EXECUTIVE NOTE

THE PLANT PROTECTION PRODUCTS (SCOTLAND) AMENDMENT REGULATIONS 2007 SSI/2007/119

POWERS

1. The Plant Protection Products (Scotland) Amendment Regulations 2007 (the Regulations) are made in exercise of the powers conferred upon the Scottish Ministers by section 2(2) of the European Communities Act 1972.

2. The Regulations amend the Plant Protection Products (Scotland) Regulations 2005 (SSI 2005/331) (the principal Regulations).

PARLIAMENTARY PROCEDURE

3. The Regulations are subject to negative resolution procedure.

POLICY OBJECTIVE

4. The principal Regulations implement Council Directive 91/414/EEC (as amended) (the Directive), concerning the placing of plant protection products on the market. The Directive establishes a system whereby plant protection products may not be placed on the market or used unless they have been authorised and added to Annex 1 of the Directive.

5. The Regulations implement 8 Commission Directives: Directives 2006/131/EC, 2006/132/EC, 2006/133/EC, 2006/134/EC, 2006/135/EC, 2006/136/EC, 2007/5/EC and 2007/6/EC which add a further 14 pesticide active substances to Annex 1 of the Directive.

6. These 8 Directives are transposed by being added to the list in Schedule 1 to the Regulations which sets out the instruments that amend the Directive.

BACKGROUND

7. The Plant Protection Products Directive (91/414/EEC) was adopted by the Council of Ministers in July 1991. It came into force in July 1993 and was implemented in Scotland by the Plant Protection Products (Scotland) Regulations, the latest consolidation of which took effect on 1 July 2005.

8. The main elements of the Directive are:

- To harmonise the overall arrangements for authorisation of plant protection products within the European Union. This is achieved by harmonising the process for considering the safety of active substances at a European Community level by establishing agreed criteria for considering the safety of those products. Product authorisation remains the responsibility of individual Member States
- To provide for the establishment of a positive list of active substances (Annex I), that have been shown to be without unacceptable risk to people or the environment

- To add active substances to Annex I of the Directive as existing active substances are reviewed (under the European Commission (EC) Review Programme) and as new ones are authorised
- To authorise the marketing and use of plant protection products by member states only after an active substance is listed in Annex I, except where transitional arrangements apply.

9. Before an active substance can be considered for inclusion in Annex I of the Directive, companies must submit a complete data package (dossier) on both the active substance and at least one plant protection product containing that active substance. The data required:

- identify an active substance and plant protection product;
- describe their physical and chemical properties;
- their effects on target pests, and;
- allow for a risk assessment to be made of any possible effects on workers, consumers, the environment and non-target plants and animals.

10. Comprehensive lists of the data required to be evaluated to satisfy inclusion in Annex I of the Directive, or the authorisation of a plant protection product are set out in the Directive, (Annexes II and III). Annex II data relate to the active substance and Annex III to the plant protection product. These data are submitted to one or more Member States for evaluation. A report of the evaluation is submitted to the European Food Safety Authority (EFSA). Following peer review of the report, EFSA makes a recommendation to the European Commission on whether Annex I inclusion is acceptable. This recommendation is then discussed by all Member States in the framework of the Standing Committee on the Food Chain and Animal Health (SCFA) previously the Standing Committee on Plant Health (SCPH). Where necessary, the Scientific Panel is consulted before the SCFA can deliver an opinion on whether an active substance should be included in Annex I.

11. Under the Directive, plant protection products are defined as active substances or preparations containing one or more active substances, formulated as it is supplied to the user, and intended to

- protect plants or plant products against all harmful organisms or prevent the action of such organisms (for example agricultural/horticultural fungicides and insecticides)
- influence the life processes of plants, other than as a nutrient (for example as a growth regulator)
- preserve plant products, in so far as such substances or products are not subject to provisions of Community law on preservatives
- destroy undesired plants or destroy parts of plants or check or prevent the undesired growth of plants (for example herbicides)

12. All the active substances being added to Annex 1 as a consequence of the eight Directives that are being transposed in this set of Regulations, fall within this definition of plant protection products.

13. Directive 91/414/EEC is continually being updated and amended through subsequent Directives, such as the eight being transposed in these Regulations. It is necessary to amend

the principal Regulations each time a substance is added to Annex 1. This is a frequent occurrence.

14. Until the EU review programme which aims to harmonize the registration of plant protection products throughout the European Community is completed around 2008, the Control of Pesticides Regulations 1986 (as amended) (COPR) will run in tandem with the principal Regulations for those pesticides which currently have UK approval but have still to be evaluated at EU level.

ADMINISTRATIVE ARRANGEMENT

15. The day to day administration of the plant protection products approval system pre and post devolution is undertaken by the Pesticides Safety Directorate, an Executive Agency of Defra operating on behalf of the Scottish Ministers under an Agency Arrangement. The arrangement rests on regulation 26 of the principal Regulations which provides that the Scottish Ministers may arrange for any of their functions under or for the purposes of the principal Regulations or the Directive to be exercised on their behalf by a Minister of the Crown.

FINANCIAL EFFECTS

16. No Regulatory Impact Assessment has been carried out in relation to the Regulations. The instrument has no financial effects on the Scottish Executive, local government or Scottish business.

Scottish Executive Environment and Rural Affairs Department
February 2007