New pesticides legislation – what are the implications for sellers and users of pesticides?

Last month saw two new pieces of legislation signed into Irish law – SI No. 155 of 2012 dealing with <u>sustainable use of pesticides</u>, and SI No.159 of 2012 dealing with <u>plant protection products</u>. SI No. 155 of 2012 will require (among other things) that individuals involved in retailing, providing advice or using professional use plant protection products (farmers) are properly trained, that those retailing pesticides have stores constructed to a suitable standard, and that boom sprayers (in excess of 3m), orchard and blast sprayers are tested to a prescribed standard. This legislation will be reviewed in greater depth in future articles in this series.

SI No 159 of 2012 marks a comprehensive revision of existing legislation in the area of marketing and use of plant protection products (PPPs), and contains a number of important changes which are outlined below.

As was the case previously, before pesticides can be legally placed on the market for sale to end users, they must first be registered with the Pesticide Registration & Control Division of the DAFM. The new legislation allows only two approaches to product registration, i.e. applicants can apply for either an *Authorisation* or a *Parallel Trade Permit (PTP)*. Essentially these differ with regard to the amount of information and data that must be provided by the applicant in order to obtain a certificate of approval from PRCD. An application for an *Authorisation* will require the applicant (normally a chemical company) to submit a large body of data in support of the product. Due to the amount of data to be assessed, such applications can take many months or even years to be approved.

Significantly less information is required from an applicant for a PTP, which is based on the principle that the PTP product is identical to a product (reference product) already authorised for placing on the Irish market. An applicant for a PTP only has to show that their product is identical to the reference product. This means that the product being imported is manufactured by the same company as the product already on the market in Ireland, and is identical in specification and content of active substance. Product can be sourced in any EU member state. The recommended uses on the label of a PTP product may not extend beyond the recommended uses of the reference product. Approval for a PTP can be completed in a matter of weeks. [Parallel trade is largely made feasible due to price differentiation for the same product in different Member States].

The new legislation marks an important change for holders of a PTP. It provides for a registration period which is based on that of the reference product and, provided there are no safety concerns impacting on the status of the reference product, the PTP product can remain on the market under the same conditions as the reference product, without a change to the PCS No. Under the previous legislation, approvals had to be renewed annually and a new PCS No assigned. The PCS No indicates to the purchaser that the product has been through the registration system and is safe for human health and the environment once it is used in accordance with the instructions on the product label.

Two types of PTP are possible. An applicant wishing to import a PTP product and to place that product on the market for **sale and use** by Third Parties must obtain a certificate of approval, a PCS No and approval for the new label. All containers of the PTP product must be labelled with the approved label. The applicant is then permitted to place his/her product on the Irish market. The fee for a PTP is €300 per product. In addition an annual fee to maintain the PTP product on the Register of approved PPPs must be paid.

It is also possible for individuals to apply for an '**Own Use Parallel Trade Permit** (OUPTP). An applicant, wishing to import a PTP product for 'own use', must obtain a certificate of approval and a PCS No. There is no requirement to re-label all containers, but the applicant must demonstrate awareness of the recommended uses and rates of use for Ireland. The fee for an OUPTP is €100 per product, renewable annually. However, the OUPTP product can only be used on the holding of the individual named on the permit. **Such product cannot be used by third parties, or offered for sale, supply or distribution to third parties**. For certain individuals there are potential savings to be had by applying for an OUPTP.

Why do PCS Numbers change? Basically such changes are driven by re-registration requirements or by amendments or modifications to the product label. These can be at the behest of the chemical company or PRCD (on foot of European legislative requirements). The information provided on the product label is pivotal to the registration process, and comprise both safety statements and directions for use which are designed to protect human health and environment from any negative effects associated with the product. As active substances currently approved for use are re-evaluated, there can be changes in the conditions of use permitted, i.e. change in safety statements in line with new legislation, or a change to the recommended uses associated with the product, e.g. Bravo 500 (PCS No 03452) was recently re-registered with a greatly reduced range of crop approvals. Alternatively, additional crops can be added to a label. It is also possible that companies may decide that they are no longer prepared to support the continued use of their product on specific crops (usually minor crops), and request that these be removed from a label. This can be prompted where Maximum Residue Levels (MRL) for specific active substances on specific crops are revised, and consequently require amendments to the directions for use that is provided on the label. Revisions to safety phrases in line with new legislation can also require that labels be modified. For all these reasons, revised labels require new PCS numbers.

Whilst the parallel trade (in general) increases competition in the market place, the underlying requirement is that the product being imported mirrors an authorised product already on the Irish Market.

It is important to remember that PRIOR approval must be obtained from PRCD before importing any PTP product into Ireland.

The new regulations also restrict the way PPPs can be advertised.

Product update

Product Name	PCS No	Comment
<u>Cereals</u>		
Amistar Opti	03408	Latest time of application to barley extended to GS 61
Larke	04185	Latest time of application to winter wheat extended from before GS 31 to before GS 41
Potatoes		
Barclay Dimethosect	90172	No longer approved for use on ware potatoes
Reglone	02453	Approved as a desiccant only - must not be used as a herbicide on potatoes
Retro	03712	Approved as a herbicide <u>only</u> – must not be used as a desiccant on potatoes
Dithane 945	91652	Last date for use 01/08/13
Penncozeb	92071	Last date for use 02/10/13
Penncozeb WDG	92072	Last date for use 02/10/13
Amistar Opti	02162	Last date for use 14/12/12
Bravo 500	00198	Last date for use 14/12/12
CT 500	03406	Last date for use 14/11/13
Orchid B	03369	Last date for use 02/10/13
Croplink Linuron	04257	Last date for use 09/09/13
Metrifar WG	03368	Last date for use 14/11/13
Rapture	04353	Last date for use 29/10/13
Unichem Linuron	04379	Last date for use 29/10/13
Whelehan Linuron	04406	Last date for use 04/11/13

Triple rinse and dispose of all containers safely - see leaflet in previous edition of IFJ

Note 1– before using a product in a knapsack check to make sure it has <u>label</u> <u>approval!!!</u>