

**EXPLANATORY MEMORANDUM TO
THE PLANT PROTECTION PRODUCTS REGULATIONS 2011**

2011 No. 2131

AND

**THE PLANT PROTECTION PRODUCTS (FEES AND CHARGES) REGULATIONS
2011**

2011 No. 2132

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 The Plant Protection Products Regulations 2011 (“the Enforcement Regulations”) lay down enforcement powers and penalties for infringements of Regulation (EC) No 1107/2009 (“Regulation 1107/2009”), which concerns the placing of plant protection products (essentially pesticides used in the agriculture, horticulture and amenity sectors, and in home gardens) on the market. They also implement various other aspects of Regulation 1107/2009.
 - 2.2 The Plant Protection Products (Fees and Charges) Regulations 2011 (“the Fees Regulations”) set fees and charges to recover the government’s costs of implementing Regulation 1107/2009 and aspects of two other pieces of EU legislation. These are Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides, and Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 The Enforcement Regulations are made to implement Regulation 1107/2009, which lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the European Union. They set out enforcement powers and penalties for infringement of that Regulation.
 - 4.2 The Fees Regulations update and replace existing Regulations which prescribe a modular fees structure covering all aspects of the authorisation process, including the

assessment of the wide range of data needed to demonstrate that a particular use of a plant protection product meets the specified standards of safety. They also include specific fees for evaluating applications for import tolerances under MRLs Regulation 396/2005 relating to active substances for which the UK is not normally the rapporteur member State and make provision for a charge on the annual turnover of crop protection companies to recover certain other costs to regulatory authorities arising particularly from Directive 2009/128/EC.

5. Territorial Extent and Application

5.1 The Enforcement Regulations apply to Great Britain. Separate but similar legislation is being made in Northern Ireland.

5.2 The Fees Regulations 2011 apply to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 Regulation 1107/2009 is essentially a revision of Directive 91/414/EEC, which currently governs the approvals regime for plant protection products, but with some new elements. It lays down rules for the authorisation of plant protection products and for their placing on the market, use and control within the European Union. The Regulation is directly applicable in all member States from 14 June 2011, but some of its provisions need to be supported by domestic legislation setting out enforcement powers and penalties for infringement. These are contained in the Enforcement Regulations. Regulation is considered the appropriate control mechanism: non-legislative mechanisms are not considered commensurate with the potential harm which could arise from breaching the requirements of Regulation 1107/2009.

7.2 The Enforcement Regulations also designate the Secretary of State as the competent authority for England and Wales, and the Scottish Ministers as the competent authority for Scotland, to carry out the obligations laid down in Regulation 1107/2009. They further designate the Secretary of State as the co-ordinating authority for ensuring the necessary contacts between applicants, other member States, the Commission and the European Food Safety Authority. Finally, these Regulations maintain existing national arrangements for the authorisation of adjuvants, pending the development of harmonised EU standards.

7.3 It has been the policy of successive governments to recover certain costs to government arising from the operation of the plant protection products regime through

fees and charges. This is achieved through two charging mechanisms as regards plant protection products: the payment of fees for evaluating applications for authorisation and dossiers for approval of active substances; and a charge on the annual turnover of authorisation holders.

7.4 The Fees Regulations update and replace existing Regulations which prescribe a modular fees structure covering all aspects of the evaluation, including the assessment of the wide range of data needed to demonstrate that a particular use of a plant protection product meets the specified standards of safety. They include increases to reflect additional work requirements which have been introduced into the evaluation process since fees were last revised in 2007 and extensions of requirements for authorisation laid down in Regulation 1107/2009.

7.5 The Fees Regulations also include specific fees for evaluating applications for import tolerances under MRLs Regulation 396/2005 relating to active substances for which the UK is not normally the rapporteur member State.

7.6 In line with Treasury guidance, the Fees Regulations provide for the progressive recovery of other costs arising from the operation of the approval system as a whole (such as providing guidance to applicants) from fees. These costs are currently all recovered through the pesticides charge.

7.7 Arrangements for the charge are currently set out in Section 18 of the Food and Environment Protection Act 1985. They enable the Secretary of State to make an annual charge in respect of certain costs incurred by regulatory authorities in carrying out their obligations. The charge is paid to the Chemicals Regulation Directorate by authorisation holders in proportion to their annual turnover of plant protection products. The Devolved Administrations are reimbursed as necessary. The Fees Regulations are made in exercise of powers under the European Communities Act 1972, as well as section 56 of the Finance Act 1973. New costs arising from the new EU regulatory regime will be recoverable by way of the charge.

- Consolidation

7.8 Not relevant.

8. Consultation outcome

8.1 A wide range of interests was consulted on these Regulations, including those involved in the manufacture, supply and use of plant protection products; consumer and environmental organisations; and government bodies. The consultation was conducted on a non-formal basis and allowed six weeks for responses. The period for response was reduced because the approach to implementation had already been decided following an earlier formal written consultation, and comments were therefore sought on only a limited number of specific points.

8.2 Eleven responses were received from the farming/growing industry and businesses, two from government advisory bodies and two from the public and NGOs. Respondents in the first two groups generally supported the overall approach of the Enforcement Regulations, but raised some concerns over legal clarity and materiality, whilst respondents in the third group sought greater regulation and stronger sanctions, including imprisonment, for breaches. Respondents in the first two groups generally supported the overall approach of the Fees Regulations, but raised concerns about some specific fees (particularly for off-label approvals and parallel trade) and matters which were proposed to be funded by the pesticide charge. One respondent in the third group proposed that costs should not be recovered from the industry and should instead be Exchequer-funded.

8.3 In light of the consultation, the Department maintained the general approach of the Enforcement Regulations, with some technical amendments to certain provisions. The Department does not consider it necessary to include imprisonment among the sanctions in these Regulations, since it is available in other legislation under which cases could be tried where this is justified. The Department has retained the overall structure of the Fees Regulations, but deleted or adjusted some individual fees and decided not to proceed with some matters which it proposed to fund from the charge. The Department does not consider it reasonable for the Exchequer to fund the entire operation of this regulatory regime. It is appropriate for the industry to continue to meet the costs of the services they receive.

9. Guidance

9.1 These Regulations carry forward, with some updating, well established regimes for regulating plant protection products and charging for the costs arising. The HSE's Chemicals Regulation Directorate provides guidance on its website and in Regulatory Updates which are sent to stakeholders.

10. Impact

10.1 The impact on business, charities or voluntary bodies arising from the Enforcement Regulations is expected to be negligible. The impact arising from the Fees Regulations is expected to be a one-off cost of £182,000 and £615,000 annually to pesticide manufacturers and related industries, £30,000 annually to pesticide users, and £8,000 annually to the food industry.

10.2 The impact on the public sector is expected to be benefits of £182,000 non-recurring and £653,000 recurring.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 Regulation 1107/2009 applies direct and makes no provision to minimise the impact of the requirements on firms employing up to 20 people. Only one consultation response indicated the size of the business. It identified itself as a micro-business (1-9 employees) and supported the approaches proposed in both the Enforcement and Fees Regulations.

11.3 As indicated above, the impact on business of the Enforcement Regulations is expected to be negligible. The more substantial fees under the Fees Regulations are met almost exclusively by large, usually multinational, companies who develop and support new products and medium companies which sell products based on those developed by the larger companies. Small companies are generally only liable for the minor fees such as those for parallel imports, reflecting the different nature of their business. Costs arising under the charge will be met by all parties in proportion to their turnover of sales of plant protection products. As indicated in the Impact Assessment, the bulk of the charges estimated to be paid under the Fees Regulations will be met by large companies (88%) and medium companies (12%), with small companies contributing less than 0.2% of the total.

12. Monitoring & review

12.1 The Secretary of State will review the Enforcement Regulations every five years to determine in particular whether they achieve their intended objective, whether those objectives remain appropriate, and, if so, whether they could be achieved with a less regulatory system.

12.2 HSE will review the Fees Regulations regularly to determine whether they achieve their intended objective of full cost recovery. HSE will consult on any changes which are found to be necessary as part of its annual consultation on revised charges to industry. The Fees Regulations are next likely to be amended in 2013.

13. Contact

Mark Hawkins at the Health and Safety Executive, tel: 01904 455759 or email: mark.hawkins@hse.gsi.gov.uk can answer any queries regarding the instrument.