

EFFICACY GUIDELINE 407: UK Pests of Cereals and Maize, including number of fully supportive trials required to demonstrate effectiveness

CRD Efficacy Team

CRD Efficacy will be developing a series of crop guides, including information on agronomy, relevant UK pests and how to support UK authorisations and label claims. In the short term, this information paper provides key information for cereals and maize on the relevant UK pests. (This replaces the previous historical information for cereals provided in Chapter 8 Guidance on Efficacy Requirements). This information paper covers only effectiveness trials on the target pest, and applicant should refer to relevant EPPO standards regarding all relevant aspects of crop yield, quality etc.

In Appendix 1, details are provided of the UK PPP scheme of differential label claims describing the expected levels of control.

UK Definition of Winter and Spring Crops

In January 2015 an important change was made to the qualifiers used to define spring and winter crops. The qualifiers changed from being based on variety to being based on the time of year in which the crop is planted. This change better reflected the environmental risk assessment and allowed growers more flexibility to plant spring varieties in the autumn.

A clarification has been added to these qualifiers to highlight that 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.

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).”

UK Pests and Supporting a UK Authorisation

Information is provided below on UK pest complex for cereals and maize, alongside an indication on the required number of fully supportive effectiveness trials to support a UK authorisation. These numbers are based on the EPPO PP 1/226 ‘Number of Efficacy trials’,

and indicated supportive results for major (6-15) and minor (3-6) pests. The indicated number (for example, 10 supportive results for a major pest), is based on assuming there are no other relevant supporting data (e.g. same/related pest on a different crop; or existing authorised uses on a relevant product). There is always scope for cross-supporting with other additional data, which may reduce the required number of results on an individual pest. (For example, cereal aphids are considered major as a group, but 10 supportive results would not be required on every individual species). As always, the applicant should fully justify and explain how the generated data support the claim.

Whether UK-only, or part of a wider sought authorisation, CRD Efficacy has always accepted data generated from non-UK regions, provided there is an appropriate case for relevance (covering agronomy, pest, climate, edaphic factors, and pest biology). The UK is within the EPPO ‘Maritime’ region (see PP 1/241 ‘Guidance on comparable climates’), and therefore climatic comparability for trials generated within this region requires no further justification. However, it should be remembered other relevant agronomic factors should also be covered in any reasoned case for relevance (described in the standard).

If data are being generated to support not only authorisation in the UK, but in a number of other countries, on a regional or zonal basis, PP 1/278 ‘Zonal data production and evaluation’ provides further relevant guidance alongside the range of illustrative examples. In such situations, the required number of supportive results indicated below would be adapted within the zonal context.

1. MAIZE

a) Insecticides

For major pests, 3 appropriate trials results are required for each pest/pest group provided there is sufficient data on cereals (and/or grassland). If there are no data on cereals, 6 trials are required for each major species, for example Frit fly and European Corn Borer. It is anticipated that general group claims for ‘aphids’ or ‘caterpillars’ will typically be requested (rather than individual named species). In such cases, a representative range of species should be included (at least 2 species per group) with a total minimum of 6 appropriate results. Individual named aphid caterpillar species can be supported as described above.

Major foliar pests:

- Frit fly, *Oscinella frit*, (OSCIFR)
- Aphids, including Bird-cherry aphid (RHOPPA),
- caterpillars (e.g diamond-back moth, *Plutella xylostella* (PLUTMA); Silver Y moth, *Autographa gamma* (PYTOGA))

Major stem pests:

- European Corn Borer, *Ostrinia nubilalis* (PYRUNU)

Minor soil pests: Wireworms (*Agriotes* sp.) (AGRISP). The EPPO Minor Use Extrapolation table for soil pests indicates extrapolations can be made between any crops. In this case wheat or barley data, see below, may be an appropriate crop where data already exist. In the absence of available data from other crops, 3 appropriate results are required.

Minor soil pests: Nematodes:

- Cereal cyst nematode (*Heterodera avenae* (HETDNA));
- Root Knot nematodes *Meloidogyne* sp (MELGSP);
- migratory (*Pratylenca* species (PRATSP)).

Cereal cyst nematode is a minor pest of cereals, and direct extrapolation from available cereal data may be possible. For other nematode species, a case should be made for relevance, and again it may be possible to extrapolate from other crops for each nematode group. Refer to the EPP0 Minor Use Extrapolation tables for nematodes to identify key indicator groups. In the absence of available relevant data from other crops, 3 appropriate results are required.

Please note: Western corn rootworm (*Diabrotica virgifera*; DIABVI) is not permanently established in the UK. It is, along with a range of other *Diabrotica* species, a quarantine (notifiable) pest, which should be reported to UK-DEFRA Plant Health and Seeds Inspectors (PHSI). As such, it is not appropriate to include on a UK plant protection product label. However, when considering ‘zonal’ data packages, CRD may still assess the data and then at a later point inform UK-Plant Health who may choose to seek an authorisation for purpose of eradication.

b) Herbicides

Major Weeds: 6 appropriate trials results for each:		
Black nightshade	<i>Solanum nigrum</i>	(SOLNI)
Common chickweed	<i>Stellaria media</i>	(STEME)
Fat hen	<i>Chenopodium album</i>	(CHEAL)
Black bindweed	<i>Fallopia convolvulus</i>	(POLCO)
Redshank	<i>Polygonum persicaria</i>	(POLPE)
Common orache	<i>Atriplex patula</i>	(ATXPA)
Cleavers	<i>Galium aparine</i>	(GALAP)
Mayweed sp.	<i>Matricaria spp</i>	(MATSS)
Knotgrass	<i>Polygonum aviculare</i>	(POLAV)
Pale persicaria	<i>Persicaria lapathifolia</i>	(POLLA)
Groundsel	<i>Senecio vulgaris</i>	(SENVU)
Volunteer potatoes	<i>Solanum tuberosum</i>	(SOLTU)
Volunteer oilseed rape	<i>Brassica napus</i>	(BRSNN)
Docks	<i>Rumex spp</i>	(RUMSS)
Thistles	<i>Cirsium spp</i>	(CIRSS)
Small nettle	<i>Urtica urens</i>	(URTUR)
Annual Meadow-grass	<i>Poa annua</i>	(POAAN)
Ryegrass sp.	<i>Lolium spp</i>	(LOLSS)
Brome sp.	<i>Bromus spp</i>	(BROSS)
Wild oats	<i>Avena spp</i>	(AVESS)
Volunteer cereals		

Minor weeds: 3 appropriate trials results for each (but locally important). Some extrapolation may be possible from other similarly competitive spring crop.		
Cockspur grass	(<i>Echinochloa crus-galli</i>)	(ECHCG)
Sorghum		(1SORG)
Millet	(<i>Panicum miliaceum</i>)	(PANMI)
Finger grass	(<i>Digitaria spp</i>)	

c) Fungicides

Major diseases: 6 appropriate trials for Northern Leaf blight (*Setosphaeria turcica* (SETOTU); Eyespot (*Kabatiella zea*) (KABAZE)* (* No extrapolation from eyespot in cereals is possible as this disease is caused by a different pathogen).

Minor Diseases: No other maize diseases are currently considered of sufficient importance to justify a UK label claim.

Seed treatments: There are currently no authorised products for use as seed treatments in the UK. Evidence would need to be provided to demonstrate that any intended target pest was present in the UK at levels that justified the treatment. Furthermore, a benefit from the proposed use must be demonstrated.

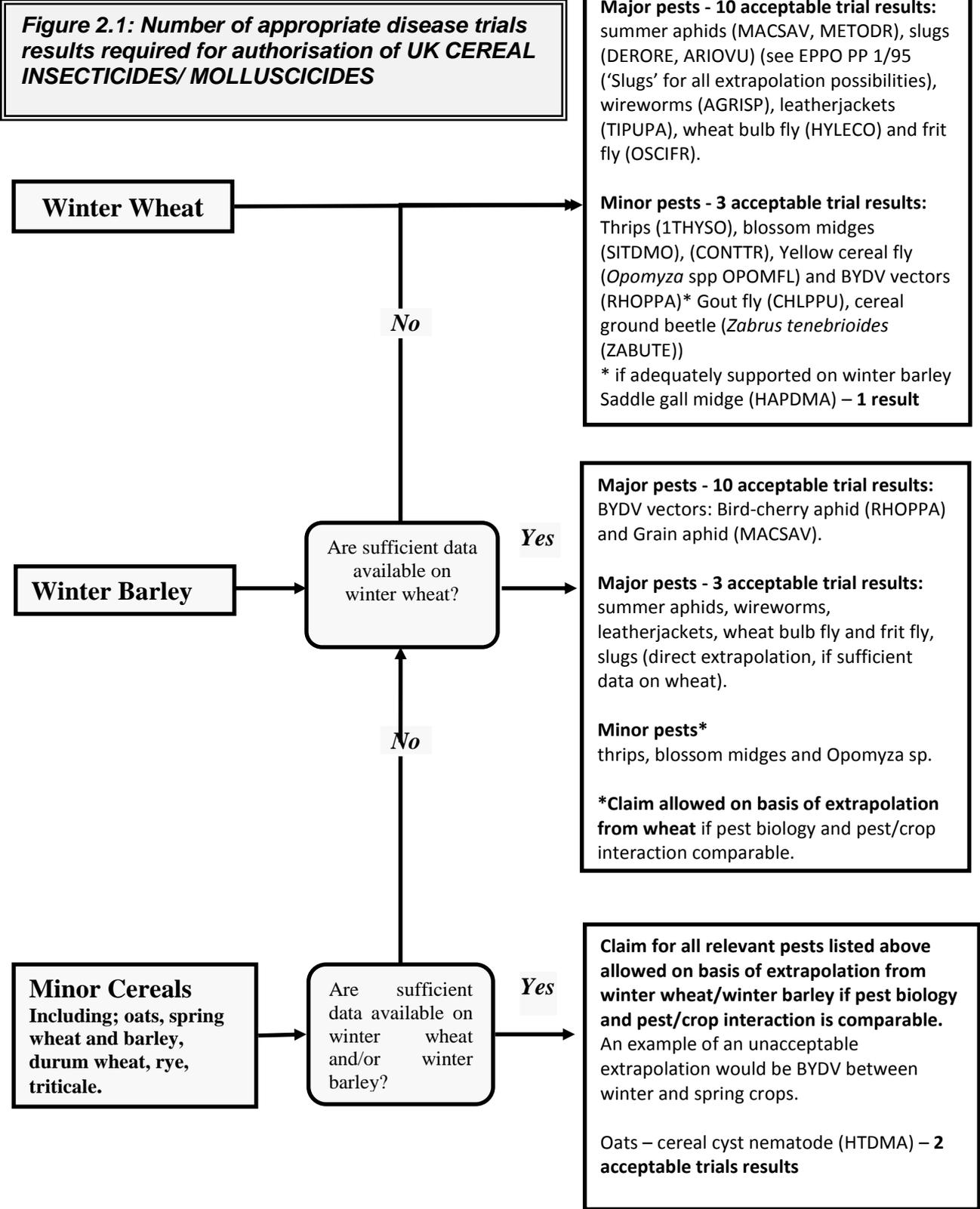
2. CEREALS

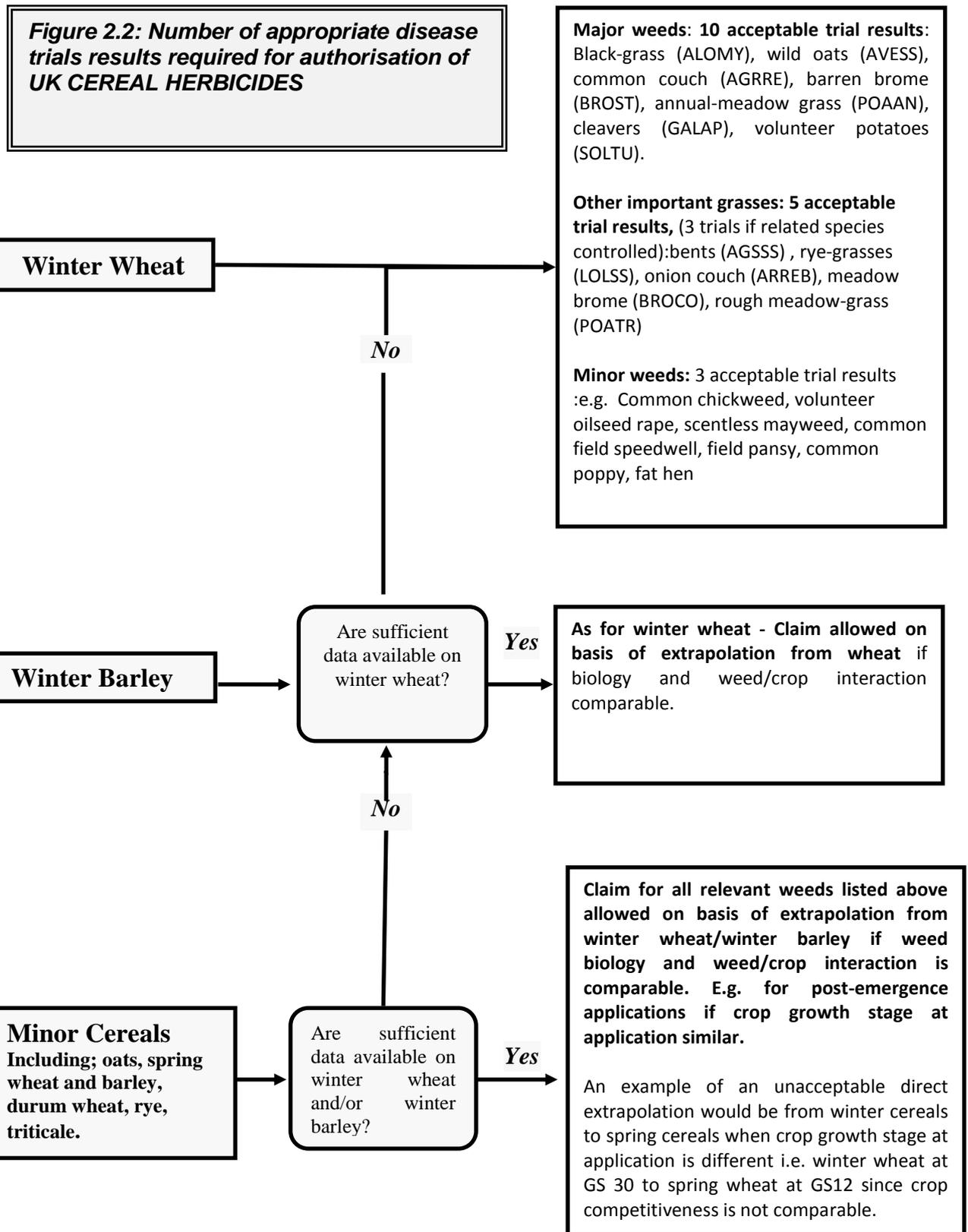
The decision making schemes for UK pests (insects, weeds, diseases) are described in the three diagrams below (Figures 2.1, 2.2 and 2.3). The scheme also indicates which cereal are considered to be the most important host for each target.

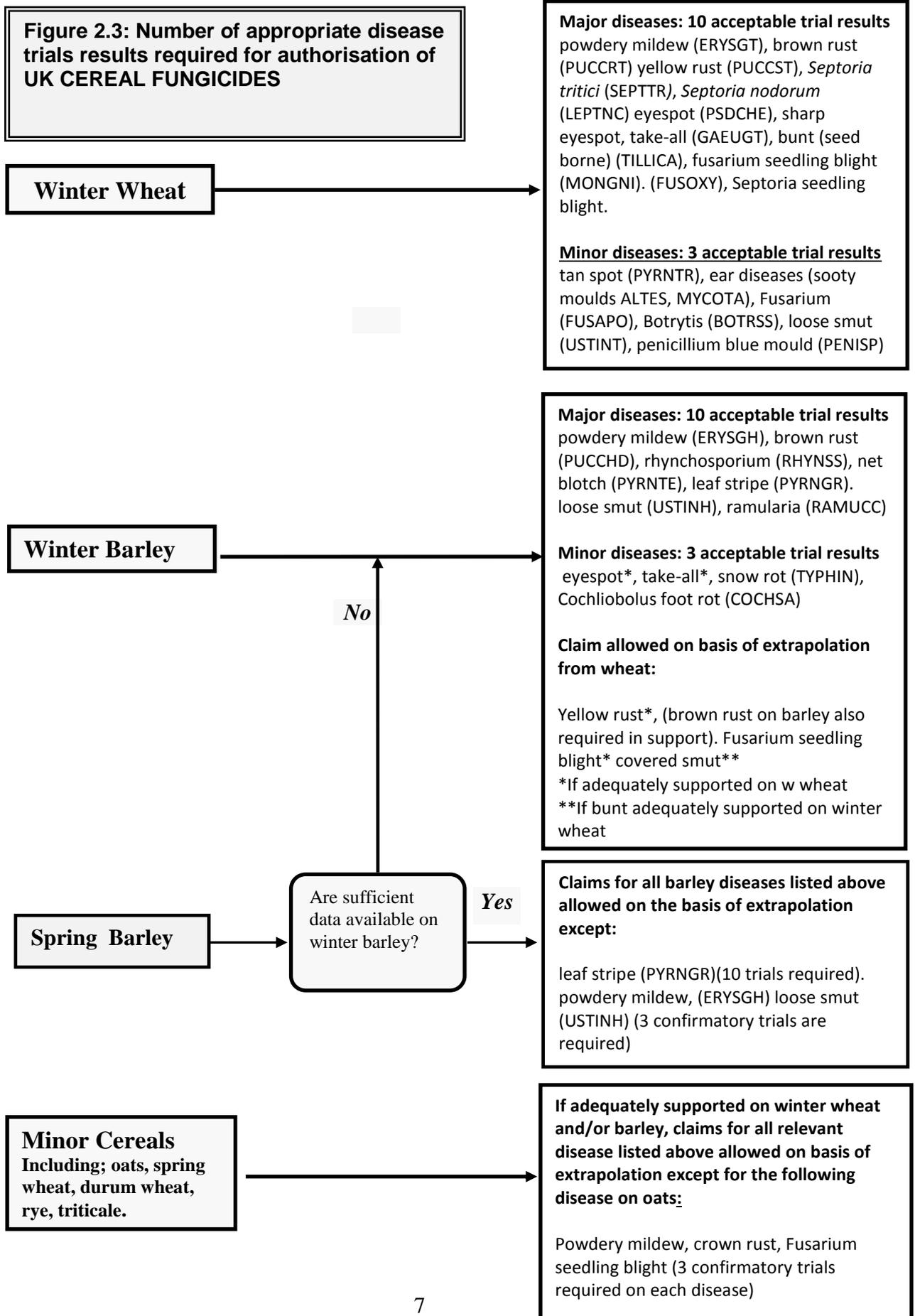
Figure 1: Insect pests (NOTES)

where different methods or timings of application are proposed (e.g. admixture and broadcasting of slug pellets, soil application and deadheart spray against wheat bulb fly), each should be fully supported. For 'generic' pest such as slugs, wireworms, leatherjacket, data may be available on other crops that can be used to reduce the number of required results on cereals (and vice versa). For full extrapolation possibilities, see 'EPPO PP 1/95 'Slugs', and EPPO extrapolation table on 'soil pests'.

There are a number of other very 'minor' cereal insect pests. These currently can be controlled by appropriate non-chemical methods (including natural predators, cultural control), and as such, a UK label claim for an insecticide product is not considered appropriate. These include: Cereal leaf beetle (*Oulema melanopus*, LEMAME); Wheat shoot beetle (*Helophorus nubilus*, HELPNU); Cereal stem sawflies (*Cephus pygmaeus*, CEPHPY), leaf sawflies; Ghost/swift moths (*Hepialus spp*, 1HEPIG).







APPENDIX 1: UK LABELLING SCHEME DESCRIBING LEVEL OF CONTROL

The UK operates a system of differential claims for any particular target species, based on the level and consistency of control demonstrated in the effectiveness trials. The schemes differ slightly between the different product groups, but the principle remains the same of providing important information for the user on the expected levels of control on individual species, or relevant groups of targets.

1. *Insect Pests*

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

Table 1a): Levels of insect pest control expected for effectiveness claims

Appropriate Label Claim	Level of Effectiveness
Control	Consistently control commonly above 80%
Partial/Moderate/Useful level of control	Control, between 60 and 80%
Reduction (in population numbers, or damage).	Lower levels of control, for example 40-60%, or lower in <u>exceptional</u> cases. Terms of 'reduction' are particularly relevant when the primary objective is to reduce plant damage (at crop establishment).

For a claim of effectiveness below 80%, it must be demonstrated that the level of control for that specific pest species is still beneficial for the protection of crop (whether quantitative yield or quality factors).

2 *Diseases*

Disease may be measured as both severity and incidence.

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. There is normally no benefit in reporting both. 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

Level of effectiveness	Label claim appropriate
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 not appropriate. 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

Level of effectiveness	Label claim appropriate
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, loose smut, leaf stripe), 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.

3. Weeds

In arable and horticultural field crops, the label claim supported by a certain level of weed control is described in Table 3a).

Table 3a): Levels of weed control expected for effectiveness claims

Appropriate Label Claim	Level of Effectiveness
Susceptible (S)	Consistent control of 85% and above (see below*)
Moderately susceptible (MS)	More variable control, mean 75-85%, but with results often above 85%
Moderately resistant (MR)	Variable control, mean 60-75%, but some results above this level
Resistant (R)	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 and wild-oats, 95% and above, cleavers 90% and above.

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