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‘Protected Urea’/Inhibitors

Background

The current rules for the sale and marketing of fertiliser in Ireland are provided for under both Irish and EU Regulations. Fertiliser manufacturers can choose to market their products under National legislation (Fertilisers, Feeding Stuffs and Mineral Mixtures Act, 1955 and Statutory Instrument No. 248/1978 (Marketing of Non-EEC Fertilisers Regulations, 1978) or EU legislation- Regulation (EU) No 2019/1009.
Contrary to most other product harmonisation Regulations in the EU and considering the principles of better regulation and subsidiarity, Regulation (EU) No 2019/1009 maintains optional harmonisation and does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law and the general free movement rules.
Compliance with harmonised rules therefore remain optional and is only required for fertiliser products which are CE marked. The regulations therefore offer the possibility for manufacturers who do not wish to CE-mark their products to choose to comply with National Regulations.
Manufacturers will still be able to sell their products in other EU countries under National rules depending on mutual recognition between the Member States.

Therefore, there are currently 3 options for placing a fertiliser product on the market in Ireland:

A. Under EU legislation
B. Under Irish Legislation
C. Under Mutual Recognition

A. <u>EU Legislation:</u>

The EU Fertiliser Products Regulation (EU) No. 2019/1009 entered into force on 5th June 2019 and applies from 16th July 2022.
It opens the single market for fertilising products, which are not currently covered by harmonisation rules, such as organic and organo-mineral fertilisers, soil improvers, inhibitors, plant biostimulants, growing media or blends.
The regulation covers 7 Product Function Categories of EU fertilising products. They are designated as follows:

1. Fertiliser
    - Organic fertiliser
    - Organo-mineral fertiliser
    - Inorganic fertiliser
2. Liming material
3. Soil improver
4. Growing medium
5. **Inhibitor**
6. Plant biostimulant
7. Fertilising product blend

The first option is to apply for a CE mark under Regulation (EU) 2019/1009 (which repealed the Fertilisers Regulation 2003/2003). By CE marking products, this gives the company full access to the EU market. Depending on the Product Function Category (PFC) and Component Material Category (CMC) you may need to contact a conformity assessment body to assess the product. There are 13 notified bodies in Europe, but currently there are no conformity assessment bodies in Ireland. The below table shows the categories that require a conformity assessment body:

No Notified Body required (self assessment)	**Require Notified Body**		
Module A	**Module A1**	**Modules B & C**	**Module D1**
PFC 1(*) – 4, if composed exclusively of one or more of CMC 1 (excl. inhibitors), CMC 4, 6, 8 and/or 11 **PFC 7** (**)	**PFC 1(C)(I)(a)(i-ii)(A)** (ammonium nitrate fertiliser of high nitrogen content) and **PFC 7** with 28% or more of nitrogen from such a fertiliser	**PFC 1 (*) – 6,** if composed exclusively of one or more of CMC 1 (incl. inhibitors), CMC 2, 4, 6, 7, 8, 9, 10 and/or 11 **PFC 7** (**)	**PFC 1(*) – 6**, if composed of one or more of CMC 1 (incl. inhibitors), CMC 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and/or 15 **PFC 7** (**)

(*) except PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory.
(**) except PFC 7 with 28% or more of nitrogen from a fertiliser belonging to PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory

In the case where a conformity assessment body is not required, self-assessment can be carried out for the product.

Definitions

INHIBITOR

- An inhibitor is defined as an EU fertiliser product, with the function to improve the nutrient release patterns of a product providing plants with nutrients, by delaying or stopping the activity of specific groups of micro-organisms or enzymes.
- Where the substance or one of the substances in the mixture is intended to improve the EU fertilising product's nutrient release patterns by delaying or stopping the activity of specific groups of micro-organisms or enzymes, that substance shall be a nitrification inhibitor, a denitrification inhibitor or a urease inhibitor.
- Under EU Regulation (EU) 2019/1009 the fertiliser manufacturer is responsible for ensuring that inhibitors made available on the market fulfil certain efficacy criteria.
- EU fertilising products containing inhibitors are subject to certain efficacy, safety and environmental criteria and are regulated as component materials for EU fertilising products under Regulation (EU) 2019/1009

Three types of inhibitor are included in Regulation (EU) No. 2019/1009
A) Nitrification Inhibitor:

- Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH 3 -N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

B) Denitrification Inhibitor:

- Compared to a control sample where the denitrification inhibitor has not been added, an in vitro test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide (N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

C) Urease Inhibitor:

- Compared to a control sample where the urease inhibitor has not been added, an in vitro test containing the urease inhibitor shall show a 20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

Requirements that apply to fertilisers containing inhibitors (as per Regulation (EU) 2019/1009):

- The label must state the words 'nitrification inhibitor', 'denitrification inhibitor' or 'urease inhibitor', as relevant.
- The nitrification inhibitor content must be expressed as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH_4^+) and urea nitrogen (CH_4N_2O).
- The denitrification inhibitor content shall be expressed as a % by mass of the nitrate (NO_3^-) present.
- The urease inhibitor content must be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).

B. **Irish Legislation**:

Fertiliser and liming products can also be marketed under Irish National legislation: Fertiliser, Feeding Stuffs and Mineral Mixtures Act 1955 (No. 8 of 1955), Statutory instrument (SI) No. 248/1978 and SI No. 205/2004. In the national legislation, there are 4 category of fertiliser a product can meet. These are:

A. Straight Fertilisers
B. Compound Fertilisers
C. Compound Fertilisers containing Organic Material
D. Low Nutrient Fertilisers

If a product can meet requirements stated in this, then it can be placed on the market. DAFM assess individual products in these cases and look for the following information:

- A description of the source of the raw materials used to manufacture the product
- Confirmation of end-of-waste status for raw materials, if applicable
- A declaration of whether the raw materials are organic or inorganic or if a combination of both – i.e organo-mineral
- A declaration of additional inert ingredients
- A brief description of the manufacturing process
- Information on effects on health, environment and safety
- A declaration of the nutrient content as fertilisers
- A declaration regarding nutrient solubility, e.g.
    i. for Phosphorous in neutral ammonium citrate, and in water
    ii. for Nitrogen and Potassium in water
- Agronomic data, if available
- A declaration, supported by certification from an accredited laboratory, of the content of heavy metals or other contaminants (see Annex I)

- A declaration of compliance with Regulation (EC) 1069/2009 on Controls re Animal By-Products
- Confirmation of REACH registration and hazard classification (Material Safety Data Sheet)
- A copy of the draft label and identification markings in line with those outlined in Part II of the Schedule of Statutory Instrument 248/1978

Under S.I. No. 205/2004, a definition of inhibitor was provided for under Irish legislation and specific inhibitors were listed. An inhibitor was defined as "a substance that may be incorporated in a fertiliser which effects the efficacy of the fertiliser." The two inhibitors included were:

- **Nitrification Inhibitor:- 3,4- Dimethylpyrazole phosphate (DMPP)**
- **Urease Inhibitor:- N-butyl-thiophosphoric-triamide (NBPT)**

C. Mutual Recognition

Products can also be placed on the market in Ireland under Mutual Recognition Regulation (EU) No 515/2019. Under Mutual Recognition, fertilisers that are allowed and regulated in member states "national" Fertiliser regulation may be marketed in another member state.

There are 2 options for assessment under mutual recognition in Ireland:

1. A mutual recognition declaration may be supplied to DAFM for the purposes of an assessment to be carried out under Article 5 of the Regulation.
2. If a mutual recognition declaration is not supplied, DAFM must assess the application and may request the economic operators concerned to provide documentation and information necessary for that assessment concerning the following as outlined in Article 5 of Regulation (EU) No 515/2019:
    - for the purposes of the assessment the competent authority of the Member State of destination may contact the competent authorities or the Product Contact Points of the Member State in which an economic operator claims to be lawfully marketing its goods, if the competent authority needs to verify any information provided by the economic operator.
    - take due account of the content of test reports by the economic operator as part of the assessment.
    - review test reports or certificates that were issued by a body accredited for the appropriate field of activity
    - review a copy of the proposed label
    - ensure that the product complies with National rules in the assessing member State
    - where, on completion of an assessment the competent authority of a Member State of destination takes an administrative decision with respect to the goods that it has assessed, it shall notify that administrative decision without delay to the economic operator. The competent authority shall also notify that administrative decision to the Commission and to the other Member States.

The economic operator is allowed to make the goods available on the market in Ireland while DAFM carries out the assessment.

Table 1 shows the products that can be marketed as urease inhibitors in Ireland as per fertiliser legislation.

Table 1. Products/ active ingredients that can be marketed in Ireland as urease inhibitors as per legislation (either EU legislation, national legislation or both)

Product*/Active Ingredient	
N-(n-butyl) thiophosphoric-triamide	NBPT
N- (2-nitrophenyl) phosphoric triamide	2-NPT
Mixture of N-butylphosphorothioic triamide and N-propylphosphorothioic triamide (ratio 3:1)	NBPT and NPPT
Nutrisphere- N ®	Maleic Itaconic Copolymer
NitroShield®	NBPT

* Where the product name is provided, these products can be CE marked under Regulation (EU) 2019/1009 (which repealed the Fertilisers Regulation 2003/2003) and means the products have been assessed by a conformity assessment body. CE marking products, gives companies full access to the EU market.

Table 2 provides the quantity of urea and protected urea (i.e. with an inhibitor) placed on the market in Ireland from 2018- 2022

Table 2. Sales of straight urea and urea with a urease inhibitor in Ireland

Year	Total Urea/Tonnes (N content)	Of which included urease inhibitor	% containing urease inhibitor
2018	55,232	3,241	5.8
2019	55,777	11,012	19.7
2020	62,571	18,595	29.7
2021	59,656	18,969	31.8
2022	82,971	30,148	36.3