials would usually be expected to be conducted over at least two seasons/years. However, for fungicides and insecticides, data from more than one season or year is not usually essential providing the reported trials include treatments made under high disease/pest pressure. Similarly, for products intended for use under less variable indoor conditions, data from a single year may be sufficient. Where environmental factors such as temperature and moisture are known to influence performance, the product must have been tested under appropriate conditions.

Some extrapolation of evidence of weed, insect, mite, or disease control between different crops or plant species may frequently be possible.

For weed control, an extrapolation of control between crops is usually possible providing the supplied evidence of control relates to a situation of equal or lesser crop competition. In other words, it is therefore possible to extrapolate evidence of weed control to use in more competitive crops, but not, without further evidence, to use in less competitive ones.

For an extrapolation of insect, mite and disease control claims between crops to be possible, it is important that the damaging organism is equivalent in the different crops, and that 'pest' location and behaviour/epidemiology are also similar. Any proposed extrapolation of evidence of control of these 'pests' must also take into account differences in morphology of the new crop. Efficacy within a crop may be affected by differences in leaf surface, possibly resulting in differences in spray retention and active ingredient penetration. Differences in shoot structure may cause differences in spray distribution, which may affect the effectiveness of control. Use in crops with a denser leaf canopy may for example result in inadequate spray penetration. Also, differences in the density of leaf canopy and leaf size may affect the amount of product reaching the undersides of leaves - which may be crucial for control of certain pests. The way the dose is specified on the label must also take into account differences in size of the proposed target crops - a statement of dose in terms of a spray concentration to be applied (as opposed to rate per unit area) may be most appropriate when treating infested crops of different sizes.

General guidance on the extrapolation of evidence of efficacy is given in EPPO guidelines. EPPO guideline PP1/306 includes information (in Appendix 6) regarding home garden products and the use of co-formulated mixtures. EPPO guideline

PP1/257 (2) provides information on Efficacy and crop safety extrapolations for minor uses.

Crop safety

Evidence of crop safety should relate to use of product in replicated trials, with (where recommended) repeat applications included at the minimum stipulated (or likely) spray interval. Seedling and mature flowering plants should be included in trials, unless label instructions exclude treatment at these growth stages. As for control claims, the availability of evidence from similar already approved professional use products is likely to reduce the extent of crop safety data required.

Results from single and double dose applications are required for herbicides. For fungicides and insecticides testing at double dose is only required where crop effects are evident at single dose.

Crop safety trials should include post-treatment observations for any adverse visual effects (eg chlorosis, necrosis) and for any effects on crop vigour. For use on edible crops, effects of treatment on yield or yield components (eg for tomatoes effects on flowering and fruit set) should ideally be assessed. For top fruit, effects on fruit finish should also be recorded. Where visual appearance is particularly important eg in ornamental crops, observations should be included for any adverse visual effects resulting from dried spray deposits.

Evidence from crop safety trials can usefully be supplemented by observations made in effectiveness or residue trials, and in some circumstances (eg ornamental use where no yield effects are required to be assessed) these may replace completely or partly the need for specific crop safety trials. However, adequate observations and assessments must be included, with these typically encompassing the range of application growth stages possible, including where permitted use during flowering. Where there is a high level of 'pest' attack, or where 'pest' attack affects quality, any possible adverse phytotoxic effects may not be readily apparent, and therefore in these circumstances observations made in effectiveness trials are likely to be of only limited or no value in supporting the crop safety of the product.

Numbers of trials required to demonstrate adequate crop safety to a particular crop or plant species will vary depending on the quality of the reported trials, the margin of crop safety shown in other crops, and on the extent of testing in other crops. Where only a single crop use is proposed, evidence would usually be required from product use in a minimum of six trials in that crop. For use in additional crops, evidence from a lesser number of trials may be acceptable. However, in order to demonstrate adequate crop safety over a range of environmental conditions, it would usually be necessary for any commercial level of approval to be granted to supply details (at least for initially proposed uses) from a minimum of three well conducted trials per crop. (A lesser number of trials may be permitted for low risk products.)

For herbicides and growth regulators proposed for general ornamental use, where evidence for the crop selectivity of the active ingredient/s has not previously been investigated and reported, replicated crop safety trials should first be conducted on a small number of species, with detailed assessments included in these trials for effects

on top growth, phytotoxicity, root growth and biomass. Given the availability of this detailed evidence, it may then be possible to establish the crop safety of more general ornamental use, by conducted additional screening trials using product at twice the proposed dose across a representative range of species.

Results from small scale replicated pot trials may also be acceptable to demonstrate crop safety, with each trial including a representative range of containerised ornamental species. Occasionally for herbicides, where it is thought that differences in pot and field soil may affect crop safety results (eg due to the often higher organic matter of pot soil), it may be more appropriate for evidence to be supplied from use around field grown plants. Therefore, where this is considered by applicants to be a possible concern, or where for other reasons use of containerised plants is considered unrepresentative of the field situation, evidence from treatment of plants growing in the 'field' should be presented either instead of or in addition to any 'pot trial' evidence.

To support a general recommendation for use in ornamentals, the numbers of ornamental species required to be assessed for crop safety will vary depending on the degree of crop selectivity shown. However, where phytotoxic affects are generally only slight or absent, assessments of crop safety from treatment (in crop safety or in effectiveness trials) of a representative range of approximately 15-20 different ornamental species may well be adequate for this.

Safety to following crops

Evidence of safety to following crops may be based on the results of trials examining the effects on subsequently planted crops (which in addition to field studies may include details of glasshouse screens) and/or on a case based on the fate and behaviour of the active ingredient. For use of a herbicide or growth regulator product on garden lawns, the potential for cuttings from treated grass to be phytotoxic to plants when applied as a mulch or when composted and used as a manure must be addressed.

Because effects on following crops are usually unaffected by formulation type, it will often be possible (assuming data access) for applicants to make a case based on evidence previously submitted for other products applied at equivalent or higher rates of active ingredient.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

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