### EXECUTIVE NOTE

### THE PESTICIDES (MAXIMUM RESIDUE LEVELS IN CROPS, FOOD AND FEEDING STUFFS) (SCOTLAND) AMENDMENT REGULATIONS 2008 SSI/2008/65

1. The Regulations are made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972, and are subject to negative resolution procedure.

### **Policy Objective**

2. The Regulations amend the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs) (Scotland) Regulations 2005 (SSI 2005/599) ("the principal Regulations") which establish a legislative framework for the control of pesticide residues in food. The principal Regulations have been amended as new maximum residue levels (MRLs) are set under an ongoing EC programme to establish MRLs for all pesticides in a wide range of foodstuffs.

3. The Regulations implement Commission Directive 2007/73/EC by amending Schedule 2 (which lists MRLs agreed under the EC programme) to the principal Regulations. The Regulations

- specify revised MRLs for 9 pesticides;
- correct an error made in Directive 2007/56/EC which was transposed in the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs) (Scotland) Amendment (No. 4) Regulations 2007 (SSI 2007/523). The error concerned the residue level set for the pesticide *deltamethrin* in respect of raspberries; and
- make provision in relation to an error in Directive 2007/73/EC. The Commission has confirmed that the Directive sets an incorrect residue level for the pesticide *acetamiprid* in relation to the food group "1 (iii) Pome Fruit" (in Schedule 2 of the principal Regulations). The level specified is ten times higher than the one supported by scientific evaluation. The intended residue level has been confirmed as 0.1 mg/kg as opposed to the specified level of 1 mg/kg.

### **Policy Background**

4. MRLs reflect levels of pesticides that can be expected to be found in produce that has been treated in accordance with good agricultural practice. They therefore provide a mechanism for statutory controls on pesticides in produce moving in trade and for monitoring the correct use of pesticides. MRLs are not safety limits and are always set below levels that would cause harm.

5. MRLs applicable to trade to or within the UK are now almost exclusively determined at EC level. The EC programme is directed to establishing MRLs for up to 550 pesticides. The Regulations implement Directive 2007/73/EC which the Scottish Government has an obligation to transpose.

6. The Regulations apply to any home-grown or imported produce put into circulation in Scotland. Separate but similar legislation applies in England, Wales and Northern Ireland.

## Administration

7. The day to day administration of the pesticides approval system (which includes MRLs) is undertaken by the Pesticides Safety Directorate (PSD), an Executive Agency of Defra operating on behalf of the Scottish Ministers under an Agency Arrangement.

## Discussion and timing

8. The majority of the provisions of Directive 2007/73/EC require to be transposed by 15 June and 15 September 2008. However, in respect of the corrective residue level for *deltamethrin*, the Commission has maintained the original transposition date of 19 December 2007 set under Directive 2007/56/EC. Directive 2007/73/EC was not published in the Official Journal until 14 December 2007, and did not come into force until 3 January 2008. It was not possible to meet the transposition deadline of 19 December 2007, but the relevant provisions are now transposed at what is considered to be the earliest practical opportunity. In the interim, PSD issued an information update to stakeholders explaining the background to the delayed transposition and clarifying the regulatory position. It can be viewed on the PSD website: <a href="http://www.pesticides.gov.uk/approvals.asp?id=2318">http://www.pesticides.gov.uk/approvals.asp?id=2318</a>

9. In connection with the incorrect MRL for *acetamiprid* specified in Directive 2007/73/EC, the balance of risk favours a precautionary approach by transposing in the Regulations the lower (correct) residue level. The higher residue level specified in Directive 2007/73/EC is unsupported by the scientific evaluation and may prove to be unsafe.

10. Relevant to this approach is article 8(1) of the parent Directive 90/642/EEC on the fixing of MRLs on products of plant origin which enables member states to reduce an MRL where it is considered that the specified level endangers animal or human health. The Scottish Government intends to rely on article 8(1) of Directive 90/642/EEC, and the Commission confirmation on the actual intended MLR for *acetamiprid* in Pome Fruit, to transpose at the lower level of 0.1 mg/kg. To do otherwise would result in the potential for an unacceptable risk to human health, and the specification of an MRL that is unsupported by scientific evaluation.

11. PSD is to issue an information update to stakeholders to explain the error made in Directive 2007/73/EC and confirm the approach being taken. The information update will also be published on the PSD website.

12. Directive 2007/73/EC also amends the temporary time limits set for MRLs for *atrazine* and *deltamethrin*. However, there is no requirement for transposing measures in this regard as we have adopted the practice of not including time limiting provisions in the principal Regulations, in order to minimise the requirement to amend.

# **Consolidation of principal Regulations**

13. The latest amendments to the principal Regulations are necessary to replace MRLs which were set down by Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC. These Directives have been amended on a fairly regular basis and frequent rapid changes to domestic legislation are required.

14. Further, more extensive changes are imminent, with the coming into force of EC Regulation 396/2005 (expected in September 2008). The EC Regulation will provide for a fully integrated EC MRLs regime, and any necessary domestic legislation will be put in place at the relevant time.

15. It is therefore considered there is little to be gained from a consolidation of the principal Regulations at this stage. The principal Regulations date only from 2005, and previous amending instruments have primarily amended only the Schedules to the principal Regulations (principally Schedule 2, which lists MRLs and totals around 250 pages). Also, a database including all the levels set by Schedule 2 along with all of the residue definitions set in Schedule 1 is available to members of the public and key external stakeholders (farmers, growers, suppliers and retailers) in an easy to read format on the PSD website. In this way, those affected by the amending legislation have access to a readily available and current consolidating database. In practice, anecdotal evidence suggests that most rely on the PSD website as opposed to the legislation as a first port of call.

16. The body of the principal Regulations is relatively unchanged, and when EC Regulation 396/2005 comes into force it will end the system of transposing Directives by statutory instruments. It is expected that these Regulations will be among the last amending regulations before EC Regulation 396/2005 comes into force in September 2008.

### **Consultation and financial effects**

17. In 2003, the Pesticides Safety Directorate undertook a consultation on a GB basis in relation to an EC proposal to amend the Community's procedures for setting MRLs. Responses indicated that compliance costs were virtually unchanged since the previous assessment made in 1999.

18. A Regulatory Impact Assessment was prepared in 2005 when the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs) (Scotland) Regulations were last consolidated and provides a basis for establishing the impact of amendments to the principal Regulations. The financial data contained in the RIA

relates to the whole cost which pesticide companies bear in providing data necessary for a pesticide product to be authorised for marketing and not simply the average cost of establishing individual maximum residue levels.

19. This instrument has no additional financial effects on the Scottish Government, local government or business.

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