and soil and minimise risks to wildlife. The industry needs to further reduce its dependence on products that have high energy input during their manufacturing and transport chain. This may increase production costs but the industry must promote its green image and publicise the steps that it takes to achieve a more environmentally safe product. This may help those customers who demand a greener approach to understand the impact on prices.

The Effect of European Union Pesticide Legislation in Ireland©

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INTRODUCTION

The Pesticide Control Service (PCS) of the Department of Agriculture and Food is responsible for developing and implementing the regulatory systems in Ireland for plant protection products (PPPs) and biocidal products (BPs). It also implements regulations controlling pesticide residues in food.

Plant protection products may be herbicides, fungicides, insecticides, nematicides, molluscicides, growth regulators, etc. intended for use in agriculture, horticulture, forestry, home gardens, and amenity areas, on stored plant products and on land not intended for cropping. Biocidal products are substances intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. There are 23 different biocidal product types, including wood preservatives, antifouling paints, rodenticides, disinfectants, and public health insecticides.

The most important pieces of European Union (E.U.) legislation involved are Council Directive 91/414/EEC (marketing and use of plant protection products), Council Directive 98/8/EC (marketing and use of biocidal products), and Council Directive 1999/45/EC (classification, packaging, and labelling of dangerous preparations). In relation to PPP residues, the main regulatory instruments are Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, and 90/642/EEC. These Directives have been transposed into Irish law by means of Statutory Instruments made under the European Communities Act of 1972.

CLEARANCE, CLASSIFICATION, PACKAGING, AND LABELLING OF PESTICIDES

Statutory Instrument (SI) 370 of 1985 introduced the first statutory registration system in Ireland for pesticides. It included provision for the "notification" of all pesticides. Any person wishing to place a "new" product on the market was required to seek and obtain clearance from the PCS. Data supporting applications were evaluated to determine risks to human health and the environment and provided a basis for hazard classification and selection of appropriate packaging and labelling phrases relating to safety precautions. The clearance procedure introduced under these regulations did not address product efficacy.

Directive 91/414/EEC introduced a harmonised system in the European Communities for the registration of plant protection products. It provided for harmonised data requirements and evaluative and decision-making criteria. The 1994 SI 139 brought it into Irish law. In 2001, a new consolidated statutory instrument, SI 624 was introduced (giving effect to Directive 1999/45/EC) concerning the classification, packaging, and labelling of "dangerous preparations", replacing earlier E.U. legislation concerning the classification, packaging, and labelling of pesticides. In 2003 a number of amendments and updates were made to SI 139 of 1994 under a new consolidated statutory instrument, SI 83 of 2003.

European Directive 91/414/EEC. Under this directive, the authorisation system for plant protection products is a two-stage process. The first is an examination of the active substance. This is undertaken by the competent authority within any Member State (known as a Rapporteur Member State) to common criteria — with a view to having the substance approved or not at E.U. level. Approved substances are listed in Annex I of the directive. Once approved, Member States can then authorise products containing it at national level for particular purposes, taking account of local agricultural and environmental conditions and any specific conditions attached to the E.U. approval.

Although authorisations granted in all Member States are assessed to the same standards the regulatory system also recognises that agricultural practices, environmental conditions etc. vary greatly throughout the E.U.

Approvals for New Substances. In order to market a product containing an active substance not previously on the European market, the applicant must apply for an authorisation to a Rapporteur Member State of their choice, which then evaluates it on behalf of the E.U. The result is a Draft Assessment Report (DAR), which includes a proposal for decision on the active substance to be made by the European Commission (E.C.). The DAR is submitted by the Rapporteur to other Member States, the European Commission, and to the European Food Safety Authority (EFSA). Following a detailed peer review, a decision is taken by the Commission, on the basis of advice provided by the Member States, whether or not to approve the substance.

Older Substances and Arrangements for Essential Uses. When Directive 91/414/EEC was introduced, a review programme was initiated for all active substances already on the market in the E.C., to ensure they were regulated to the same standards as new ones. The substances were divided into four groups and Member States were allocated a number of them to review on behalf of the E.C. — from the first list in 1994, the second list in 2000, the third list in 2002, and the fourth list in 2004.

When a positive approval is granted, the European Commission publishes the result as an amendment to Directive 91/414/EEC in the Official Journal. Following publication, the Member States are obliged to review all plant protection products on their markets containing the active substance, in accordance with the same uniform principles that apply to new actives.

Refused approvals are also published by the European Commission in the Official Journal. Member States are then obliged to revoke registrations for plant protection products containing the refused actives, resulting in their removal from the market. Provision has been made for the granting of temporary "Essential Use" derogations, for products where a Member State establishes that there are no

satisfactory alternative products available. All essential use derogations granted are for specified crops and target organisms and are valid for specified periods to allow alternative control measures to be identified or developed. Irish growers currently have 25 essential use derogations. Member States are required to report to the Commission on progress made in developing alternatives during the period for which the essential use has been granted.

PESTICIDE RESIDUES

To remove artificial barriers to trade and to protect consumers, maximum residue limits (MRLs) are set for individual plant protection products on individual crops. Residue limits established must not pose a risk to consumers' heath. Each MRL represents the maximum amount of a pesticide residue that might be expected on a commodity if good agricultural practice has been followed.

An E.U. Directive concerning pesticide residues in fruit and vegetables was adopted in 1976 (Council Directive 76/895/EEC). In 1990, Council Directive 90/642/EEC concerning pesticide residues in and on certain products of plant origin, including fruit and vegetables, was introduced. This provided for mandatory MRLs for an extended range of products. The scope of the pesticide residues directives was further extended in 1997 to include processed products (Council Directive 97/41/EC). In 1999, Council Directive 99/39/EC was introduced to place severe restrictions on the use of plant protection products in the production of food for infants and young children.

Recently, as part of the Simplified Legislation of the Internal Market (SLIM) initiative, efforts have been made to simplify and rationalise existing E.U. legislation in this area. Proposed new legislation will incorporate all the above Directives together with additional amendments.

To seek establishment of an MRL the applicant must supply data on the toxicological properties of the product and its residue profile following use on food crops. The regulatory authority evaluates the data and uses it to derive a proposal for an MRL. The MRL must be agreed at E.U. level by the Standing Committee on the food chain and animal health.

Residue Monitoring Programme. The PCS implements Ireland's national monitoring programme for the Food Safety Authority of Ireland (FSAI), to control pesticide residues in food. The programme is agreed with the FSAI each year. It analyses samples of fruit, vegetables, milk and other dairy products, meat, and cereals to ensure that MRLs have not been exceeded. Results obtained are published annually.

Sampling is mainly carried out at wholesale level or point of collection, so that producers can be traced and produce containing residues higher than MRL removed from the supply chain. Sampling is biased in favour of food items of greater dietary importance and items, which have historically been more likely to contain residues above MRLs. Both imported and home produced food products are sampled.

BIOCIDES

Biocides include rodenticides, disinfectants, and preservatives for use in industry and the home, public health and household pest control products, anti-fouling products, taxidermy, and embalming fluids. E.U. harmonised legislation was agreed in 1998 (Council Directive 98/8/EC transposed into Irish law through SI 625 of 2001).

It covers all biologically active products not already covered by legislation on plant protection products, veterinary products, or cosmetics.

The legislation is intended to simplify and harmonise Europe's regulatory system for biocides, remove trade barriers, and improve the protection of both people and the environment. The European Chemicals Bureau (ECB) produced and manages a list of existing active substances which can be marketed pending the outcome of an active substances review programme similar to that for plant protection products.

For each substance a dossier on its physical, chemical and analytical properties, toxicological and ecotoxicological properties, environmental effects and, where appropriate, any effects it has if brought in to contact with food, must be provided to the designated Rapporteur Member State. The aim is to establish that biocidal products are sufficiently efficacious without having any unacceptable side effects.

In Ireland, companies were requested to notify PCS of any biocidal products that were on the Irish market on or before 1 Feb 2002. Biocidal products introduced to the Irish market since then must be notified as new products before being offered and their safety and efficacy will be reviewed following the inclusion of the active substances concerned in the relevant annex of the Directive. If any substance fails its review, registration of products containing it will be revoked requiring their removal form the market.

CONCLUSION

Over the last 10 years there has been much progress in pesticide regulation at E.U. level. As a result of the implementation of Directive 91/414/EEC, one regulatory system exists for all of the European Community. However, much remains to be done, not least the revision and updating of the Directive to reflect advances in science and technology and opportunities offered by increased levels of cooperation. As scientific progress is made, additional guidance on its application to the evaluation of plant protection and biocidal products will be required. There is also continuing work at OECD (Organization for Economic Co-operation and Development) level to harmonise pesticide regulation among the OECD member countries.

The ambitious biocide review programme, currently in its infancy, will take time to develop. The regulatory system introduced is new to many of the companies involved, most of which are small- or medium sized-businesses. In many cases, these are much smaller companies than those involved in the agrochemical industry. Consequently they face a major burden unless they cooperate in commissioning studies and preparing dossiers for submission to the regulatory authorities.

Work done over the years on pesticide residues has had an impact on attitudes about food safety and crop protection. Consumers can now have increased confidence in the system for controlling pesticide residues in food. The amount of work required to establish a MRL will continue to represent a considerable cost to industry and may influence the number of product uses supported. The residue-monitoring programme in Ireland will continue to be strengthened with increased number of samples analysed and an increase in the number of compounds included in the analytical screen.