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Information Note

Re: Official Recognition of Testing Facility and trials performed

S.I. No. 159 of 2012 European Communities (Plant Protection Products) Regulations 2012 gives effect to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC.

Article 54 of Regulation (EC) No 1107/2009 and **Regulations 9, 10 and 11 of S.I. No. 159 of 2012** provide the legal basis for conducting trials using plant protection products.

This Information Note clarifies the requirements for organisations/businesses requiring Official Recognition of a testing facility, and the trials carried out by that facility. The procedures and conditions outlined below are effective from 01 January 2020 and replace all previous procedures and requirements relating to Efficacy Trials carried out in Ireland.

Submitting a TFTP application is a two-stage process whereby i) the facility is Officially Recognised (either on foot of an inspection if not previously known to the DAFM, or on the basis of the previous year's inspection and performance) and a permit (TFTP) issued; and ii) trials carried out by the TFTP holder are Officially Recognised. This takes the form of a Certificate of Approval (issued at the end of the growing season) listing those trials that have been deemed to be carried out to an appropriate standard. Note that trials which are not carried out to an appropriate standard, or where they are not notified to the DAFM according to the Terms and Conditions of the TFTP may not be recognised and will not be included in the Certificate of Approval.

Application for a Test Facility Trial Permit (TFTP)

Who needs to apply?

i. A person/institute/body intending to operate as a specialist testing facility offering a trials/experiment service or a person/institute/body intending to conduct a 'once-off' trial requiring Official Recognition as a Plant Protection Product Testing Facility.

ii. Application for a TFTP must be made using the appropriate form – Form TFTP see http://www.pcs.agriculture.gov.ie/plantprotectionproducts/plantprotectionproducts/trials/

TFTP application information and requirements

- A completed TFTP application must be submitted and a TFTP granted prior to the commencement of any trial/experiment. Applications can be made via submission of a scanned signed copy of Form TFTP to Prd_trials@agriculture.gov.ie or via post to Efficacy Unit, Pesticide Registration Division, DAFM Laboratories, Backweston Campus, Celbridge, Co. Kildare, W23 VW2C.

- On receipt of a completed application, an invoice will be issued. The application will not be progressed until the appropriate fee has been paid. Current fees are listed on the PCS website http://www.pcs.agriculture.gov.ie/fees

- Following evaluation and approval of the TFTP application, a TFTP will be issued by the DAFM, Officially Recognising the testing facility and, outlining the specific Terms and Conditions that apply (Annex I). At this point you will also receive an Xcel template for declaring summary trial information.

- An authorised officer of the DAFM may inspect the test facility premises or sites at any time during the year (as per Section 3.3 of the Annex to Commission Regulation (EU) No. 284/2013).

- Further to achieving Official Recognition of the testing facility, the TFTP holder must forward to the DAFM comprehensive details of each trial carried out using unauthorised plant protection products (PPPs), regardless of purpose (e.g. marketing, product development or registration etc.) This should include the following information:

    - Trial reference number(s)
    - Trial type
    - A complete list of treatment codes/names
    - ATP number(s) (where appropriate)
    - Treatment dose rates
    - Trial randomizations
    - Crop type
    - GPS coordinates

This information should be forwarded to Prd_trials@agriculture.gov.ie, with the completed PRD Xcel submission spreadsheet, prior to the first application of test products to the trial area.

The product code/name and ATP number, for each unauthorised test PPP that has DAFM APPPT approval, must be recorded appropriately in trial treatment plans and Xcel trial summaries submitted to the DAFM for Official Recognition. The product code/name and associated ATP number should be furnished to the TFTP holder by the trial sponsor, prior to the commencement of the trial.

Only PPPs authorised for such use or PPPs that have DAFM APPPT approval for such use may be used in trials/experiments conducted by a TFTP holder. The use of an unauthorised PPP in a trial where the relevant trial details have not been supplied to the DAFM may constitute an illegal placing on the market by the applicant company and an illegal use by the TFTP holder.

- In the event that changes are made to the trial plans/descriptions originally submitted to the DAFM, these changes must be notified to the DAFM immediately. Failure to comply with this requirement may result in the trial being omitted from the Certificate of Approval issued at the end of the growing season.

- If during the year changes are required to the original TFTP (facility permit) e.g. additional crops not previously declared are required, then these changes should be notified to the DAFM using the Form TFTP. Such applications can be sought at any time and may be subject to a fee.

- A TFTP expires annually on 31 December.

- All TFTP holders are required to furnish an annual report to the DAFM, containing all detailed information necessary to demonstrate compliance with the principles of good experimental practice (GEP). An electronic copy of the Annual Report should be submitted to Prd_trials@agriculture.gov.ie by 31 January in the succeeding year. The report should include the following headings at a minimum to comply with GEP.

    1. A comprehensive summary of all trials conducted or ongoing in the reference year. You should also include details of any trials carried out that are not to EPPO guidelines and purely for demonstration purposes.
    2. Details of the management chain and current area(s) of work responsibilities.
    3. Details of test product(s) disposal.
    4. Crop destruction details.
    5. Maintenance and equipment calibration records/schedules.
    6. List of all equipment/machinery and facilities.
    7. Contract details with external cooperating growers.
    8. Staff training records.
    9. SOP's.
    10. Quality assurance details.
    11. Data handling and records.
    12. Where appropriate, describe any proficiency used to improve testing.

No new TFTP will be issued until the Annual Report from the preceding year has been submitted and deemed to be complete by the DAFM.

- A register of approved testing facilities will be maintained by the DAFM. Only Test Facilities that are on the current register may conduct trials/experiments using unauthorised PPPs. Any trials/experiments conducted by a TFTP holder must be in accordance with the specific conditions described in Annex 1 of the relevant TFTP.

- The Minister reserves the right to withdraw a TFTP where the conditions of the approval issued have not been fulfilled - see S.I. No. 159 of 2012.

- Any queries re this Information Note or the completion of the TFTP form should be addressed to Prd_trials@agriculture.gov.ie