

**EXPLANATORY MEMORANDUM TO THE  
PESTICIDES (MAXIMUM RESIDUE LEVELS IN CROPS, FOOD AND FEEDING  
STUFFS) (ENGLAND AND WALES) (AMENDMENT) REGULATIONS 2005**

**2005 No. 432**

**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. This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Description:**

2.1 This Statutory Instrument establishes maximum residue levels (MRLs) for two different pesticides in a wide range of foodstuffs.

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

3.1 The Committee will wish to know why the Department has again amended the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff)s (England and Wales) Regulations 1999 (S.I. 1999/3483) rather than consolidate them.

3.2 The latest amendments to the 1999 Regulations are necessary to implement new or replacement maximum residue levels which are set down by the three Community Directives (Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC). These Directives are each amended on a regular basis and accordingly frequent rapid changes to the domestic legislation are required.

3.3 The Department had hoped that a proposed new EC Regulation that will consolidate and repeal these Directives would have been made by now, but the Community timetable has slipped.

3.4 In the meantime, the House of Lords Committee on the Merits of Statutory instruments has made clear its preference for instruments to be revoked and re-made rather than amended. In the case of the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff)s (England and Wales) Regulations 2005 this will require an affirmative resolution instrument. In the circumstances, the Department undertook in correspondence reported in the 24<sup>th</sup> Report of the 2003 –04 session of the Committee on Merits of Statutory instruments to consolidate the SI after this amendment.

3.5 Members of the public are most likely to need to use Part 2 of Schedule 2 to the 1999 Regulations. A consolidated version of this Part of the Schedule and Schedule 1 to the 1999 Regulations (which lists for each pesticide the specific compound(s) which comprise(s) the pesticide residue) are posted by the Pesticides Safety Directorate (an executive agency of the Department) in an easy to read format, on its website.

**4. Legislative Background:**

4.1 This Instrument transposes an EC Directive developed as part of an on-going Community program to establish MRLs for all pesticides in a wide range of foodstuffs.

4.2 This instrument transposes this Directive by amending the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff)s(England and Wales) Regulations 1999. These

Regulations establish a legislative framework, enabling MRLs to be set monitored and enforced.

4.3 A transposition note is attached.

4.4 This Instrument transposes Commission Directives which are not subject to Parliamentary Scrutiny. The Directives do, however, amend three similar Council Directives 86/362/EEC (fixing MRLs for cereals), 86/363/EEC (fixing MRLs for foodstuffs of animal origin) and 90/642/EEC (fixing MRLs for fruit and vegetables and other foodstuffs of plant origin). Details of the scrutiny history of 90/642 are detailed below.

Legislation	Council Directive 90/642/EEC
Adopted	27 November 1990
Official Journal	L350 of 14 December 1990, page 71
Explanatory Memorandum	4092/89 of 1 February 1989 9271/90 of 8 November 1990

#### EXPLANATORY MEMORANDUM 4092/89

#### SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Politically important for debate	Date: 8 March 1989 Report ref: 10920 HC 15- xiii and xiv; HC 220- iii (Session 1988-89) Paragraph 7	Referred to Sub Committee (List B)	Date: 13 February 1989 Sub – Committee D
Debated by Standing Committee on European Community Documents	Date: 10 May 1989	Cleared without report (List C)	Date: 21 March 1989

#### EXPLANATORY MEMORANDUM 9271/90

#### SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Not legally or politically important	Date: 14 November 1990	Cleared without report (List A)	Date: 13 November 1990

#### **5. Extent:**

5.1 This Instrument applies to England and Wales only. Similar legislation is being prepared by the Scottish Executive, Environment and Rural Affairs Department and Department of Agriculture and Rural Development, Northern Ireland.

#### **6. European Convention on Human Rights:**

Not applicable

## **7. Policy background**

7.1 MRLs reflect levels of pesticides that are expected to be found in produce that has been treated in accordance with good agricultural practice. Thus, they provide a mechanism for statutory controls on pesticides in produce moving in trade and for monitoring correct use of pesticides. MRLs are not safety limits and are always set below safety limits.

7.2 MRLs applicable to trade to or within the UK are now almost exclusively determined at EC level. The EC programme is expected to establish MRLs for approximately 450 pesticides. This Instrument will introduce MRLs for a further two pesticides. This will bring the total number of pesticides with MRLs to approximately 240.

7.3 There is not a great deal of public interest in this policy. Consultations held prior to issue of the 1999 Regulations and in 2003 (in relation to an EC proposal to amend the Community's procedures for setting MRLs) attracted approximately 20 responses in total. The only substantive comments were received from farming, growing and crop protection industries and focussed on technical details, not the overall policy of setting MRLs.

7.4 This Instrument is not politically or legally important. This is a long established and well understood piece of legislation which is being amended in an uncontroversial and relatively minor fashion.

## **8. Impact:**

8.1 A Regulatory Impact Assessment (RIA) is attached. The RIA was prepared in 1999 when the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations were last consolidated and provides a basis for establishing the impact of amendments to the Regulations.

8.2 In 2003 the Pesticides Safety Directorate undertook a consultation in relation to an EC proposal to amend the Community's procedures for setting MRLs. Responses to the consultation indicated that compliance costs were virtually unchanged from those quoted in the 1999 RIA. We are, therefore, content that the cost information quoted in the RIA remains relevant but will continue to keep under review.

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## Transposition Note

### Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs)(England and Wales) (Amendment) Regulations 2005

Commission Directive 2004/95/EC

<b>Article</b>	<b>Purpose</b>	<b>Implementation</b>	<b>Comment</b>
1	Amends Directive 90/642/EEC in relation to the MRLS for Bifenthrin and Famoxadone.	Regulation 2(3) and the Schedule.	Regulation 2(3) amends Part 2 of Schedule 2 to the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuffs)(England and Wales) Regulations 1999 to substitute new MRLs for Bifenthrin and Famoxadone.
2	Member States to implement Directive by 25 March at latest and to apply new MRLs from 26 March at the latest.		Regulation 1. Regulations to come into force on 26 March.

## REGULATORY IMPACT ASSESSMENT

### The Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 2000

#### Purpose and Intended Effect of the Measure

1. These regulations consolidate the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) Regulations 1994 and 5 subsequent amendments to those regulations. They establish maximum residue levels (MRLs) for pesticide residues in and on fruit and vegetables, cereals, foodstuffs of animal origin and processed and composite foodstuffs.
2. The regulations also introduce new maximum residue levels in relation to the active ingredient, azoxystrobin, which are set out in Directive 1999/71/EC.

#### Risk Assessment

3. Directive 1999/71 is due to be implemented by 31 January 2000. Failure to do so would represent a breach of the UK's treaty obligations.

#### Options

4. There is no option but to implement Directive 1999/71/EC into UK law.

#### Benefits

5. Statutory MRLs benefit the consumer by providing a mechanism to ensure that pesticide residues are at safe levels and that the rules on pesticide approvals can be effectively enforced. This is not quantifiable in monetary terms. MRLs also harmonise the rules on pesticide residues in food thus facilitating international trade. Consolidation of earlier regulations will improve the clarity of the regulations

#### Compliance Cost for Businesses, Charities and Voluntary Organisations

6. Only a small number of new MRLs will be introduced through this proposal and the costs associated with their introduction are small. Additionally as explained in paragraph 20 below these costs should be viewed as falling to the approvals regime rather than the MRLs programme. However, the opportunity of consolidation of the regulations has been taken to re-visit previous assessments on the financial impact of MRLs and, as far as possible, to put a cost on the EC's MRLs programme as a whole. This should also provide a firmer basis for the estimation of costs in relation to future EC MRLs Directives.
7. The Community's MRL programme began in 1976 although the first main Directives on cereals and animal products were not adopted until 1986. These were followed in 1990 by a Directive on fruit and vegetables. Since then a succession of Directives has extended the MRLs regime which now includes approaching 10,000

limits. The European Commission's intention is to establish MRLs for all the main pesticide/commodity combinations which could require around 200,000 MRLs.

8. Each MRL 'position' may involve different compliance costs depending on a variety of factors. It would be unrealistic to attempt a case by case analysis of compliance costs in relation to the hundreds or thousands of MRLs that may be included in a single Commission proposal. Instead the approach proposed seeks to calculate a total cost for the MRLs programme so far and an average cost per 100 MRLs adopted on the basis of experience to date.

9. Some of the compliance costs associated with the MRLs programme – particularly the costs of residues trials – can be quantified with some degree of accuracy. However, little or no information is available on others such as where MRLs have to be set sub-optimally from the efficacy viewpoint (paragraphs 15-16 below) or where an MRL precludes third country imports (paragraph 18 below). In these cases a broad estimate has been made, or if this is not possible, the item has had to be left unquantified. Thus this RIA represents a qualitative but only partly quantitative assessment of costs. The estimates are thus likely to be minimum figures.

10. The introduction of MRLs involves potential costs for a number of businesses as illustrated below.

(a) Agrochemical Companies

11. In order to maintain marketing authorisations it may be necessary for a company to conduct experimental trials to support a particular MRL. Eight trials are required if the crop concerned is viewed as "major" (e.g. wheat) and four if it is viewed as "minor" (e.g. radish). Agrochemical companies generally support major crops whereas grower groups support minor crops. Trials costs include those associated with the experimental trial itself plus analytical costs to determine residues in the crop and overheads. Assuming a total cost of £12,000 per trial and that an average of 6 trials are required, each MRL position "defended" involves a potential cost of £72,000. Such costs do not necessarily fall on UK – based companies since the MRL programme is a Community wide system. The approved usage which leaves the highest residue (the "critical Good Agricultural Practice (GAP)") determines the MRL. The cost of determining that MRL thus falls on the company whose approval represents the critical GAP. Experience to date suggests that in around 50% of cases a UK approval represents the critical GAP. In the calculation at Annex A this percentage is taken as the proportion of the total potential costs of defending MRLs through residues trials relevant to the calculation of UK industry compliance costs.

12. Occasionally additional more complex studies have to be undertaken specifically to defend a particular MRL. This arises in particular where there is little information on the behaviour of the compound in similar crops and a specific plant metabolism study has to be commissioned to assess which residues will be present at a cost of around £200,000. This is estimated to occur in relation to around 1% of all substantive MRLs. It should be noted that the studies that contribute to securing MRLs under the EC arrangements may also be used in regulatory submissions

elsewhere in the world. However, no suitable basis for apportionment is available and all costs are therefore allocated to the EC programme.

13. Costs may also arise for companies in relation to MRL positions which are not defended in terms of lost markets or potentially the disposal of stock. Such costs seem likely to be less than the costs of defending the MRL but it has not proved possible to quantify them. A qualitative reference only is thus included in **Annex A**.

(b) Farming Businesses

14. Farming businesses face three potential areas of compliance cost. First, in some instances, generally for commercial reasons, agrochemical companies will choose not to defend a particular MRL. In some such cases grower organisations (particularly the Horticultural Development Council) may then fund the necessary trials in order to maintain a use which is of importance to a particular crop sector. The costs of such trials will be essentially the same as those indicated in paragraph 11 above.

15. Second, in some cases, for consumer protection reasons, MRLs may have to be set at levels which only allow usage at below "optimal" conditions. For instance the usage permitted might not be effective against the full range of pests. This might, in theory, require growers to use less pesticide with a consequential risk of pest damage and economic loss. In this situation the agrochemical industry or growers would face the cost of defending the MRL as usual but growers could face further costs from its conditions of approval being (from their perspective) sub-optimal. In the extreme case it may be that an MRL position would be "closed off" because an acceptable MRL could only be set at levels which would not support a rate of pesticide use of practical value.

16. Experience suggests that situations in which MRLs cause approvals to be set "sub-optimally" thus causing economic loss are not common but they do occur. In some cases harvest intervals can be extended so that an approval complies with an MRL and this is unlikely to result in serious economic loss. However, there have been a few instances where the MRL impacts on economic use (e.g. the use of mancozeb on grapes) or precludes any use. This is estimated to have occurred in 0.5% of substantive MRLs. A guesstimate of the losses involved has been included in the calculations in **Annex A**.

17. Third, farming businesses may need to undertake analytical work to monitor the pesticide residues present in their crop. Such monitoring is good practice and should form an integral part of the controls instituted to demonstrate 'due diligence' under food safety legislation. It is also sometimes required to meet contractual obligations. Nevertheless monitoring costs are attributed to the MRLs programme for the purpose of this RIA. An estimate of total monitoring costs by all sectors is included in **Annex A**.

(c) Importers

18. MRLs apply equally to imported food as to UK produced food. Importers may face similar monitoring costs to those faced by growers. They may also face more substantial costs if data are not supplied to support a particular overseas use. It is possible that a particular commodity could then not be imported. However, no quantitative information is available on this point and a qualitative reference only is therefore included in **Annex A**.

(d) Food Manufacturers and Food Retailers

19. Companies in this sector face costs for monitoring their produce for pesticide residues. An estimate of total monitoring costs by all sectors is given in **Annex A**.

(e) Relationship with Pesticide Approvals

20. The setting of MRLs is essentially an extension of the pesticides approval arrangements. Indeed it is a condition of the EC Plant Protection Products Directive that new approvals should not be issued by member states unless the corresponding MRL has been established. All the costs associated with MRLs could thus be viewed as arising from the approvals system rather than the MRLs Directive. However, a pragmatic distinction is probably to view costs associated with the first MRLs set for all new active substances, such as azoxystrobin, as attributable to the pesticide approval arrangements. All costs associated with defending MRLs which relate to existing active substances would then be attributed to the MRLs programme. Virtually all the MRLs included within the 2000 Regulations (with the exception of azoxystrobin) fall into this latter category.

### **Compliance Costs for a "typical" business**

21. As indicated above several different types of business may be affected by the MRLs legislation. Within each sector companies will vary markedly in size. There is thus no typical business in this context.

### **Total Costs**

22. An estimate of the total average recurring and non-recurring costs of complying with MRLs legislation and an estimate of the total costs of complying with the EC MRLs programme since 1986 are given in **Annex A**.

### **Consultation with Small Business: "The Litmus Test"**

23. Small farm businesses will contribute towards funding residues trials through horticultural levy arrangements. However, the contribution will be proportionately similar to larger businesses. Monitoring costs, where testing is required by contractual arrangements may be proportionately higher for a small business. Previous consultation suggests that in the food retailing sector relatively little testing for pesticides is undertaken by small businesses and the legislation is unlikely to impact significantly on such businesses.



## Other Costs

24. The Directive requires member states to conduct some monitoring of raw, processed and composite foodstuffs against the MRLs. The costs of the UK's current monitoring programme are some £1.6M per annum. These costs are currently met through receipts from a levy on pesticide sales (60%) and by Government (40%).

## Results of Consultations

25. Consultations have been conducted with a wide range of industry, consumer and other bodies. There is general support for consolidation of the regulations.

## Summary and Recommendations

26. The Regulations will introduce MRLs for the new active substance, azoxystrobin, and consolidate the six existing S.I.s on pesticide residues in food. Bringing MRLs together in one document will improve the transparency of the rules. Additional compliance costs associated with the azoxystrobin MRLs are small and more appropriately attributed to the approvals arrangements. However, the opportunity has been taken to estimate the average costs per 100 MRLs adopted for existing substances and to calculate a total cost for the residues programme as a whole at current prices. Ministers are invited to approve the regulations.

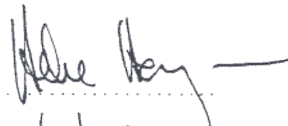
## Enforcement, Sanctions, Monitoring and Reviews

27. Enforcement of the Regulation will be carried out by MAFF. The impact on enforcement costs will depend on whether the number of MRLs exceedences increases. These are monitored on an annual basis through a Government surveillance programme carried out by the Working Party on Pesticide Residues. Sanctions for the residues legislation are laid down in Section 20 (5) of the Food and Environment Protection Act 1985. A person found guilty under this section of the Act can be fined up to an amount not exceeding level 5 on the standard scale.

## Declaration

28. I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the responsible Minister:



BARONESS HAYMAN

Date

14/11/99

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(a) Trials Data

In resolving 100 MRLs "positions" typically 70 are closed off because there are no corresponding uses or are not defended and 30 are eventually filled with substantive MRLs.

There are no compliance costs associated with MRLs for which there are no corresponding uses. There is no ready means of assessing costs associated with undefended uses. They are at least likely to be less than the costs of residues trials data reflecting the fact that in most cases there will be an alternative pesticide available

The costs associated with defending uses are the costs of conducting residues trials plus, in 1% of cases, plant metabolism studies or:

$$30 \times £72,000 + (30 \times 1\% \times £200,000) \\ = £2,160,000 + £60,000 = £2,220,000$$

However' the UK use represents the critical GAP in only 50% of cases. Thus compliance costs relevant to UK based companies are £1,110,000.

[An estimated 80% of those MRLs positions which are defended, are defended by agrochemical companies with the balance of 20% being defended by growers.]

(b) Undefended Uses

No information is available on potential costs in this area.

(c) Restricted or Lost Uses

As previously noted, the occasional loss of a use for which there is no alternative is likely to be the main potential source of economic loss. For the purpose of this RIA a cost of £1m per year is estimated to occur in relation to 0.5% of "defended" MRLs, which is equivalent to 0.15% of all MRLs adopted. Costs per 100 MRLs are thus estimated at £150,000.

(d) Lost Imports

No estimates are available for this potential category of costs.

(e) Produce Monitoring

Previous cost compliance assessments (which have been subject to consultation) have estimated the total cost of pesticide residues monitoring by, or on behalf of, farming, food manufacturing, importing or retailing companies at around £2m per annum in total. These costs are likely to have grown as the MRLs programme has progressed and the number of statutory limits against which to check standards has increased.

There are also other influences on the volume of testing, such as the Government's decision to include brand name information with published surveillance results. The previous monitoring figure is now generally viewed as an underestimate and current costs are assessed at around £3 million in total. For the purposes of this RIA, this total cost has been apportioned across the approximately 10,000 EC MRLs adopted to date. Monitoring costs per 100 MRLs are thus approximately £30,000. Unlike costs under (a) above, which are one-off (at least until MRLs are reviewed), monitoring costs recur on an annual basis.

## TOTAL COSTS

### (a) One-off Costs

	£
<b>Cost per 100 MRLs positions</b>	<b>( '000)</b>
Trials Data	1,110
Undefended Use Costs	(a)

### (b) Recurring Costs (per annum)

Restricted/Lost Uses	150
Restricted/Lost Imports	(a)
Monitoring Costs	30
<b>Sub Total</b>	<b>180</b>

## TOTAL COSTS OF PROGRAMME (10,000 MRLs INTRODUCED SINCE 1986)

	£m
Trials Data	111
Recurrent Annual Costs (total per annum)	18

(a) no quantitative information available

All costs are at 1999 prices