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Information Note

Re: Approval to use unauthorised Plant Protection Products in trials/experiments

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 seeking approval to use unauthorised Plant Protection Products (PPPs) in trials/experiments. The procedures and conditions outlined below are effective from 01 January 2020 and replace all previous procedures and requirements relating to IE APPPT applications.

Application for approval to use an unauthorised Plant Protection Product in a trial(s)

Who needs to apply?

i. An applicant intending to have trials/experiments conducted on an unauthorised PPP or on an unauthorised use of an authorised PPP, regardless of the trial purpose (e.g. marketing, research and development or registration) must apply to the DAFM using the appropriate form – Form APPPT – see http://www.pcs.agriculture.gov.ie/plantprotectionproducts/plantprotectionproducts/trials/

ii. It is the responsibility of the applicant (or the organisation/body wishing to have a product tested) to apply to the 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 approval.

iii. Applications must be submitted and approved before the products are supplied to a test facility or used in a trial.

iv. Application for APPPT approval may be made by the holder of a product authorisation or by another person or organisation/body.

v. The APPPT form should also be used when proposing to trial micro-organisms, macro-organisms or adjuvants. If the intention is to test non-native micro-organism species, for an unauthorised plant protection use in IE, approval is first required from the National Parks & Wildlife Service (NPWS) to release the micro-organism into the environment. Applications can be made to Wildlife Licensing Unit, Department of Housing, Local Government and Heritage, NPWS, 90 King Street North, Smithfield, Dublin 7, D07 N7CV.
Applications by email to: wildlifelicence@housing.gov.ie

APPPT application information and requirements

- A completed APPPT application must be submitted to the DAFM prior to commencement of any trial/experiment using an unauthorised PPP.

- Section 2 (2.1): Detail all the names/codes by which the product will be recorded in trial(s) in IE. It is acceptable for product(s) to have alternative names/codes if/when used in trials carried out by alternative TFTP holders, provided that the information has been included in the original APPPT application submitted to the DAFM. On approval the DAFM will issue an email detailing separate ATP numbers in respect of each product code/name declared. This email will also specify the Terms and Conditions that apply.

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

- There is no need to include IE authorised products being trialled for an IE authorised use in this form. However, if an applicant wishes to trial an IE authorised product for an IE authorised use using a code/name other than its IE trade name, Section 2.1 & Section 3 of the form should be completed.

- 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.

- Completed APPPT forms should be submitted to prd_apppt@agriculture.gov.ie.

- All relevant MSDS must be supplied for each formulation with the APPPT application.

- Invoicing procedures should be forwarded annually with the first APPPT application. APPPT applications will not be progressed until all relevant fees are paid. Current fee schedules are listed on the PCS website http://www.pcs.agriculture.gov.ie/fees/

- Only one application and approval is required for a product formulation. This remains valid in any subsequent year that the product has the same crop use(s). **However,** if there are changes in the details of the original application, (e.g. formulation, new trial crop use, max rate of use, method of application or changes in name/code from year to year etc.), a new APPPT application must be submitted prior to commencement of trialling. On approval this will result in the issuing of a new ATP number.

- Changes which require further evaluation work may be subject to a fee.

- All PPP details supplied by APPPT applicants will be treated as confidential by the DAFM.
- All specific requirements in relation to the PPP (e.g. risk and safety requirements etc.) must be relayed by the APPPT applicant to the TFTP holder.

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