The Labelling Handbook
Volume 4

Requirements for Labels of Products used under Permits for Trial Purposes

Contents

1. INTRODUCTION

Permits for Trial Purposes are defined as covering 'any substance, preparation or organism made available for research and development work involving the release into the environment of an authorised or unauthorised active substance and/or product that is not authorised for the proposed use'. The 'pesticide' must be stored, handled, applied and disposed of in accordance with the Code of Practice for the Safe Use of Pesticides on Farms and Holdings and should preferably be declared on the container label, or as a second choice, on a separate leaflet accompanying the container.

Details of making applications for Permits are CRD website Applicant Guide. This guidance applies to labelling any permit whether issued by the Administrative process or subject to a technical assessment.

2. LABELLING CATEGORIES

There are two labelling categories which apply to the four different types of Permit for Trial Purposes and the two categories have there own labelling requirements:

Category A:
Products which have a commercial authorisation for uses other than those for which the Permit for Trial Purposes was obtained and for which an agreed label exists.

Category B:
Formulations which have not received a commercial authorisation and for which no agreed label exists (these would include formulations of new substances, major formulation changes of existing products etc).

Important Note

For all experimental samples, and always those under Category B it is advisable to obtain a written receipt for the sample and the safety information. This may take the following form:

I……..acknowledge receipt of sample ……(code), and of the relevant safety information.
Signed:
Address/organisation:

Date:

3. LABELLING REQUIREMENTS

3.1 General Labelling Requirements

3.1.1 You do not need to submit a draft label with the application but will need to produce a label for the experimental product once the permit has been issued in the line with the following:

(a) Guidance in this Volume 4;

(b) The general guidance in Volumes. 1 to 3;

(c) All of the information on the actual Permit issued by CRD **must** be conveyed to the user for the safe handling and use of the product/formulation (i.e. conditions of use, operator protection, environmental protection, other specific restrictions and conditions of storage as appropriate).

3.1.2 The labelling requirements differ slightly between labelling categories A and B :

Category A:
The existing authorised label may be used if appropriate in which case the Important Information/Safety Precautions/ Directions For Use should be suitably amended in line with the requirements of the Permit and a statement to identify the use as experimental should be included (e.g. as a separate 'stick-on' label).

Category B:
The available chemical and biological information must be taken into account in the preparation of the label, leaflet and data sheet and this includes ALL of the information on the Permit relating to the safe handling and use of the product/formulation.

3.2 Specific Labelling Requirements

In addition to the information on the Permit relating to the safe handling and use of the product/formulation and the guidance in Volumes 1 to 3 in this Handbook the following additional information must be conveyed to the user (some of these requirements will already be met if you are carrying out experimental work with a product with an authorised label):

i) The words **'EXPERIMENTAL USE'** for category A formulations and **'EXPERIMENTAL SAMPLE/FORMULATION'** for category B formulations.

ii) Identification of the formulation sample either by the product code or tradename (there must also be some means of identifying the batch on the label or container).

iii) The name and content of each active substance, as specified on the Permit, must be given (usually included in a single 'contents statement' with the formulation type). If one has not been agreed, the chemical name according to IUPAC rules (as interpreted by the Royal Society of Chemistry) or if not available, the Company code for the active substance should be used.

iv) A statement of the products classification together with the appropriate hazard symbol(s) and risk and safety phrase(s), where this is known.

However, where the toxicological data are insufficient to permit full classification the sample should be labelled **'CAUTION SUBSTANCE NOT YET FULLY TESTED'**

v) For any Permit where we have not carried out an operator exposure assessment the following personal protective equipment (PPE) will be specified on any Permit where we have not carried out an operator exposure assessment

'Personal protective equipment must be worn when handling and applying the product in accordance with the guidelines given in the 'Code of Practice for Using Plant Protection Products Annex E - Guidance on using personal protective equipment'.

This will apply to the following

a) **For all Administrative Permits for Trial Purposes.** However if you are using a Category A formulation and the experimental use falls within the uses already authorised then the same PPE may apply. However, if there are any differences then PPE in line with the Code of Practice must apply (e.g. in the case of higher doses, different application technique).

b) **For all assessed Permits** if we have not carried out a full toxicological and operator exposure assessment.

For additional guidance, a summary of the specific ppe for various formulations and operations based on the Code of Practice is detailed in Appendix 1.

vi) Appropriate medical advice if applicable must appear

vii) A warning that the container or pack must not be re-used for any purpose, unless there is a specific instruction about re-use, re-charging or re-filling and the pack is designed for this (this is only required for products which are classified as very toxic, toxic or harmful or where the classification is unknown).

viii) For emergencies the name, address and telephone number (extension number or department if appropriate) of the Company must appear.

ix) Any additional information required under Section 6 of the Health and Safety at Work Act 1974.

Appendix 1- Personal Protective Equipment

1. All products

1.1 A Permit for Trial Purposes (including all Administrative Permits**)** may specify that PPE be worn in accordance with the guidelines given in the 'Code of Practice for Using Plant Protection Products Annex E - Guidance on using personal protective equipment'. The following is a summary of the required PPE that must be worn for different formulation/operations as set out in the Code of Practice and which must appear on the experimental product label

• All situations for all products	• Coverall, • Gloves, • Boots

In addition to the above, the following PPE are required for specific operations and formulations as specified

• Preparing liquid products • Handling contaminated equipment and containers after use of products applied as a liquid	• Apron • Face-shield • Hood
• Handling and applying dusts • Handling contaminated equipment and empty containers after applying dusts • Handling and applying 'very toxic' granules (or where classification unknown) • Applying fogs, smokes or gases	• Face-shield • Hood, • Respiratory Protective Equipment (RPE) (full-face type if product is 'very toxic' or 'classification unknown'),
• Applying to targets above waist height • Applying indoors (for example, to protected crops) • Cleaning equipment used to apply pesticides (if not liquid or dust- see above)	• Face-shield • Hood
• Reduced-volume spraying outdoors by vehicle-mounted downward-directed sprayers (without a closed cab) or hand-held sprayers	• Face-shield • Hood for 'harmful' or 'irritant' products or 'classification unknown '
• Reduced-volume spraying by indoor sprayers and outdoor air-assisted broadcast sprayers (without a closed cab)	• Face-shield, • RPE • Hood, • Apron for 'harmful' or 'irritant' products or 'classification unknown'
• Applications using ATV-mounted or trailed equipment • Applying from tractors without closed cabs	• Face-shield • Hood

See Notes below for clarification of PPE type and also Section 2 for additional PPE for products containing micro-organisms

Notes

(a) Coveralls
Choose coveralls for the particular purpose, in line with the following table.

Purpose	CEN type	Description
Protection against: liquid jets	Type 3	Chemical protective clothing where liquid cannot pass through the connections between different parts of the clothing
Sprays	Type 4	Chemical protective clothing where spray cannot pass through the connections between different parts of the clothing
Solid particles	Type 5	Reusable and limited-use protective clothing which particles cannot pass through
Liquid splashes and solid particles	Type 6	Reusable and limited-use protective clothing offering limited protection against liquid splashes and aerosols and solid particles

(b) Gloves
Unless the pesticide label or a specific COSHH assessment says otherwise, gloves should be made from nitrile rubber, be at least 0.5 millimetres thick and at least 300 millimetres long. Gloves should be taken off when entering 'clean' areas such as tractor cabs.

(c) Boots
Appropriate boots are wellington boots or waterproof footwear.

(d) Face-shields
Choose faceshields that give full protection of your face and do not mist up when you use them (anti-mist visors).

(e) Respiratory Protective Equipment (RPE)
Your choice will depend on the product label and a COSHH assessment. Consider the following as the basic conditions.

- Potential dust particles or Use an EN 149 particle-filtering half mask FF2-SL or spray droplets in the air EN 140 + 143 half mask connected to particle filter P2
- Potential vapour in the air Use an EN 140 + 141 half mask connected to combined filters A1P2

(f) Open-backed cabs
Open-back cabs (including cabs with open rear windows) do not count as closed cabs as spray can be drawn inside.

2. Products containing a micro-organism

For an experimental product containing a microorganism, the PPE specified in Section 1. above are appropriate plus the minimum PPE as set out below:

i) For solid formulations-
Wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when handling the product or applying the product. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

ii) For Liquid formulations-
Wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when handling the concentrate or applying the product. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

This PPE is required because all such products must carry the phrase 'Micro-organisms may have the potential to provoke sensitising reactions':