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| D:\Dep of Agriculture Brandmarks\JPEGS\Low Resolution 72dpi\Department_Logo_2011_CMYK LoRes.jpg | **Pesticide Registration & Control Divisions**  **Department of Agriculture, Food and the Marine Backweston Campus, Young’s Cross**  **Celbridge**  **Co. Kildare**  **Ireland**  Email: **pesticidetrials@agriculture.gov.ie**  Web: **www.pcs.agriculture.gov.ie** |
| Telephone: **++353 1 615 7552**  Fax: **++353 1 615 7575** |

12th November 2013 (TP-IN/2013.02)

(updated 23rd December 2015)

Information Note for Applicants

Approval to use Plant Protection Products in Trials (APPPT form)

and Test Facility Trials Permit (TFTP form)[Official Recognition]

**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 aims to clarify the process and the requirements for testing facilities and for applicants wishing to conduct trials on plant protection products in Ireland.

The procedures and conditions outlined below are effective from 1st January 2016 and replace all previous

procedures and requirements relating to efficacy trials (trials authorisations and trials permits) carried out in

Ireland.

The procedure consists of two separate but linked processes, namely:

1. Application for approval to use a plant protection product in a trial(s) – APPPT form
2. Application for a Test Facility Trial Permit – TFTP form
3. **Application for Approval to use a Plant Protection Product in a trial(s) –** APPPT form

**Who needs to apply?**

1. An applicant intending to have trials/experiments conducted on an unauthorised plant protection product or on an unauthorized use of an authorized plant protection product, regardless of the trial purpose (e.g. marketing, research and development or registration) must apply to DAFM using the appropriate application form – APPPT/2016.01.
2. It is the responsibility of the applicant (or the organisation/body wishing to have a product tested) to apply to DAFM for approval to use products described in (i) above in trials.

It is not the responsibility of the testing facility (TFTP holder) to apply for this.

1. Applications must be submitted and approved before the products are supplied to a test facility or used in a trial.
2. Application for APPPT approval may be made by the holder of a product authorisation or by another person or organisation/body.
3. This form should also be used when trialling micro-organisms or macro organisms as plant protection products or for adjuvants.

**Information on completing APPPT form.**

* Where an IE authorised product is to be trialled for an IE authorised use with its IE trade name there is no need to complete this form.
* Note re Section 2 (2.1) of the application form: Include all names/codes by which the product will be recorded in any IE trial. A product may have a number of different codes/names. It is acceptable to use different names/codes for the product in various trials provided that the information has been included in the APPPT application form submitted to DAFM.
* If an applicant wishes to trial an IE authorised product for the IE authorised use using a code/name other than its IE trade name, complete Sections 2.1 & 3 of the form.
* Where the product to be trialled is registered in another Member State but an identical product is also registered in IE under a different trade name, the IE registered PCS Number should be entered in column 3 of Section 2.1 and complete column 4.

If “Yes” is entered in column 4 go directly to Section 3

If “No” is entered in column 4, complete Section 2.4 and then go to Section 3.

* On receipt of an APPPT application, an invoice will issue if appropriate. The application will not be progressed until the appropriate fee has been paid. The current fees are listed on the website.
* Following evaluation and approval of the APPPT application, an email will issue to the applicant with specific Terms and Conditions as appropriate.
* Application and approval is required only once for a product formulation that may be trialled in subsequent years for the same crop use(s).
* **However,** for changes in the details of the original application, (e.g. new trial crop use, max rate of use, method of application or changes in code names from year to year), the applicant must notify DAFM prior to commencement of trialling.

A new APPPT application form with these changes highlighted should be submitted to DAFM at pesticidetrials@agriculture.gov.ie.

* Changes which require further evaluation work may be subject to a fee.
* The plant protection product details that applicant companies supply with the APPPT forms will be treated as confidential by DAFM.
* All specific requirements in relation to the plant protection product (e.g. risk and safety requirements) must be relayed by the APPPT applicant to the test facility trial permit holder.
* Please note that failure of the test facility trial permit holder to comply with the terms and conditions of the TFTP may result in a trial being deemed to be not officially recognised (as per in section 3.2 of the Annex to Commission Regulation (EU) No. 284/2013).
* Any queries or completed APPPT forms can be emailed to pesticidetrials@agriculture.gov.ie

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1. **Test Facility Trial Permit (TFTP)**

**Who needs to apply?**

1. 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 on an unauthorised plant protection product or on an unauthorized use of an authorized plant protection product must apply.
2. 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.
3. Application for a TFTP must be made using the appropriate form –TFTP/2016.01.

**General requirements/information**

* Application must be made and a TFTP granted prior to commencement of any trial/experiment.
* On receipt of a completed application, an invoice will issue if appropriate. The application will not be progressed until the appropriate fee has been paid. The current fees are listed on the website.
* Following evaluation and approval of the application, a TFTP will be issued. The TFTP will outline specific terms and conditions in Annex I to the TFTP, which apply.
* The TFTP holder must forward details of trial products and locations(s) to the Competent Authority (DAFM) by the time of first application of test products to the trial area.
* Only plant protection products authorised for such use or plant protection products that have APPPT approval for such use may be used in trials/experiments by the TFTP holder. If a TFTP holder receives an application form for APPPT approval, the application form should be forwarded immediately to the Competent Authority (DAFM).
* The applicant must notify DAFM immediately of any changes in the details specified in the application form. Changes which require an amendment of the Permit may be subject to a fee. Notifications of changes should be sent to pesticidetrials@agriculture.gov.ie
* Application is required for an extension of an existing TFTP (e.g. for any additional crop types) using the form (TFTP/2016.01). Such application can be sought at any time and is subject to a fee. A new application form with the extension highlighted should be submitted to DAFM at pesticidetrials@agriculture.gov.ie.
* As a condition of the TFTP, the applicant will be required to submit an annual report to DAFM. The report should be submitted at the end of this permit period and prior to an application for renewal of this permit.
* An authorised officer of the Competent Authority (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)
* A register of approved testing facilities will be maintained by DAFM. Test facilities that are registered may conduct trials/experiments only in accordance with the specific conditions in Annex 1 of their TFTP.
* TFTP holders approved for a programme of trials may be published on the DAFM website. TFTP holders for ‘once-off’ trials will not be published but will be included on the DAFM register.
* The Minister reserves the right to withdraw a Test Facility Trial Permit where the conditions of the approval issued have not been fulfilled. (See Statutory Instrument 159 of 2012)

* Failure to comply with any specific condition(s) of the TFTP may result in the Test Facility being removed from the register/website until the condition(s) have been fulfilled. It may also require submission of a new TFTP application and fee for re-instatement.
* Please note that failure of the test facility trial permit holder to comply with the terms and conditions of the TFTP may result in a trial being deemed to be not officially recognised (as per in section 3.2 of the Annex to Commission Regulation (EU) No. 284/2013).
* A TFTP expires annually on December 31st.
* Any queries or completed TFTP forms can be emailed to pesticidetrials@agriculture.gov.ie

**Renewal of a TFTP**

* Test Facility Trials Permits can be renewed annually upon payment of the fee and subject to a satisfactory annual report and any other conditions required by the Competent Authority (DAFM) being fulfilled.
* Failure to pay the fee within the specified time may result in the Test Facility being removed from the register/website. Submission of a new TFTP application and fee will be required for re-instatement.
* Where extension of a TFTP is being sought at the time of renewal, then only the renewal fee will apply.