

EXPLANATORY MEMORANDUM TO
THE FEES FOR ASSESSMENT OF ACTIVE SUBSTANCES (THIRD
STAGE REVIEW) REGULATIONS 2005

2005 No.117

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. Description

This Statutory Instrument establishes fees to cover the costs of the UK's input (other than as rapporteur) to the 3rd stage of the EU programme to evaluate older pesticides to modern safety standards.

3. Matters of special interest to the Joint Committee on Statutory Instruments

None.

4. Legislative Background

This SI establishes new fees to cover the costs of the UK's input to the evaluation process for active substances on the 3rd stage list where the UK is either a non-rapporteur or co-rapporteur Member State. It also includes charges designed to cover the costs of administrative handling and evaluations of pesticide active substances on the 3rd stage list of the EU review programme where the UK is the rapporteur Member State which were originally established by the Fees for Assessment of Active Substances (Third Stage Review) Regulations 2004 (S.I.2004/695) (now revoked).

5. Extent

This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

Not applicable.

7. Policy background

An EU review programme was established under Council Directive 91/414/EEC to provide a systematic and co-ordinated approach aimed at ensuring that all older pesticides are reviewed using a common approach to ensure that they met current safety standards. Under these arrangements Member States are, on a staged basis, allocated lead responsibility (rapporteur status) to carry out the evaluation of the safety data for various existing active ingredients of pesticides. Their reports/recommendations are discussed and agreed with the Commission and other Member States before coming to a decision on whether the pesticide can continue to be used.

It is well established policy and a key principle that the full costs of evaluating the pesticides is recovered from the crop protection industry through a statutory charging system based on specific fees. Charging arrangements have already operated

successfully under the 1st and 2nd stages of the review programme and have included fees to cover the costs both as rapporteur and co-rapporteur (i.e. when working with the lead rapporteur), as well as non-rapporteur activity (i.e. to cover the costs of considering the evaluations carried out by other Member States) where there is a UK interest. The fees provided for in this instrument relate to the 3rd stage of the review and build on the existing arrangements, replicating the existing fee rates provided for the 2nd stage fees for co-rapporteur and non-rapporteur work.

8. Impact

A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

Kevin McCay
Defra
Pesticides Safety Directorate
Room 313
Mallard House
Kings Pool
3 Peasholme Green
York
YO1 7PX
Tel 01904 455920
Email: kevin.mccay@psd.defra.gsi.gov.uk

REGULATORY IMPACT ASSESSMENT

IMPLEMENTATION OF NEW FEES TO COVER THE UK'S CONTINUED INPUT TO THE REVIEW OF OLDER PESTICIDES UNDER THE THIRD STAGE OF THE EU REVIEW PROGRAMME:

THE FEES FOR ASSESSMENT OF ACTIVE SUBSTANCES (THIRD STAGE REVIEW) REGULATIONS 2005

Issue

1. It is well-established Government policy that all regulatory approvals work should be carried out on a full cost recovery basis with charges calculated in accordance with Treasury's Fees and Charges guidance. There is already an existing fee structure covering PSD's costs in respect of active substances included on the 2nd stage list under the EU Review Programme where the UK is either a non-rapporteur or co-rapporteur Member State.
2. The non-rapporteur work covers PSD's consideration of assessments prepared by other Member States on the suitability of an application for inclusion of an existing active substance in Annex I of Directive 91/414/EEC and is necessary in order to ensure that we have no safety or other concerns and to establish the UK position. This enables us to fully participate in the EU level decision making process that can lead to active ingredients being on the EU "approved" list that can subsequently result in an approval in the UK. Based on our existing experience and work recording data it is necessary to apply the same fee rate of £5,000 for 3rd stage list substances as applied to the 2nd stage list. We estimate that this charge could be applied to a maximum of 180 cases and affects up to 67 data notifiers over the next 36 months.
3. The "co-rapporteur" role was established in order to allow other designated Members States to work specifically with rapporteur Member States. This involves providing assistance to the designated Rapporteur Member State such as peer-reviewing their draft assessment prior to submission to the Commission for inclusion in the decision making process. Also to process any comments received concerning the assessment. This would directly benefit the data notifiers as it leads to a more robust assessment which speeds-up the EU decision making process. Once again, it is necessary to apply the same fee of £10,000 for the 3rd stage list as used for the 2nd stage list. We forecast that the UK is likely to be designated as co-rapporteur for only 2 or 3 substances.

Objective

4. To introduce fees in respect of the UK's input into the third stage of the EU Review Programme in respect of active substances for which the UK is either "non-rapporteur" (£5,000) or "co-rapporteur" (£10,000). This is necessary to ensure that the relevant full costs of the regulatory regime continue to be recovered from industry.

Risk

5. If the charging provisions are not put in place Government may either need to subsidise the costs of the regulatory regime or the UK will not be able to fulfil its obligations to the EU Review Programme or be satisfied that older pesticides meet modern safety standards.

Equity and Fairness

6. The fees are designed to extend the existing arrangements whereby notifiers are charged for the costs of the work undertaken on their behalf. We forecast that this charge would be applied to a maximum of 180 cases and affects up to 67 data notifiers over the next 36 months.

Benefits

7. The fees are consistent with the existing charging arrangements and ensure that we continue with the approach that those benefiting from the service meet the costs.

Enforcement

8. If fees are not paid the active substances may not be placed on the EU “approved” list and existing products will be removed from the market.

Costs to Industry

9. The fee would result in charges to the European agrochemical industry (based on current forecasts) of approximately £920,000 over the next 36 months. However, this must be seen in the context of total industry charges of approx. £22-24m over this same period. Furthermore, the proposed charges are insignificant compared with the costs to the notifiers of generating the data necessary to support the review process.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister: Alun Michael

Date: 24th January 2005

Department for Environment, Food and Rural Affairs

Contact: Kevin McCay
Defra Pesticides Safety Directorate
Room 313, Mallard House
Kings Pool
3 Peasholme Green
York
YO1 7PX
Tel 01904 455920
Email: kevin.mccay@psd.defra.gsi.gov.uk