Efficacy Guideline 110

Efficacy Official Recognition of Efficacy Testing Organisations

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Introduction

It is a requirement of Regulation EC No 1107/2009 as it applies in NI/GB that the tests and analyses required to demonstrate the efficacy of plant protection products must be conducted by 'Official' or 'Officially Recognised' testing facilities or organisations. The data to be generated demonstrating efficacy in support of plant protection product authorisations are outlined in Section 6 Part A and Part B of Commission Regulation (EU) No 284/2013 as it applies in NI/GB.

The requirements that organisations conducting efficacy trials within NI/GB must satisfy in order to become 'Officially Recognised' are outlined in paragraph 3.2 and 3.3 of the Annex of Commission Regulation (EU) No 284/2013 as it applies in NI/GB.

The original UK 'Official Recognition of Efficacy Testing Organisations' (UK ORETO) scheme was designed in response to Commission Directive 93/71/EEC. The scheme came into force on 1st January 1998 and efficacy data generated from trials commencing in the UK after this date must be supported by copies of appropriate certification.

Efficacy trials/tests for those products that fall within scope of the Biocidal Products Regulation (BPR) Regulation (EU) 528/2012 as it applies in NI/GB do not require to be carried out by 'Officially Recognised' efficacy testing facilities or organisations.

Obtaining 'Official Recognition'

Application

Organisations who wish to become 'Officially Recognised' to carry out efficacy trials in the UK must complete and return the application form together with the appropriate remittance. Copies of the application form (ORET1) and accompanying 'Notes for Guidance' (ORET2) are available from the 'Official Recognition' section of the HSE website.

Certification

Upon receipt of a satisfactory application and supporting evidence, CRD will grant 'Official Recognition' and will issue a certificate, normally valid for a five-year period. The facility/organisation will also be listed on the CRD website.

Certification may be in one or more of the following categories:

- Agricultural/Horticultural trials/tests
- Stored Crop trials/tests
- Vertebrate Control Agents trials/tests
- Biological Agents and Semiochemicals

Inspection

Certification is subsequently confirmed (or revoked) by an 'Official Recognition' inspection. At least one 'Official Recognition' inspection will be carried out on each company during the five-year period.

Further guidance on the responsibilities of organisations applying for 'Official Recognition' in specific areas is available in the 'Notes for Guidance' (ORET 2) document and the 'Further guidance on requirements for Official Recognition' web page.

Applications for Approval Containing Efficacy Data – CRD Requirements

Data produced in the UK

All applications for the approval of products which contain efficacy data generated from trials carried out in the UK after 1 January 1998 must be supported by copies of *relevant* and *valid* 'Official Recognition' certificates. The 'Official Recognition' category or categories stated on the certificate must be relevant to the type of data supplied (e.g. Stored Crops), and the certificate must be valid for the period during which the data were produced.

Where the data supplied in support of an application have been generated by more than one organisation, copies of relevant and valid certificates must be provided for all of the organisations concerned. This means that applicants must make it clear in their overview which organisations have carried out the work.

Data produced in the European Union

When an application for product approval in NI/GB contains efficacy data produced in the European Union, CRD require evidence of whatever constitutes 'Official Recognition' in that country. This evidence should show that the organisation carrying out the work was 'Officially Recognised' at the time. The exception to this is where the data were produced before the 'Official Recognition' scheme was established in that country (e.g. before 1st January 1998 in the UK).

'Official Recognition' (or 'Good Experimental Practice') schemes vary slightly between different countries, both in terms of their scope and of the evidence required to achieve certification. This is because at the time, EU countries were individually responsible for implementing the requirements of Directive 93/71/EEC. CRD do not have details of the 'Official Recognition' schemes of other countries. Further details will be available from individual countries.

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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