

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

2005 No. 1811

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**
 - 2.1 This Statutory Instrument establishes fees to cover the costs of the UK's input to the 4th 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**
 - 3.1 None.
4. **Legislative Background**
 - 4.1 This SI establishes new fees to cover the costs of the UK's input to the evaluation process for active substances on the 4th stage list of the EU review programme.
5. **Extent**
 - 5.1 This instrument applies to all of the United Kingdom.
6. **European Convention on Human Rights**
 - 6.1 Not applicable.
7. **Policy background**
 - 7.1 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 arrangement Members 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.

7.2 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, 2nd and 3rd 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.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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REGULATORY IMPACT ASSESSMENT

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

THE FEES FOR ASSESSMENT OF ACTIVE SUBSTANCES (FOURTH 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 earlier lists under the EU Review Programme.
2. The rapporteur work covers PSD's evaluation and the production of the Draft Assessment Report 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. Based on our existing experience and work recording data it is necessary to apply a fee of £25,000. We estimate that this charge could be applied to a maximum of 16 substances and affects up to 30 data notifiers over the next 12 months.

Objective

3. To introduce a fee (£25,000) in respect of the input into the fourth stage of the EU Review Programme in respect of active substances for which the UK is rapporteur. This is necessary to ensure that the relevant full costs of the regulatory regime continue to be recovered from industry.

Risk

4. 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

5. 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 16 substances and affects up to 30 data notifiers over the next 12 months.

Benefits

6. 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

7. 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

8. The fee would result in charges to the European agrochemical industry (based on current forecasts) of between £400,000 and £750,000 over the next 12 months. To put this in context the total industry charge over the same period is forecast to be approximately £8m. However, the £25,000 fee may be significant for some notifiers and therefore, to ease the financial burden, the fee will be payable in instalments. There is the possibility that some notifiers may find the costs prohibitive and as a result they could withdraw their products from the market.

Declaration:

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

Signed by the responsible Minister: *Lord Bach*

Date: *6th July 2005*

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