

Non Formal Consultation on

The Plant Protection Products Regulations 2011

The Plant Protection Products (Fees and Charges)
Regulations 2011

March 2011



This non-formal consultation is carried out by the Chemicals Regulation Directorate of the Health and Safety Executive on behalf of:

Department for Environment, Food and Rural Affairs

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PART I – THIS CONSULTATION

- 1.1 This consultation is being conducted on a non-formal basis because it focuses on a limited number of specific points. It is being sent to all stakeholders who were involved in an earlier [consultation](#) on the broad policy issues, but asks questions which are of interest to particular stakeholder groups.
- 1.2 It seeks views on two sets of draft Regulations. The first would support the operation of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market¹. In this document, these will be called the Enforcement Regulations. The second would set fees and charges to recover the government's costs of implementing Regulation 1107/2009 and aspects of two other pieces of EU legislation: Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides² and Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin³. In this document, these will be called the Fees Regulations.
- 1.3 The enclosed draft Enforcement Regulations cover England, Scotland and Wales; Northern Ireland's Enforcement Regulations will largely mirror them. Primarily, the new Regulations lay down enforcement powers and penalties for infringements of Regulation 1107/2009, and also implement various other aspects of it.
- 1.4 The draft Fees Regulations cover the United Kingdom, reflecting existing arrangements whereby fees and charges are collected on a national basis. They concern primarily the recovery of costs to government arising under Regulation 1107/2009, but also certain aspects of Directive 2009/128/EC and MRLs Regulation 396/2005. The elements relating to Regulations 1107/2009 and 396/2005 would apply from 14 June 2011, whilst those relating to Directive 2009/128/EC would apply from 26 November 2011, when the Directive will be implemented in the UK.
- 1.5 The Chemicals Regulation Directorate (CRD) of the Health and Safety Executive (HSE) is the delivery body for Defra's responsibilities on pesticides. It is undertaking the consultation on behalf of Defra, the Scottish Government, the Welsh Assembly Government and the Northern Ireland Assembly.

¹<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0001:0050:EN:PDF>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:309:0071:0086:EN:PDF>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:EN:PDF>

What previous consultation has been carried out on this subject?

- 1.6 A [consultation](#) on the Commission's proposals for the MRLs regime was published in 2003. An [initial consultation](#) on the Commission's original proposals for the Regulation on placing plant protection products on the market, and for the Directive on sustainable use of pesticides, was published in 2006. A [consultation](#) on options for implementing the adopted legislation was published by Defra on 9 February 2010. It included provisions in Regulation 1107/2009 for recording and disclosing information, and options for recovering the government's costs under the various pieces of EU legislation. The outcome of that consultation was presented in the [paper](#) published by Defra on 15 December 2010. The present consultation will be followed by one on the implementation of measures for the sustainable use of pesticides under Directive 2009/128/EC.

Who is affected by the Regulations?

- 1.7 These Regulations will affect primarily those involved in the manufacture, advertising, sale, supply and use of plant protection products.

What will be the outcome of this consultation?

- 1.8 Following this consultation, CRD, Defra and the Devolved Administrations will consider the responses and take them into account in finalising the Regulations. They are expected to be laid in Parliament, the Welsh Assembly Government and the Northern Irish Assembly in May 2011 and to come into force on 14 June 2011.

Deadline for comments?

- 1.9 This consultation focuses on specific measures to implement the Government's preferred approach in light of the earlier consultation on options (paragraph 1.6). Since the policy decisions have been taken, we are adopting a shorter timescale for this exercise and comments should be submitted by 12 April 2011. Given the tight timetable for the implementation of the legislation, late comments cannot be considered.

What comments are requested?

- 1.10 The consultation sets out specific areas on which we are seeking views, and the questions are summarised at Annex A. You are welcome to comment on any or all of the questions or any issues relevant to the two draft statutory instruments and this consultation process. The policy decisions reflected in the December 2010 Defra publication referred to at paragraph 1.6 above are not revisited here. Views are invited only on the provisions within the two draft statutory instruments.

- 1.11 When responding, it would be helpful if you would make clear the nature of your organisation (if any), and the capacity in which you are responding (e.g. an officer representing an organisation or an individual) and provide an explanation of how the views of your members were gathered. If you represent a business, it would be helpful if you would indicate whether it is micro (1-9 employees), small (10-49 employees), medium (50-249 employees) or large (250 or more employees).
- 1.12 Any responses received will be made public, unless you have specifically asked for them (or any part of them) to remain confidential. Any confidentiality disclaimer generated by your IT system in e-mail responses will not be treated as such a request. There may be circumstances in which government will be required to communicate information to third parties on request, in order to comply with its obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004.

- 1.13 Responses should be sent by email or post to:

Consultation Coordinator
Pesticides Legislation Consultation (Part 2)
Room 214
Chemicals Regulation Directorate
Kings Pool
Peasholme Green
York
YO1 7PX

E-mail: ConsultationCoordinator@hse.gsi.gov.uk

- 1.14 Consultees in **Scotland** should also copy their responses to:

Marie Coventry
Scottish Government Rural and Environment Directorate
Agriculture and Rural Development Division
CAP Reform & Crop Policy
D Spur, Saughton House
Broomhouse Drive
Edinburgh
EH11 3XD

E-mail: EUPestlegconsult@scotland.gsi.gov.uk

1.15 Consultees in **Wales** should also copy their responses to:

David Thomas
Plant Health and Biotechnology Branch
Sustainability and Environmental Evidence Division
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ
E-mail: planhealthandbiotech@wales.gsi.gov.uk

1.16 Consultees in **Northern Ireland** should also copy their responses to:

Deborah Currie
Department of Agriculture and Rural Development Northern Ireland
Environmental Policy Branch
Room 654 Dundonald House
Upper Newtownards Road
Belfast
BT4 3SB
Northern Ireland

E-mail: deborah.currie@dardni.gov.uk

PART II – ENFORCEMENT REGULATIONS

Regulation (EC) No 1107/2009

- 2.1 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 in commercial form and for their placing on the market, use and control within the European Union.
- 2.2 The Regulation will apply direct 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:
- Article 28 plant protection products must not be marketed or used unless authorised. In the case of parallel trade, the requirement for authorisation may be replaced by a parallel trade permit in accordance with Art. 52;
 - Article 49 requirements for placing treated seed on the market;
 - Article 55 plant protection products must be used properly;
 - Article 56 authorisation holders must notify safety problems immediately, and efficacy problems annually;
 - Article 58 adjuvants must not be marketed or used unless authorised. By way of derogation, Article 81(3) allows national rules to continue whilst EU rules are developed;
 - Article 62 authorisation holders and applicants must make every effort to agree sharing of vertebrate data;
 - Article 64 packaging of plant protection products and adjuvants must not resemble food and drink containers;
 - Article 65 product labelling must comply with Directive 1999/45/EC (note: this has been amended and will ultimately be repealed by Regulation (EC) 1272/2008);
 - Article 66 plant protection products must not be advertised unless authorised;
 - Article 67 producers, suppliers, distributors, importers and exporters of plant protection products must keep records for five years, and users for three years. They must make them available to the competent authority on request;
producers must undertake post-authorisation monitoring when requested by the competent

authorities;
Article 69 emergency measures.

- 2.3 Detailed requirements relating to use of plant protection products will be included in additional legislation which will implement Directive 2009/128/EC on the sustainable use of pesticides. A separate consultation will be held on proposals for this legislation.
- 2.4 Article 75(1) of Regulation 1107/2009 requires each member State to designate a competent authority (or authorities) for carrying out the obligations laid down in the Regulation. Article 75(2) requires member States to designate a national authority to co-ordinate contacts between applicants, other member States, the Commission and the European Food Safety Authority.
- 2.5 Article 58(1) of Regulation 1107/2009 prohibits the marketing of unauthorised adjuvants, but Article 81(3) provides that member States may maintain existing national arrangements for their authorisation pending the adoption of harmonised measures.

Proposed operation in Great Britain

- 2.6 Draft Enforcement Regulations needed to give effect to these provisions in Great Britain are set out at Annex B and are summarised below. Separate but similar Regulations would be introduced in Northern Ireland.
- 2.7 They prescribe offences similar to those already included in the Plant Protection Products Regulations 2005⁴, the Plant Protection Products (Scotland) Regulations 2005⁵ and the Plant Protection Products Regulations (Northern Ireland) 2005⁶ in relation to the aspects identified at paragraph 2.2 above. They include offences of breaching the specified requirements, giving false information, and obstructing officials in the performance of their regulatory functions.
- 2.8 In addition, the draft Enforcement Regulations prescribe offences for breaches of requirements of Regulation 1107/2009 which are new to the regulatory regime. They concern:
 - seed which has been treated with a plant protection product (regulation 10), which must in future be authorised in at least one member State and must be labelled. This closes a legal loophole under which products which are not authorised in the UK may be applied to seed elsewhere and introduced into the UK without

⁴ S.I. 2005/1435

⁵ S.S.I. 2005/331

⁶ S.R. 2005/526

labelling. It puts on a legal basis a voluntary industry agreement which has been in place since 1990;

- an obligation on authorisation holders to report annually any adverse data relating to efficacy, resistance or unexpected effects on plants or plant products (regulation 13). These provisions would apply only to significant changes involving loss of product performance, or changes in susceptibility of target populations which are likely to lead to such loss, or to crop damage, in the same way as existing voluntary arrangements. Thus they would put on a legal basis what is already established practice for authorisation holders;
- packaging of adjuvants, so that those which may be mistaken for food, drink or feed must minimise the risk of such a mistake's being made. If available to the general public, they must contain components to discourage or prevent their consumption (regulation 16). These provisions are consistent with the general practices of adjuvant manufacturers and thus would put on a legal basis what is already established practice;
- keeping records, and making information from them available to the competent authorities on request (regulation 19). This aspect of the Regulation was included in Stage One of the [consultation](#) and the associated impact assessment, and is not considered further here.

Question 1: Do you have any views on the proposed approach to offences?

- 2.9 The draft Enforcement Regulations include enforcement powers similar to those already included in the Plant Protection Products Regulations 2005, the Plant Protection Products (Scotland) Regulations 2005 and the Plant Protection Products Regulations (Northern Ireland) 2005 in relation to powers of inspectors (including powers of entry, service of notices, and seizure and disposal of plant protection products).

Question 2: Do you have any views on the proposed approach to enforcement powers?

- 2.10 The draft Enforcement Regulations designate the Secretary of State as the competent authority for England and Wales, and the Scottish Ministers as the competent authority for Scotland, for carrying out the obligations laid down in Regulation 1107/2009 (as required by Article 75(1)). Northern Ireland's Enforcement Regulations will make a similar designation for this role in Northern Ireland.

Question 3: Do you have any views on the proposed designations of competent authorities?

2.11 The draft Enforcement Regulations 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 (as required by Article 75(2) of Regulation 1107/2009).

Question 4: Do you have any views on the proposed designation of the Secretary of State as the co-ordinating authority?

2.12 The draft Enforcement Regulations also maintain existing national arrangements for the authorisation of adjuvants, pending the development of harmonised EU standards. They have been transferred from Schedule 3 of the Plant Protection Products (Basic Conditions) Regulations 1997⁷, in exercise of the derogation in Article 81(3) of Regulation 1107/2009.

Question 5: Do you have any views on the proposed retention of existing arrangements for authorising adjuvants?

⁷ S.I. 1997/189

PART III – FEES REGULATIONS

- 3.1 It has been the policy of successive governments to recover certain costs to government arising from the operation of the pesticides 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.

Fees

- 3.2 Fees are currently set by the Plant Protection Products (Fees) Regulations 2007⁸. They 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.

Annual charge

- 3.3 Arrangements for the charge are currently set out in section 18 of the Food and Environment Protection Act 1985⁹. 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 CRD by authorisation holders in proportion to their annual turnover of plant protection products. The Devolved Administrations are reimbursed as necessary.

Proposed operation in the United Kingdom

- 3.4 Draft Fees Regulations are set out at Annex C. They maintain the existing fees and charge structure and arrangements, but also introduce a number of developments, which are explained below.
- 3.5 Fees for evaluating applications and related work were last revised in 2007. The draft Fees Regulations revise fee levels in light of a recent review to ensure that they continue to secure full cost recovery. The review has identified a need to increase fees to recover an additional £425,000 per annum to reflect additional work requirements which have been introduced into the evaluation process since 2007. These include the development of the risk envelope approach and increased preparation for mutual recognition, increased complexity of environmental risk assessments, and additional reports for applications for new sources of technical material.

⁸ S.I. 2007/295

⁹ 1985 c. 48

- 3.6 The Regulations also reflect the extension of requirements for authorisation laid down in Regulation 1107/2009, to include costs relating to:
- preparing applications for basic substance authorisations;
 - evaluating adverse data for active substances;
 - assistance given to other member States in evaluating applications.
- 3.7 The draft Fees Regulations include specific fees for matters arising in two other pieces of EU legislation. These concern the requirements in Directive 2009/128/EC regarding applications for aerial spraying of pesticides, and 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. Altogether, the new fees identified in paragraphs 3.6 and 3.7 are estimated to cost £298,000 per year, shared between all applicants.

Question 6: Do you have any views about the proposed coverage of fees?

- 3.8 Existing fees do not include certain activities associated with the authorisation of plant protection products. Costs associated with processing a particular application are recovered through the fee, but costs associated with the authorisation process as a whole (such as providing guidance to all applicants) are currently recovered through the charge. The draft Fees Regulations would assign these latter costs to fees too; there would be a corresponding reduction in the charge. It is estimated that around £1.4 million per year would be transferred to fees in this way.
- 3.9 These costs are not reflected in the proposed fees set out in the draft Fees Regulations at Annex C and could be incorporated in a number of ways:
- Option 1. As a set amount uplift added to each fee – this would have the effect of increasing each fee by approximately £280.
- Options 2. As a percentage uplift to each fee – this would have the effect of increasing each fee by about 36%.
- Option 3. As a combination of the above, with a percentage uplift applied to applications for new active substances and a set amount uplift applied to product applications – this would have the effect on increasing new active substance fees by about 36% and increasing each product fee by approximately £229.

Option 4. Target the product fee changes to those activities (and hence fees) to which the additional activities are most relevant – this would have the effect of increases ranging from less than £100 to £700.

Question 7: Do you have any views about the proposal to recover all costs associated with authorisations from fees (with a corresponding reduction in the charge) and the method of applying the increase?

- 3.10 The draft Fees Regulations maintain the same broad structure as the current 2007 regulations with one exception. Recent discussions with other EU member States and with crop protection companies have indicated that some lead zonal product applications will involve a far greater level of complexity and hence evaluation resource than is currently the case for a UK product approval. The draft Fees Regulations, therefore, propose a system of ‘partial dossier’ fees on the lines of those applicable to active substance applications. Such a system would be tailored to reflect more accurately the costs of evaluating larger data packages.
- 3.11 At this very early stage, it is difficult to assess how complex some lead zonal applications might be. It seems likely that those applications involving the zonal re-registration of a lead product or products (where more than one active ingredient is involved) in which a ‘risk envelope’ can be established to cover a range of trailing products of differing formulation and/or use) would require charges of up to £40,000, although charges at the very top end of the scale shown seem unlikely. The fee to be charged in each case would be established on receipt of an application by CRD and would be agreed with the applicant before the application was accepted at CRD’s ‘sift’. The partial dossier approach proposed would not change the fees payable for standard technical stream applications (involving the consideration of only UK uses) which are a distinct category in the proposal.

Question 8: Do you support the proposed ‘partial dossier’ approach for products? What are your views on the level of fees proposed for partial product dossiers?

- 3.12 The draft Fees Regulations are made in exercise of powers under the European Communities Act 1972¹⁰, as well as the Finance Act 1973¹¹. New costs arising from the new EU regulatory regime will be recovered by way of the charge.
- 3.13 New costs arising from Regulation 1107/2009 that could be charged in this way are those for:

¹⁰ 1972 c. 68

¹¹ 1973 c. 51

- special reviews of the approval of active substances, safeners or synergists necessitated by emerging scientific information;
 - setting restrictions or other interim measures to address safety concerns.
- 3.14 New costs arising from Directive 2009/128/EEC that could be charged in this way are those relating to:
- support for pesticide equipment testing;
 - measures supporting the Water Framework Directive (developing a regulatory risk assessment process and measures focussed on user practice);
 - establishing safeguard zones where pesticides cannot be used or stored;
 - developing harmonised risk indicators;
 - the provision of educational facilities and information to professional users;
 - monitoring and enforcement of compliance with integrated pest management;
 - updating guidance on storage;
 - a one-off amnesty period allowing the recovery of unauthorised pesticides from stores;
 - updating the statutory Codes of Practice and the Herbicide handbooks;
 - setting up an aerial use authorisation system, and for maintenance of a monitoring system.
- 3.15 The total additional sum collected through the charge to reflect new costs arising from Regulation 1107/2009 and Directive 2009/128/EC are estimated at non-recurring costs of £494,500 and recurring costs of £337,500 per year. This estimate is at the bottom end of the range of estimates included in the Stage One consultation, reflecting the governments wish to minimise burdens on business to the maximum extent possible within the EU obligations.

Question 9: Do you have any views about the proposal to recover new costs arising under Regulation 1107/2009 and Directive 2009/128/EC from the charge?

PART IV – IMPACT ASSESSMENT

- 4.1 An impact assessment was included in the [initial consultation](#) on the Commission's original proposals for Regulation 1107/2009, and supplemented by [detailed assessments](#) of key aspects of the proposals during the negotiations.
- 4.2 A further impact assessment of provisions in Regulation 1107/2009 for recording and disclosing information about pesticides was included in [Stage One](#) of the consultation.
- 4.3 The obligations the draft Enforcement Regulations impose are substantially the same as those already contained in the Plant Protection Products Regulations 2005 and parts of the Plant Protection Products (Basic Conditions) Regulations 1997. There are some slight technical differences between the existing and new regimes, which lead to consequential differences in the offences and enforcement powers. However, enforcement and compliance costs should not be significantly different from current levels.
- 4.4 The draft Fees Regulations essentially follow existing arrangements for the recovery of the government's costs in regulating plant protection products. They revise fees in line with changes in costs since they were last set and include certain activities currently funded by the charge (with a corresponding reduction in the charge). They introduce new fees to reflect the extension of authorisation requirements in Regulation 1107/2009, the authorisation of aerial spraying in Directive 2009/128/EC, and the evaluation of certain applications for import tolerances under Regulation 396/2005. Finally, they provide for the recovery of certain costs arising under the new EU regulatory regime from the charge.
- 4.5 The most difficult issue to quantify is the impact of the incoming zonal authorisation system. The fees payable will clearly increase when CRD is the zonal rapporteur. On the other hand, there is likely to be an offsetting saving for companies when the UK is not and CRD can use the core evaluation provided by another member State. Additionally, when the UK is the lead zonal rapporteur, there will be savings in the time and cost of registering the product in other member States. For the purpose of the initial impact assessment, we have assumed that the two situations would offset each other and would not increase overall costs for the crop protection industry.
- 4.6 These factors are considered in the detailed impact assessment at Annex D.

Question 10: Do you have any comments on the impact assessment?

PART V – DRAFT STATUTORY INSTRUMENTS

- 5.1 A draft of the proposed Enforcement Regulations is at Annex B, and of the proposed Fees Regulations at Annex C.

PART VI – CONSULTATION PROCESS

- 6.1 This non-formal consultation is being carried out as a shorter, more focused exercise than the earlier formal written consultation on options for implementation (paragraph 1.1). This reflects the facts that policy decisions on those options have already been taken in light of responses, and comments are now sought on only a limited number of specific points.

Question 11: Do you have any comments on the consultation process?

Annex A

Summary of questions

1. Do you have any views on the proposed approach to offences?
2. Do you have any views on the proposed approach to enforcement powers?
3. Do you have any views on the proposed designations of competent authorities?
4. Do you have any views on the proposed designation of the Secretary of State as the co-ordinating authority?
5. Do you have any views on the proposed retention of existing arrangements for authorising adjuvants?
6. Do you have any views about the proposed coverage of fees?
7. Do you have any views about the proposal to recover all costs associated with authorisations from fees (with a corresponding reduction in the charge) and the method of applying the increase?
8. Do you support the proposed ‘partial dossier’ approach for products? What are your views on the level of fees proposed for partial product dossiers?
9. Do you have any views about the proposal to recover new costs arising under Regulation 1107/2009 and Directive 2009/128/EC from the charge?
10. Do you have any comments on the impact assessment?
11. Do you have any comments on the consultation process?

