



# **Efficacy Guideline 120**

GB and NI Efficacy Advice and Product  
Labelling

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# DRAFT REGISTRATION REPORT

## Part B

### Section 3

#### Efficacy Data and Information

Concise summary

Product code: xxx

Product name(s): xxx

Chemical active substance(s):

Active substance 1, xxx g/L or g/kg

Active substance 2, xxx g/L or g/kg

Active substance 3, xxx g/L or g/kg

Active substance 4, xxx g/L or g/kg

Applicant: company name

Submission date: dd/mm/yyyy

Finalisation date: dd/mm/yyyy

## **3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)**

This document specifically addresses the requirements of a Part B, Section 3 (Efficacy Data and Information) draft registration report (dRR) where a GB/NI authorisation is required. National Efficacy assessments are based on complying with relevant European and Mediterranean Plant Protection Organisation (EPPO).

However, this guidance provides advice (under the relevant sections) on the very limited number of GB/NI-specific Efficacy issues that may require additional supporting data. It also includes information in relation to those issues where there is no EPPO guidance (like convenience tank mixtures or supporting IPM claims). In doing so, it also brings together, into one document, the various specific National labelling requirements relating to Efficacy that should be considered when drafting the label. References are also made to GB/NI resistance management restrictions and label phrases. (See 3.2 for further explanation).

Applicants may also find this guidance useful if they wish to base a request for GB/NI authorisation on existing Biological Assessment Dossiers and the accompanying dRRs submitted originally to other Regulatory Authorities. The information here will help applicants amend such documents appropriately.

This guidance should be used in conjunction with the information and examples provided in the EU dRR template and guidance notes for the core Part B, Section 3, which illustrate relevant approaches when summarising data from the BAD into the dRR.

### **3.1 Summary and conclusions of HSE-CRD on Section 3: Efficacy (KCP 6)**

#### **Abstract**

HSE-CRD will provide the main conclusion on whether authorisation of the use is acceptable in GB/NI and briefly explaining the reasons for the conclusions (data missing, relevance of uses, relevant restrictions and proposed warning).

HSE-CRD proposed label amendments will usually appear in Part A.

### **3.2 Efficacy data (KCP 6)**

Applicants should follow EPPO standards, with the information below providing additional guidance on specific GB/NI issues or for situations where there is no

current EPPO standard. Efficacy guideline 106 'General Principles on Conducting Efficacy Trials to Support Registration of Plant Protection Products (PPP) in GB and NI' provides more general background information on conducting efficacy trials.

## General Introduction

In the introductory sections of the dRR it is important to explain:

- how the proposed uses relate to relevant GB/NI existing authorised products and how the uses are supported
- a summary of any changes to currently authorised uses, justifying these changes and indicating how they are supported
- **the relevance of the generated data and proposed GAP to UK conditions.** Applicants should be aware of any statutory conditions imposed due to resistance management (see below). Local target pressure and treatment thresholds for example will determine the number and interval of applications in the treatment programme in any one season. Broadly speaking, for many insect species in the UK there is a tendency not to complete as many generations in a season as elsewhere in Europe. Conversely, disease pressure in the UK tends to be high, reflected by a need for shorter, more frequent applications (particularly curative) or higher doses.
- how the draft label uses and recommendations for GB/NI have been derived from the data for example by using a fully supportive Efficacy package or through comparability to an authorised use
- whether there are particular National issues that should be reflected in the proposed labels

This explanation is particularly relevant when using regional data packages or if basing the proposed use on existing data and submissions that have supported authorisations in other countries. It may be possible for applicants to cross reference to an existing dRR submitted to another regulatory authority, depending on how relevant it is the proposed GAP in GB/NI and the individual uses. Applicants are advised to discuss this with HSE-CRD first.

## Formulation changes

Where applications are made to change an authorised formulation, reference should be made to EPPO standard PP 1/307 'Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products'. This standard provides the criteria in relation to formulation components (and certain situations) where such changes can be made by reasoned

case, comparing the proposed change to the original authorised formulation. Where data are required, the standard also outlines the type and number of supporting trials.

These principles also apply to new generic products, where the application is based on Efficacy data out of protection. The criteria are also relevant where some trials have been generated using earlier prototype formulations and an argument is being made to use these trials in support of the final proposed formulation. The EPPO standard replaces long standing UK guidance, although many of the principles remain closely aligned.

The EPPO standard does not include guidance on supporting changes in active substance content, with this aspect currently subject to individual National requirements. Where changes are proposed for active substances, the GB/NI National guidance is relevant (which is based around permitting up to 10% changes in content compared to the original authorised formulation, without supporting data).

Further information is provided in Efficacy Guideline 105 'Formulation changes and use of 'EPPO PP 1/307'.

## **GB & NI PLANT PROTECTION PRODUCT LABELLING: Efficacy aspects**

### **a) Relevance of proposed target species**

Applicants should consider the relevance of the proposed target species included on the draft label to the current situation in GB/NI, particularly when supported by regional data packages generated in a number of countries. Whilst including data on all species present in the trials can provide useful support, it is important to clearly highlight and justify the relevant situations and/or targets to prevent the need for clarification and delays in evaluation. HSE-CRD has produced several efficacy guidelines and crop guides which give information on what are considered to be major/minor target species. This includes information in the 'CRD efficacy working document summarising UK major 'pests' on a range of UK crops' ([www.hse.gov.uk/pesticides/assets/docs/majorukpests.pdf](http://www.hse.gov.uk/pesticides/assets/docs/majorukpests.pdf)).

Applicants are advised to consult these when drawing up labels **and** also when determining if the pest is supported by an appropriate number of trials (i.e. is the pest major or minor in GB/NI).

It is acknowledged that the pest/target spectra on a particular crop can change over time, as indeed can the commercialisation of new crops. There are instances, particularly for insect pests, where the prevalence of some existing species (or new species) is becoming more common. The onus is on the applicant to demonstrate that the proposed target species are found in GB/NI. It is accepted that these instances may be sporadic, in either location or frequency over the seasons. But to be considered as a named target on a GB/NI label, evidence is required that when

the pests do occur, economic damage justifying treatment with a plant protection product is warranted. In this regard, information and evidence of the impact of the proposed target provided by relevant growers can be very helpful.

HSE-CRD has operated a system of 'qualified recommendations' designed to support claims for minor/sporadic pest species. This recognised the costs and sometimes the impracticality of generating data on such species or generating data in crops not widely grown in the UK. The scheme was based on extrapolation from either limited data (or no data) generated on relevant related crops/targets. It is noted that applicants now often generate data across wide ranging locations outside the UK, and therefore appropriate data may be available on the pest/use from trials generated in other countries where the pest/use is more prevalent.

The same principles were subsequently taken forward in the development of the relevant extrapolation possibilities specified in the EPPO Minor Use Extrapolation Tables. Applicants should use EPPO as the primary approach to supporting uses based on limited data and/or direct extrapolation from other relevant authorised uses. If the proposed use is not specified in the relevant EPPO tables, applicants may still propose a reasoned case for a 'minor' use (i.e. sporadic pest or use not widely distributed in UK) explaining how the use is being supported. (EPPO standard PP 1/257(1) 'Efficacy and crop safety extrapolations for minor uses' describes the various relevant approaches to consider in making the case). If acceptable, there should be a sentence noting that the relevant use is based on limited effectiveness and/or crop safety data (as appropriate).

For example, a disease claim on leeks in addition to other fully supported label disease claims might be described as:

Limited effectiveness data indicate some control of White tip (*Phytophthora porri*) (PHYTPO). Conditions of use for leeks described in the 'Important Information' box must be followed'. (NB in this example because other diseases on leeks were fully supported, crop safety was established and it is not necessary to indicate 'limited crop safety')

There are some common European pest species that are statutory pests in GB/NI and subject to specific plant health measures, or on the UK Plant Health Risk register but are not yet established. Such pest species are not permitted as targets on GB/NI product labels, but DEFRA Plant Health will be informed on the potential availability of relevant authorisations, should control measures be required. Current examples include Colorado beetle (*Leptinotarsa decemlineata*, LPTNDE ) and Western corn rootworm (*Diabrotica virgifera*, DIABVI ); Japanese leaf rust (*Gymnosporangium asiaticum*, GYMNAS).

## **b) Claims of control**

GB/NI operates a system of differential claims for any particular target species, based on the level and consistency of control, and applicants should draft the label in accordance with this scheme. Where relevant, it may be helpful to point to the appropriate sections of the assessment to illustrate the levels of control obtained. This is reproduced below:

### **Insect Pests**

In considering data submitted towards justification of claims of effectiveness against pests, a number of factors will need to be taken into account when considering and interpreting the level of control demonstrated. These include the time of assessment in relation to application, the duration of effectiveness and the potential for re-invasion, and any recommendations for repeat applications.

**Table 1: Levels of pest control expected for effectiveness claims**

<b>Level of effectiveness</b>	<b>Label claim appropriate</b>
Consistent control commonly above 80%	Control
Control, between 60 and 80%	Useful level of control (moderate control may also be used)
Lower levels of control e.g. 40-60%; lower in exceptional cases	Some control/reduction (in numbers or damage)

For a claim for effectiveness below 80% to be supported authorisation, the level of control demonstrated for that pest must be considered beneficial for protection of the crop. For some pests particularly those affecting the quality of the crop, higher levels of consistent control (i.e. above 85%) would need to be demonstrated to support a claim of 'full' control. Examples of pests falling into this category are pea moth (LASPNI) and codling moth (CARPPO).

### **Diseases**

Disease may be assessed as either severity or incidence however, for the majority of foliar diseases, severity is used. Measurement of disease incidence is particularly useful when low levels of disease are present but may be of little value when infection is more widespread, when severity is more likely to give a useful

measurement of disease control. Guidance on what should be reported is usually given in the EPPO standards for the disease. Table 2 a) indicates the levels of control expected to be demonstrated to support label claims for diseases and should be used where either severity or incidence are recorded as a percentage or other linear scale.

**Table 2a: Levels of disease control expected for effectiveness claims**

<b>Level of effectiveness</b>	<b>Label claim appropriate</b>
80% and above	Control
60-80%	Partial/moderate/useful level of control
40-60%	Reduction/some control

These criteria are not appropriate in cases where disease control is assessed as a score on a non-linear scale. These scales are often relatively coarse with as few as four divisions. With such scales meaningful levels of control can be difficult to determine unless disease pressure is relatively high. Table 2b) indicates the levels of control expected to be demonstrated to support label claims for diseases where measurements are made on a non-linear scale. In addition, statistical analysis of assessments on a non-linear scale is generally inappropriate. Even the calculation of means should be avoided. When recording and assessing such results it may be better to assign letters rather than numbers to the steps on the scale to avoid the temptation to analyse them numerically.

**Table 2b: Levels of disease control expected for effectiveness claims when using a non-linear scale**

<b>Level of effectiveness</b>	<b>Label claim appropriate</b>
Consistently reduces disease to below 20-25%, normally the lowest class.	Control

Reduces disease to <20-25% in the majority of cases	Partial/moderate/useful level of control
Clear reduction in disease	Reduction/some control

For some diseases, particularly those affecting the quality of the crop, higher levels of consistent control will need to be demonstrated. For a claim of control of seed borne pathogens (e.g. bunt (*Tilletia caries*, TILLCA), loose smut (*Ustilago segetum var. tritici*, *Ustilago segetum var. nuda*, *Ustilago segetum var. avenae*, and *Ustilago segetum var. hordei*, USTINT, USTINH, USTIAV and USTIAV), leaf stripe (*Pyrenophora graminea*, PYRNGR)), a product needs to be 98% effective or better. For leaf stripe and loose smut, control in the region of 85-95% would allow the claim for moderate control with the condition that seed cannot be used for multiplication purposes.

In some cases, an argument may also be made for higher claims than are justified by disease control alone. For stem base diseases of cereals, for example, a claim of control may be appropriate even when disease control is not consistently above 80%, if it can be shown that the treatment significantly reduces lodging and/or disease levels are kept to a level where they have no significant effect on yield.

## Weeds

In arable and horticultural field crops, the label claim supported by a certain level of weed control is as follows:

**Table 3: Levels of weed control expected for effectiveness claims**

Label claim appropriate	Level of effectiveness
Susceptible	Consistent control of 85% and above (see below †)
Moderately susceptible	More variable control, mean 75-85%, but with results often above 85%

Moderately resistant	Variable control, Mean 60-75%, but some results above this level.
Resistant	Poor control below the levels given above

† To ensure worthwhile levels of control of certain important weeds in field crops, all these categories are raised with the susceptible rating being as follows: pernicious grass weeds where seed return must be prevented, e.g. black-grass (ALOMY) and wild-oats (AVESS), 95% and above, cleavers (GALAP) 90% and above.

For perennial weeds, assessments of control levels in the year following treatment will be important in determining the claim allowed.

### **c) Population levels in trials**

It is essential that populations of the target organisms (weeds/pests/diseases) in effectiveness trials are present at agronomically significant levels in order to provide a sufficient challenge to the treatments applied. In most cases, the size of the pest population present immediately before treatment application will be the most relevant measure of the initial pest challenge. However, in the case of pre-emergence herbicides or fungicides claiming 'protectant' activity for example, this information will not be available and the pest levels on untreated plots at later assessment timings will need to be considered instead.

Note that the initial level of the target organism is not the only measure of an adequate pest population. Pest levels on untreated plots must be maintained, or increase, throughout the duration of the trial. Trials where adequate initial pest levels on untreated plots subsequently decline (in the absence of treatment) are unlikely to provide evidence that a sufficient pest challenge existed on the treated plots, however it may be possible to utilise the results from assessments made just before the population starts to significantly decline.

For fungicide and insecticide trials, where the target population does not reach (or maintain) an adequate level, phytotoxicity assessments (and yield, if required) can still be carried out to provide support for crop safety. It is not appropriate to have a prescriptive list of 'minimum populations' for all possible target organisms but indicative levels for weeds, diseases and insects/other arthropods in various crops are given below. Where data are submitted from non-UK based trials, information on local thresholds should, where available, be provided in the Biological Assessment Dossier.

It would normally be expected that at least some trials would be conducted on pest populations much greater than the minimum acceptable population. However, provided the majority of trials within a dataset have above minimum pest levels, the occasional near-but-below-threshold level should not be considered unacceptable. Note that it would not generally be acceptable to have all trials with infestations at or close to the minimum level. At least some trials in a series should have infestations considerably above the minimum.

It is recognised that applicants may include data generated at non-UK trials sites in their submissions. It is important that in these cases information is provided on the local relevant threshold for the pest(s) in these trials. This information should be used to provide a reasoned justification both for the validity of the trial and their relevance to UK conditions.

## Weeds

In general, a minimum population of 5 plants/m<sup>2</sup> for each weed species being tested is required for a trial to be considered valid. However, particularly for major weeds such as black-grass (ALOMY) or cleavers (GALAP), some data should be submitted from much greater population levels.

For grass weeds, the definitive assessment will often be the 'head count', and in general the minimum acceptable number of tillers in the untreated plots is 20/m<sup>2</sup>.

In the case of major grass weeds such as black-grass (ALOMY), ideally some data should be submitted from trials where populations exceed 100 heads/m<sup>2</sup>.

Overall, trials should cover a range of weed population sizes and should include some large, challenging populations.

## Diseases

For most diseases, an incidence of at least 5% plants infected or 5% leaf area infected is the minimum level required. For curative claims this should be the level of infection at application. For preventative claims it will be the level at assessment. In some cases, depending on the pathogen, the assessment methodology and sample size, higher disease levels may be required. For example, diseases of oilseed rape are often assessed on a scale of 1-4 and disease levels must reach at least the second point on such scales, which may be equivalent to 50% infection. For diseases such as potato late blight (*Phytophthora infestans*, PHYTIN), measurement of the delay in foliage blight reaching a specific level of infection (usually 25% leaf area affected) would be acceptable. In trials with low levels of infection, there may still be scope to use these data by increasing the sample size assessed and providing a case and justification why the data would be acceptable. However, sufficient data are required from trials where there has been an adequate level of disease challenge to determine the claim level.

Certain seed-borne diseases on cereals e.g., bunt (*Tilletia caries*, TILLCA) and smuts (*Ustilago sp.*, USTISP), typically occur at very low levels in commercial seed. However, use of seed with low infection levels in trials may be acceptable where there is potential for very rapid multiplication of the pathogen and where very high levels of control are required. However, sample size for assessment may need to be increased.

Artificial inoculation of a pathogen may be used to obtain challenging levels of disease. If artificial inoculation is used, the whole trial should be inoculated evenly, and a suitable period of time must be allowed to permit disease establishment before treatments are applied. The inoculum used should be representative of the disease pathogen in the UK. Natural or artificial level of infection of seed lots should be assessed prior to the trial by an appropriate method.

### **Insect and other arthropods**

Specific agronomic treatment thresholds have been established for many of the main crop/pest combinations, and available by various advisory/research organisations. For example, the Agriculture and Horticulture Development Board (AHDB) 'Encyclopaedia of pests and natural enemies in field crops' provides detailed information for field crops on the current range of pests and associated available UK treatment thresholds. In general, available thresholds should be viewed as the minimum level for efficacy trials. Where no treatment-threshold exists, the occurrence of agronomic damage on untreated plots may be used to justify the pest population. The majority of trials should be carried out on naturally occurring pest infestations, but artificial introduction may be used to boost pest populations in some trials. Where this is used, sufficient time must be allowed for the introduced individuals to become established before treatments are applied.

### **d) Winter and Spring Crops**

Note that under UK Crop Definitions 'winter' and 'spring' refers to the time of the year when the crop is planted rather than the variety sown. Therefore; For products authorised on winter crops:

"This product is authorised in winter sown crops. Growers choosing to apply this product to winter sown spring varieties should note that crop safety has not been demonstrated in spring varieties. As a result, application of this product to winter sown spring varieties is done so at the growers own commercial risk (and this also applies to unclassified varieties)."

For products authorised on spring crops:

"This product is authorised in spring sown crops. Growers choosing to apply this product to spring sown winter varieties should note that crop safety has not been demonstrated in winter varieties. As a result, application of this product to spring sown

winter varieties is done so at the growers own commercial risk (and this also applies to unclassified varieties).”

(Full information on the UK Crops Definition List is available from the HSE website):

[www.hse.gov.uk/pesticides/databases/crop-hierarchy-introduction.htm](http://www.hse.gov.uk/pesticides/databases/crop-hierarchy-introduction.htm)

Application to spring varieties sown in the winter (and vice versa) **is likely to be at the growers own commercial risk**. This is because crop safety and effectiveness may not have been demonstrated on spring varieties sown in the winter (or vice versa). The relevant phrase will be added to the label of professional products which have a specific authorisation for winter crops but not spring (or vice versa) (and which are not seed treatments), where relevant data on all varieties is not provided.

### **e) Reducing product label water volumes**

It is recognised that, to reflect changes in agronomic practice, lower water volumes than those previously specified on PPP labels may be required. In order to make such changes to the label, CRD introduced a specific procedure to address both Operator Exposure and Efficacy concerns. Full details on where efficacy can be addressed by a reasoned case, or may need specific data, are provided in our guidance on supporting label changes for pesticide product use in reduced water volumes at: [www.hse.gov.uk/pesticides/applicant-guide/supporting-label-changes-reducedwatervolumes.htm](http://www.hse.gov.uk/pesticides/applicant-guide/supporting-label-changes-reducedwatervolumes.htm)

### **f) Environmental protection recommendations using drift reduction technology**

Where drift reduction technology is recommended on the PPP label but has not been used within the supporting effectiveness trials, the following phrase must be added in the 'Directions for Use' section: *'Effectiveness using three star drift reduction technology may be reduced'*.

Full details can be found in 'the Labelling Handbook', Volume 2 - Requirements for Professional Product labels, Appendix 5 – Environmental Protection, available at [www.hse.gov.uk/pesticides/labelling-handbook/index.htm](http://www.hse.gov.uk/pesticides/labelling-handbook/index.htm)

### **g) Labelling of Molluscicide Products**

In the UK traps baited with molluscicide pellets were historically used to assess the risk of damage in cereals by estimating slug populations. The potential hazard to wildlife meant this practice was stopped and has been replaced with non-toxic chicken layer's mash (commercial poultry food). A research project calibrated the method using this bait to establish a threshold for winter wheat and established a relationship

between numbers trapped in cereal crops and stubble prior to drilling winter oilseed rape.

The method and relevant thresholds are published on the Agriculture and Horticulture Development Board (AHDB) website. The following label wording must appear on all professional molluscicide products:

*“For further information on slug trapping and damage risk assessment, please refer to AHDB Information Sheet 02 ‘Integrated slug control – risk assessment and monitoring slug damage’, available on the AHDB website’*

In addition, there are further advisory paragraphs which applicants may choose to add:

- for product labels that wish to include specific information on damage risk assessments using bait trap methods in winter wheat and winter oilseed rape, the following, or words of similar meaning, can be added.

*“To establish the need for pellet application on winter wheat or winter oilseed rape, monitor for slug activity. Where bait traps are used, use a foodstuff attractive to slugs e.g. chicken layer’s mash which has proven to be particularly effective. DO NOT use slug pellets as bait in traps since they are a potential hazard to wildlife and pets.”*

- for product labels that wish to include details of the actual method on their product labels, appropriate suggested wording is as follows:

*“Put slug traps out before cultivation, when the soil surface is visibly moist and the weather mild (5-25°C). Traps consist of a cover about 25cm across, with a small heap (20ml or 2 heaped teaspoonfuls) of chicken layers’ mash (NOT slug pellets) beneath. In each field, nine traps (13 in fields larger than 20ha) should be set out in a ‘W’ pattern. Also concentrate on areas known to suffer damage.*

*Leave traps overnight and examine early the following morning.*

*FOR WINTER WHEAT, a catch of 4 or more slugs/trap indicates a possible risk, where soil and weather conditions favour slug activity. FOR WINTER OILSEED RAPE a catch of 4 or more slugs in standing cereals, or 1 or more in cereal stubble, if other conditions were met, would also indicate possible risk of damage.”*

## **h) Use of PPP products with adjuvants**

There are some PPPs which include recommendations for use in tank-mixture with an adjuvant. This is generally:

- to enhance activity (such as broader pest spectrum or higher control levels) compared to the product used alone as in a positive tank-mixture
- where the PPP must always be used with an adjuvant to achieve efficacy with no claims associated with use of the product alone

**In all cases** where use with a specific adjuvant is recommended:

- evidence of physical and chemical compatibility is required - for further details, read our guidance on tank-mix recommendations on pesticide product labels at [www.hse.gov.uk/pesticides/applicant-guide/tank-mixrecommendationspesticidelabels.htm](http://www.hse.gov.uk/pesticides/applicant-guide/tank-mixrecommendationspesticidelabels.htm)
- the adjuvant must appear on the UK's Official List of Adjuvants (<https://secure.pesticides.gov.uk/adjuvants/Search.aspx>)
- the adjuvant must be named on the label
- efficacy data must be generated with that adjuvant
- the amount of adjuvant required must also be stated on the label and efficacy trials must be conducted in accordance with this

In some cases, the label may recommend use of the product with any adjuvant from an adjuvant class for example petroleum oils. In this case data are required to show that the efficacy of the product is similar for a range of different adjuvant products within the same adjuvant class.

However, if the product has been tested with a specific adjuvant and the applicant wishes to include use with any other adjuvant of the same type then this is acceptable. For example if the efficacy data were generated using a 99.0 % w/w oil (petroleum oils) then it may be appropriate for the label to specify use with any other 99.0 % w/w oil adjuvant (petroleum oils).

### **3.2.1 Preliminary tests (KCP 6.1)**

This point is usually considered to be addressed by reference to the information submitted for the first authorisation of the active substance. However, the section can be particularly relevant for proposed new co-formulated mixture products in providing data/evidence to support the inclusion of actives and ratio within the co-formulation. (Alternatively, this can be provided under 3.2.2). Full details are available in PP 1/306 'General principles for the development of co-formulated mixtures of plant protection products'.

Initial screening data demonstrating lack of, for example, fungicidal activity for an insecticide or herbicide can also be referred as support, if proposing a new use where transformation processes need to be addressed. Or demonstrated lack of herbicidal activity could help support crop safety on succeeding and adjacent crops.

### 3.2.2 Minimum effective dose tests (KCP 6.2)

Where the submission includes regional data, not only that from the UK, it is important to consider the relevance of the target pest and crop to the UK (including major/minor status) and proposed GAP, and agronomic conditions. For example, supporting ‘aphids on Brassicas’ may include data generated in several countries with several aphid species.

But is there sufficient dose ranging evidence for key species such as peach-potato aphid (MYZUPE). The introduction should also discuss pest pressures. For example, HSECRD may accept data from Southern Europe to support effectiveness against insect species – because this will represent a particularly challenging pest pressure situation. However, such data would not be acceptable to support dose justification because under GB/NI conditions a lower dose may be sufficient. Other circumstances may include dose expression in three dimensional crops, where further justification and explanation must be provided. This particularly applied in pome fruit, where EPPO PP 1/239 recommends using amount/ha leaf wall area (LWA), but UK labels express as amount/ha (see 3.2.3).

### 3.2.3 Efficacy tests (KCP 6.2)

#### a) General

Efficacy submissions to GB/NI must follow all relevant EPPO standards. Authorisations can be supported by ‘regional’ data packages, which include non-UK data. Reference should be made to EPPO PP 1/278 ‘Principles of zonal data production and evaluation, which provides principles on all those factors to consider when trials planning and/or justifying the use of the data. Examples are also provided, some of which are relevant for

GB/NI:

[https://www.eppo.int/ACTIVITIES/plant\\_protection\\_products/zonal\\_assessments](https://www.eppo.int/ACTIVITIES/plant_protection_products/zonal_assessments)

Applicants should also refer to the relevant EPPO Minor Use Extrapolation tables and associated EPPO PP1/257 ‘Efficacy and crop safety extrapolations for minor uses’.

Guidance on the number of fully supportive trials required for a ‘pest’ are given in the Efficacy Crop Specific Guidelines at

[www.hse.gov.uk/pesticides/efficacyguides/index.htm](http://www.hse.gov.uk/pesticides/efficacyguides/index.htm). It is noted that these guidelines specify the number of ‘fully supportive trials’ and therefore more than this number of trials may need to be undertaken in order to obtain a sufficient number of trials to support the authorisation (for example where the effectiveness trials have low pest infestation).

Where there are potential problems in supporting a GB/NI authorisation, commonly, it is due to insufficient data on target pests which are major in GB/NI, or the data are not typical of conditions. This tends to apply to fungal pathogens, where GB (and NI) disease pressures can be higher than in other EPPO zones; certain cereal diseases

which are also major in GB/NI but minor elsewhere; or important grass weed species in GB/NI where there is widespread resistance to a number of current herbicides. In these cases the data package should include a proportion of UK trials. And as noted above, more challenging conditions than the UK can provide a robust data set, but are not suitable evidence by themselves to support dose rates in GB/NI. It is also important to remember and address in the argumentation for relevance, other issues, such as any differences in timings, thresholds, growth stages of pest/crop etc. For example, winter sown cereals and winter sown oilseed rape predominate in the UK, which can impact on target pest species, and should be reflected appropriately in the data package.

As noted above, information is available in various efficacy guidelines on major/minor pest status for some crops. Applicants should also refer to other relevant published guidance, such as Agriculture and Horticulture Development Board ([www.ahdb.org.uk](http://www.ahdb.org.uk)), which has a number of detailed guidelines on cereals, oilseed rape, and horticultural crops. These include information on major UK pests. For insects, the AHDB '*Encyclopaedia of pests and natural enemies in field crops*' is a comprehensive guide and includes the available information on UK treatment thresholds. For weeds the AHDB '*Encyclopaedia of arable weeds*' contains information on common broad-leaved and grass weeds in the UK, including how to identify and manage them.

For product labels, the correct English common name for each weed species can be found on the Botanical Society of Britain & Ireland website ([www.bsbi.org](http://www.bsbi.org)).

### **b) High growing crops, including pome fruit**

EPPO PP 1/239 recommends leaf wall area (LWA) as an appropriate common dose expression method in efficacy trials for high growing crops. It also emphasises the need to record all relevant structure parameters in order to then convert, where relevant, to any National dose expression method. In GB/NI, dose is generally expressed on product labels as an amount/ha (sometimes % concentration is also included, but amount/ha is a requirement both for efficacy and other areas of the risk assessment). Therefore whilst the dossier may express the dose applied in the effectiveness trials as LWA, this must be appropriately converted onto GB/NI GAPs and draft labels as amount product/ha. It is possible for both a LWA rate as well as a rate/ha to be given on the label, but it must always be ensured that they both make sense. In pome fruit, the relevant UK conversion from LWA into product/ha is based on a standard UK orchard structure of 3.5 m single row distance and 3 m high). The conversion factor for a standard UK orchard (as described above) is therefore 1.7 LWA per ha (ground). This is based on a UK standard orchard having a LWA of 17 143 m<sup>2</sup>.

It is recognised that growers use their experience to adjust the label recommended dose during the season in response to tree size and growth. UK funded research developed a common scheme for use in apple orchards: Pesticide adjustment to the Crop Environment (PACE) scheme. The scheme provides a series of pictographs of typical apples trees of different canopy density to aid assessment of the 'Crop

Adjustment Factor' (CAF) used to calculate the applied pesticide dose in a given orchard. The label should generally recommend the higher dose applicable to a full tree height in a typical UK orchard (e.g. 33.5 m) at full canopy density (CAF value of 1). (This is unless the label specifies a particular pre-blossom or early season recommendation). Ideally the tree height should also be specified on the label. In addition, the label could usefully include wording to note that where tree height and or canopy density is reduced, the dose (and water volume) should be adjusted in accordance with an appropriate dose adjustment scheme (see AHDB for further details).

Applicants should also be aware that typical UK practice is to use low water volumes (100300 l/ha) on pome fruit, and some other high growing crops. The data package should ideally include trials conducted at this lower range, since the package should be typical of the range of conditions.

### **c) Concentration**

Some products are specified for use at a given concentration and the trials undertaken must use the specified concentration. Additionally, the rate/ha must also be given and it may be necessary to specify a maximum water volume for the crop so the rate/ha is not exceeded.

## **3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)**

For those targets considered to be a high resistance risk in GB/NI, and for which a resistance management strategy is required, applicants are expected to consider, and where necessary adapt, any proposed strategies (for example as recommended by the industry 'Resistance Action Committee' (RACs)) to UK conditions. As part of this, consideration should be given to pest pressures, and relevance of the GAP (including number of applications as part of the required season long treatment programme). There is a range of available information, starting with the UK Resistance Action Groups (RAGs), which give information on current resistance issues, as well as publish various specific guidance. The groups are hosted by the Agricultural and Horticultural Development Board: <https://ahdb.org.uk/irag> <https://ahdb.org.uk/wrag> <https://ahdb.org.uk/frag>

In addition, CRD have produced specific product type guidance, which includes information on GB/NI specific label wording and, in some cases, statutory restrictions. These restrictions are based around limiting the number of applications for a specific mode of action (MOA) group on particular targets, for example neonicotinoid insecticides, azole fungicides, and ACCase/ALS inhibitor herbicides.

### **Guideline**

601:      Insecticides/acaricides }



### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

This should be addressed in accordance with relevant EPPO standards.

### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

As a general comment, appropriate assessments of the relevant quality parameters for a crop are often poorly addressed in the data submissions. Applicants are reminded they should address this, for all product types, through reference to relevant EPPO standards, particularly EPPO PP 1/135 'Phytotoxicity Assessment'.

#### Apples and pears

The principal UK commercial varieties are 'Gala', 'Cox' and 'Bramley' (apple), and 'Conference' (pear). All these varieties are prone to russetting, and there have been historical cases of pesticides increasing these effects. It is important that this aspect of crop quality is satisfactorily addressed for these UK varieties. Applicants may be able to refer to an appropriate range of tested varieties within the data package, but it is important to highlight which of the non-UK varieties tested are also sensitive to russetting. Alternatively, specific data should be provided on the above-named UK varieties. If there is insufficient data/evidence of safety to the major UK varieties the following label warning will be added: "*Crop safety on 'Gala'/'Cox'/'Bramley'/'Conference' has not been established*".

#### Taint

For certain crop/product type uses, it is necessary to consider the possibility of taint. Full details on when and how to address these issues are available in EPPO standard PP 1/242 'Taint tests'. CRD require the high-risk situations described in the standard to be addressed. This should include all crops destined for processing, but other crop uses may need some further consideration, on a case by case basis.

Where taint has not been addressed for the relevant crops, the UK label will carry the warning as described in 1/242(1), listing the specific crops where taint has not been addressed:

'CONSULT PROCESSOR BEFORE USING ON [*listed crops*] FOR PROCESSING.'

### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Please refer to the core assessment Part B, Section 3.

For certain crop/product type uses, it is necessary to consider the potential impact on (biological) transformation processes. Full details on when and how to address these issues are available in EPPO standard 1/243 (1) 'Effects of plant protection products on transformation processes'.

### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Please refer to the core assessment Part B, Section 3.

Applicants should refer to EPPO 1/135 on the requirements for any further testing, and under what circumstances. It is important to note (particularly for herbicides/PGR), that if appropriate data is not provided restrictions may be added that could have significant commercial impact on using the product (for example not to be used on crops grown for seed).

## 3.5 Observations on other undesirable or unintended side effects (KCP 6.5)

### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

#### Herbicides: Succeeding Crops, and ALS Sequences

- A detailed risk assessment covering succeeding crops (rotational and replanting/crop failure) is required, covering an appropriate range of crops, and more than one typical UK crop rotation scenario (encompassing the worst case situation). This should be conducted in accordance with relevant EPPO standard PP 1/207. Applicants should focus on, particularly if basing on existing data/assessments, what are the sensitive indicator crop species and crop rotation scenarios (including planting intervals) relevant to the UK? For example, maize is not common in a UK crop rotation. Has the predominance of autumn sowing in the UK been covered in the core risk assessment? The applicant may need to consider further the need for specific UK risk mitigation and label warnings.
- In addition to the above, the applicant must address the specific issue of the use of sequences or mixtures of acetolactate synthase (ALS) inhibiting herbicides. Such herbicides have been identified in the past as presenting a particular risk to succeeding crops when used under UK conditions and UK labels typically prohibit mixtures or sequences of herbicides containing ALS inhibitors. It is possible to remove this restriction, by submission of appropriate data. Applicants should refer to Efficacy Guideline 303 for full details. (**This restriction is distinct from those in place on resistance grounds** as outlined in Efficacy Guideline 611).

#### Fungicides/Insecticides

- This point must be addressed for new active substances in accordance with EPPO standard PP 1/207. Particular use of screening data on a range of mono- and di-cotyledon plant species may demonstrate inherent lack of herbicidal properties. And therefore the assessment can stop at the first stage. For product authorisations, reference can be made to information on the activity of the active substance, but it is important to consider and at least provide a reasoned case for any proposed new crops. An updated succeeding crop assessment is required where the Predicted Environmental Concentration (PEC) in the soil is higher than that previously evaluated for that active.

### **3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)**

This should be addressed in accordance with relevant EPPO standard (PP 1/256).

### **3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)**

Detailed studies on the potential adverse effects to beneficial organisms are summarised in part B, Section 9 Ecotoxicology. Any observations in the Efficacy trials should also be recorded.

Further specific data are only required if specific positive claims are proposed on labels regarding compatibility of the product with Integrated Pest management. Claims such as 'IPM compatible' are generally discouraged because such a broad based statement is difficult to support without an extensive data package (unless an argument can be made based on the mode of action e.g. a biopesticide). Instead claims relating to specific beneficial species (usually commercial species used in certain crops) are more easily supported by data, for example safe re-introduction periods or highlighting temporary adverse effects. Such claims can be supported in part by reference to relevant ecotoxicology data. However, further data would be required under more realistic conditions to consider e.g. effects of predators eating treated prey, effects of contact with pesticide residues on plants (either direct lethal affects or on fecundity).

In situations where biological control is commonly practised (e.g. top fruit, glasshouse crops), if no information is provided on IPM compatibility, a label warning will be added:

*'Safety to beneficial organisms used in IPM systems has not been established and cannot be assumed'*.

## **3.6 Other/special studies**

### **a) Molluscicide pellets**

GB/NI has specific requirements for molluscicide pellets, based on their long-term use in the UK and high slug pressures. The requirements relate to quality aspects of the pellet to ensure there is not a significant breakdown of pellet during application, or for the duration of control. There is also specific standardised methodology where labels include claims over the properties of pellet in relation to periods of rainfall. Both methodologies are included in EPPO PP1/95(4) 'Slugs':

- Observe palatability and pellet integrity over the course of the effectiveness trial.
- Evidence of satisfactory flow and retention of pellet/seed integrity during application through representative commercial machinery is required. The applicant can argue on the relevance of the commercial machinery used in this assessment.
- Molluscicides also have specific requirements if the product label makes specific statement on the 'shower proof' or 'rain proof' properties of the pellets, these must be supported by data.

When conducting a **pellet integrity** test, applicants are reminded to use the intended commercial formulation and extrusion method. The data should be generated from a rolling test as opposed to standing, and to make appropriate observations during hopper loading and actual application in addition to the pellet integrity score post application. If significant pellet breakage occurs during application when the application machinery is set-up to represent the 'worst case', applicants may wish to consider re-iterations of the test using different set-up parameters to identify those conditions which result in the acceptable retention of pellet integrity. Such information could then be used to support appropriate label wording and advice to users on the set up of the application machinery rather than, for example, having to apply label restrictions which may arise from 'worst case' scenarios. HSE-CRD Efficacy team can always be contacted if further advice is felt useful prior to testing.

## **b) Seed treatments**

It should be noted that claims of activity against unnamed seed/soil-borne pests are generally not allowed. In addition, GB/NI labelling policy is to have only one recommended dose, which is based on the major pest target (and on which dose justification is based).

All seed treatments must be labelled with the following precautionary general statement:

*'Sowing treated seed that has been stored for prolonged periods (beyond the season of treatment) may adversely affect effectiveness and/or crop safety'*

This does not preclude companies from choosing to support a specific label claim concerning the period of time treated seed may be stored before sowing. In such instances, data should be generated with the storage period in any studies reflecting the length of time proposed on the label. These data follow the requirements for seed treatments when not stored and are fully described under the relevant chemistry sections of the data requirements.

The data should cover the satisfactory retention of the chemical and physical properties of the seed treatment product in its container, and demonstrating satisfactory loading of the product on the seed when treatment is made by commercial seed treatment machinery.

The suggested minimum retention of active ingredient(s) is 70 % of the initial target dose, and this is the level that would be usually expected after the claimed storage period. Alternatively, a case for satisfactory retention of active ingredient(s) may be made based on the biological effectiveness of the product. For example, effectiveness trials using treated seed that has been stored for the relevant time period before sowing.

**Seed drill tests** – Please note that for all treated seed (and pelleted formulations), evidence must be provided to demonstrate the satisfactory flow of treated seed through the relevant seed drill mechanism(s) available commercially.

Comparison should be made with untreated and standard treated seed from the same batch.

### **c) Convenience tank mixtures**

A convenience tank mix is the combination, by the user, of two or more pesticides in the same spray tank to reduce the number of spray operations. No efficacy data are required to support applications for convenience tank-mixes. Evidence of physical and chemical compatibility continues to be required.

Further details are available in the Applicant Guide: Tank-mix recommendations on pesticide product labels at <https://www.hse.gov.uk/pesticides/applicant-guide/tankmixrecommendations-pesticide-labels.htm>. NOTE – this does not change the requirements for positive recommendations (with other pesticides or adjuvants), which still require supporting efficacy data; or for ALS herbicides (see Efficacy Guideline 303: Effects on Non-Target Crops of Highly Active Herbicides – including Mixtures and Sequences’; or anticholinesterase products.

### **d) Rainfastness**

An evaluation of rainfastness is only required where the applicant is making a specific positive label claim that their product is rainfast within a specified number of hours. Example label claims might be:

- ‘Rainfastness within 6 hours’
- ‘Rain within 4 hours will not affect product performance’
- ‘Apply to dry foliage when rain is not expected for at least 2 hours’
- ‘Do not apply if rain is expected within 6 hours’

Such phrases generally, but not exclusively, appear under the ‘Restrictions/Warnings’ section of the label. Information on how to support such claims is in Efficacy Guideline

119 (Efficacy Guideline 119 Rainfastness of foliar applications) at [www.hse.gov.uk/pesticides/assets/docs/g119.pdf](http://www.hse.gov.uk/pesticides/assets/docs/g119.pdf).

Many products contain the phrase ‘Do not apply if rain is expected’. This is not a positive specific rainfastness claim but is good agricultural practice and does not need efficacy consideration.

### **3.7 List of test facilities including the corresponding certificates**

Please provide appropriate details about the test facilities. For any trials conducted in the UK by a GEP facility, reference to the relevant UK-ORETO number may be made instead of submitting the actual certificate.

## Further information

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