

EXPLANATORY MEMORANDUM TO

THE PESTICIDES (MAXIMUM RESIDUE LEVELS IN CROPS, FOOD AND FEEDING STUFFS) (ENGLAND AND WALES) REGULATIONS 2005

2005 No. 3286

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 pesticides in a wide range of foodstuffs.

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

3.1 This instrument, the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 2005, is a consolidation of the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 1999 (S.I. 1999/3483) and subsequent amendments to those Regulations. It also prescribes certain new or replacement maximum residue levels in implementation of four Council Directives (Council Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC, as amended). These Directives are each amended on a regular basis and accordingly frequent rapid changes to the domestic legislation are required.

3.2 Since all of the maximum residue levels prescribed by the regulations are set in implementation of EC Directives, the regulations are made exclusively under the European Communities Act 1972, and are subject to the negative resolution procedure.

4. Legislative Background:

4.1 This Instrument re-transposes four Council Directives, namely 76/895/EEC (fixing MRLs for fruit and vegetables) 86/362/EEC (fixing MRLs for cereals), 86/363/EEC (fixing MRLs for foodstuffs of animal origin) and 90/642/EEC (a further directive fixing MRLs for fruit and vegetables, and also fixing MRLs for other foodstuffs of plant origin). These Council Directives have most recently been amended by Commission Directives 2005/37, 2005/46 and 2005/48.

Details of the scrutiny history of 90/642 are detailed below. This is the only one of the above Directives that has been previously scrutinised, as its provisions are mirrored in the other Directives.

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

4.2 This instrument re-transposes these Directives via a consolidation of the Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 1999. These Regulations establish a legislative framework, enabling MRLs to be set, monitored and enforced.

4.3 This Instrument transposes three EC Directives developed as part of an on-going Community programme to establish MRLs for all pesticides in a wide range of foodstuffs.

4.4 A transposition note is attached.

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 the Department of Agriculture and Rural Development, Northern Ireland.

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

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 seventeen pesticides. This will bring the total number of pesticides with MRLs to approximately 190.

7.3 There has not been a specific consultation regarding this consolidation. 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 focused on technical details, not the overall policy of setting MRLs.

7.4 This Instrument is not politically or legally important. It consolidates a long established and well understood piece of legislation, with relatively minor amendments.

8. Impact:

8.1 A Regulatory Impact Assessment (RIA) is attached.

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 RIA previously prepared in 1999. We are, therefore, content that the cost information quoted in the RIA remains relevant but will continue to keep this under review.

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NOTE ON THE TRANSPOSITION OF COUNCIL DIRECTIVES 76/895/EEC, 86/362/EEC, 86/363/EEC AND 90/642/EEC ON THE FIXING OF MAXIMUM RESIDUE LEVELS OF PESTICIDES IN PRODUCTS OF PLANT ORIGIN, INCLUDING FRUIT AND VEGETABLES, CEREALS AND FOODSTUFFS OF ANIMAL ORIGIN

THE PESTICIDES (MAXIMUM RESIDUE LEVELS IN CROPS, FOOD AND FEEDING STUFFS) (ENGLAND AND WALES) REGULATIONS 2005

Pesticide maximum residue levels (MRLs) are statutory limits on the amount of pesticides which may remain in food and feeding stuffs when they are marketed. They are intended to facilitate trade in produce which has been treated with pesticides and must be supported by scientific data which show they are safe for consumers.

The European Commission has a major programme to develop MRLs for all the active substances used as pesticides on all significant crops and foodstuffs. These are contained in four Council Directives:

- Council Directive 90/642/EEC on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables;
- Council Directive 86/362/EEC on the fixing of maximum levels for pesticide residues in and on cereals;
- Council Directive 86/363/EEC on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin; and
- Council Directive 76/895/EEC relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables.

These Regulations enable regulatory authorities to implement the obligations laid down in these Directives, as last amended by Commission Directive 2005/48/EC. They establish a wide range of MRLs (regulation 3(1) and Schedule 2), create offences of failure to comply with the legislation (regulation 3(4)) and provide powers to seize and dispose of material which contains residues in excess of MRLs (regulation 4). The Regulations also prescribe how much of a particular product is to be taken into account in determining whether an MRL has been exceeded (regulation 5(a) and Schedule 3) and provide for determining whether MRLs have been exceeded when residues are found in dried or processed products or composite foods, so far as these are the subject of the Residues Directives (regulation 5(c) and (d)).

The responsible authorities are the Department for Environment, Food and Rural Affairs in England and the Welsh Assembly in Wales. Separate but similar legislation is being introduced in Scotland and Northern Ireland.

A correlation table detailing the transposition of the main Articles of the Directives into the Regulations is set out below.

Directive 76/895	Directive 86/362	Directive 86/363	Directive 90/642	Regulation
3(1) and Annex II	4(1) and Annex II	4(1) and Annex II	3(1) and Annex II	3(1) and Schedule 2, establishing MRLs 3(4), establishing offences of failure to comply 4, giving powers to seize and dispose material with residues in excess of MRLs
1(1) and Annex I	1(1) and Annex I	1(1) and Annex I	1(1) and Annex I	5(a) and Schedule 3, for determining how much of a product to take into account
1(2) and Annex II	4(2) and (3) and Annex II	4(2) and (3) and Annex II	3(2) and (3) and Annex II	5(c) and (d), for determining whether MRLs have been exceeded in processed or composite foods

**Department for Environment, Food and Rural Affairs
November 2005**

REGULATORY IMPACT ASSESSMENT

1. Title of proposal

The Pesticides (Maximum Residue Levels in Crops, Food and Feeding Stuff) (England and Wales) Regulations 2005.

2. Purpose and intended effect

Background/objective

These Regulations enable regulatory authorities to implement EC obligations relating to the setting and control of pesticide maximum residue levels (MRLs) in food and feeding stuffs. They establish a wide range of MRLs, create offences for those who do not comply with the legislation and provide powers to seize and dispose of material which contains residues in excess of MRLs.

These Regulations consolidate existing legislation, a number of amendments having been issued since they were last made in their entirety in 1999. Previous Regulations have employed both the European Communities Act 1972 (ECA) and the Food and Environment Protection Act 1985 as enabling legislation; however these Regulations proceed on the basis of the ECA alone, simplifying their content and readability.

As a consolidation, these Regulations do not create additional costs. However the opportunity has been taken to provide an updated Regulatory Impact Assessment to address the overall costs of this regime.

In addition to consolidating existing MRLs, the Regulations set new MRLs for the active substances carfentrazole-ethyl; fenamidone; flufenacet; fosthiazate; iodosulfuron-methyl sodium; isoxaflutole; mecoprop; mesotrione molinate; picoxystrobin; silthiofam and trifloxystrobin. Also, revisions are made to existing MRLs for the active substances amitraz; iprodione; maleic hydrazide, propiconazole and propyzamide. These changes are required under the terms of EC Directives 2005/37, 2005/46 and 2005/48.

Rationale for Government intervention

These regulations will meet the UK's obligations to implement EC Directives. Failure to promptly implement EC Directives would represent a breach of the UK's treaty obligations, and would lead to infraction proceedings being taken against the UK.

3. Options

Options for consideration in respect of EC Directives 2005/37, 2005/46 and 2005/48:

- **Option 1** – Do nothing. This would result in failure to implement EC Directives 2005/37, 2005/46 and 2005/48 in England and Wales.
- **Option 2** – Adopt the Regulations, consolidating the existing Regulations and ensuring that the competent authorities for England and Wales fulfil their obligations under the EC Directives.

Given that these Regulations consolidate and update existing legislation, rather than introduce entirely novel controls, this RIA does not consider whether MRLs should be subject to statutory control.

Failure to promptly implement EC Directives would represent a breach of the UK's treaty obligations.

4. Costs and Benefits

Sectors and groups affected

Business sectors affected by the proposal are:

- chemical/agrochemical manufacturing;
- agriculture, forestry and fishing;
- food manufacturing;
- wholesale, retail, storage and repairs.

The proposal would bear on all sizes of companies, from small businesses to large multi-nationals.

Issues of equity and fairness

The EC authorisation and MRL setting regimes are fair in that they apply standard requirements on all sectors. However the horticultural sector can be disadvantaged compared to other farming and growing businesses. This is because the crop protection industry tends to develop products for use on crops grown on a large acreage (e.g. cereals) to generate an economic return from the sale of pesticide products.

Crops that are grown on a relatively small scale (e.g. watercress, celery, etc) generate insufficient returns when the expense associated with obtaining an authorisation for a use (including data required to support an MRL) is taken into account. Because of this, in some cases the crop protection often chooses not to provide the data needed to support authorisations on these 'minor' crops.

To fill the gap, grower organisations will undertake the work necessary to secure an authorisation on minor crops. But budgetary constraints may mean they are unable to secure all potentially available solutions to pest problems; or secure these as quickly as they would like.

Benefits

Option 1

There are no tangible benefits to this option as failure to promptly implement EC Directives would represent a breach of the UK's treaty obligations, and would lead to infraction proceedings being taken. This would also risk a situation where England and Wales would not have the same maximum residue levels as Scotland or Northern Ireland (who are taking forward their own regulations) or the rest of the

European Community. Such an outcome could present an obstacle to free trade, create confusion and increase costs to the business sectors affected.

Option 2

Statutory MRLs benefit the consumer and food industry by providing a mechanism to ensure that pesticide residues are at safe levels, that there is consistency of food standards, and that the rules on pesticide approvals can be effectively enforced. This is not readily quantifiable in monetary terms. MRLs also harmonise the rules on pesticide residues in food thus facilitating ready trade within the European Community and establishing trading standards for imports from third countries. Consolidation of earlier legislation will improve the clarity of the Regulations, and the transposition of new MRLs set under EC Directives enable the UK to meet its Treaty obligations.

Costs

Option 1

It is not possible to quantify the cost of doing nothing, as this would be dependent on external factors outside of the control of the UK Government. However it is likely that inaction on the part of the UK would result in legal infraction proceedings taken by the EC Commission. There would also be likely costs to UK industry not being subject to the level playing field of controls applied in the rest of the Community.

Option 2

Non-recurring costs to business

This Regulatory Impact Assessment is directed to assessing, as far as possible, the cost of the EC MRLs programme as a whole. This should also provide a basis for the estimation of costs in relation to future EC MRL Directives.

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 produce of plant origin. Since then a succession of Directives has extended the MRLs regime which now includes around 40,000 limits. The European Commission's intention is to establish MRLs for all the main pesticide/commodity combinations which could require around 76,500 MRLs.

Each MRL 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 adopted seeks to calculate a total cost for the MRLs programme and an average cost per MRL.

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

- Crop Protection Companies

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).

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.

The cost of defending each MRL is estimated at £11,629 (see Annex A). Such costs do not necessarily fall on UK-based companies, as data will be supplied from a variety of sources, including companies supporting MRLs abroad.

- Farming Businesses

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 above.

Recurring costs

There are a number of on-going costs related to monitoring food for the presence of residues, which have been incurred since MRLs were introduced in the mid-1980s.

- Food suppliers and retailers

Retailers and suppliers operate specific residues monitoring programmes that incur costs on themselves. It is expected that these risk-based programmes will continue at the present scale.

- Food producers and manufacturers

Food producing businesses often undertake their own analytical work to monitor the pesticide residues present in their crops, and manufacturers may monitor the raw ingredients they receive. 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 the conditions of supplying retailers. Nevertheless monitoring costs are attributed to the MRLs programme for the purpose of this RIA.

It is difficult to estimate the overall annual costs of these programmes with confidence. However, details of company monitoring data supplied to the Pesticides Safety Directorate suggest that these may be in the order of £5m per annum across all these businesses.

- Cost of Government monitoring programme

The Government monitoring programme has an annual recurring cost of £2m. Currently 60% (£1.2m) of the costs are met by the agrochemical industry through a levy on audited turnover and 40% (£0.8m) are funded by the Exchequer.

Added to the estimated £5m per annum cost for industry monitoring, this gives an overall figure of £7 per annum for residues monitoring (as set out in Annex A).

- Importers

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 included in Annex A.

Other costs

No other costs are anticipated.

Costs for a “typical” business

The cost of providing residues trial data to support MRLs is estimated at £110m. These costs will arise independently as a result of other EC legislation on the authorisation of pesticides. 80% of these costs (£88m) will be shared between the five or six main manufacturers giving rise to costs in the region of £15m-£18m each. These tend to be multi-national companies and it is not possible to determine how far costs would be incurred by UK-based businesses.

UK and European farming and growing organisations will meet the remaining 20% of these costs (£22m). These organisations are funded by a variety of means including industry levies (this model being prevalent in the UK with bodies such as the Horticultural Development Council) and government support (this model is more prevalent in other EU member states).

Additional costs for monitoring and enforcement of the Regulation would potentially be shared between a range of food producing and selling businesses. In this case there would be no ‘typical’ business.

6. Small/Micro Firms Impact Test

In 2003 the UK authorities undertook a fundamental assessment of the impact of the arrangements for setting and controlling MRLs following publication of a Commission proposal to recast the procedures used by EC member states. This proposal was subsequently adopted as a Regulation of the European Council and Parliament (EC Regulation 396/2005).

This assessment concluded that some aspects of the pesticide approvals and MRL regimes might give rise to disproportionate effects on small businesses. Substantial numbers of agricultural and horticultural producers, feed and food suppliers and retailers, and some pesticide manufacturers come into the category of small businesses.

7. Test run of business forms

No new business forms are being introduced.

8. Competition assessment

Application of the competition filter test in the business sectors affected indicates that this regime would not be likely to raise issues of competition.

9. Enforcement, sanctions and monitoring

Enforcement of the Regulation will be carried out by Defra. The impact on enforcement costs will depend on the number of MRL exceedances. These are monitored on an annual basis through a Government monitoring programme overseen by the Pesticide Residues Committee. Sanctions for the residues legislation are laid down in Section 21(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.

10. Implementation and delivery plan

The implementation of these regulations does not represent a change of policy.

The Regulations will be laid before Parliament on 1 December 2005 with a coming into force date of 22 December 2005.

11. Post implementation review

UK regulatory authorities will monitor the effect of the EC regime which underpins these Regulations and raise any difficulties with the Commission and other member states.

12. Summary and Recommendations

The Regulations will consolidate the thirteen existing statutory instruments and transpose EC MRLs Directives, setting MRLs for a number of additional active substances, and amending a number of existing MRLs. Bringing MRLs together within one statutory instrument and under a simple legislative base will improve the transparency of the rules.

This Regulatory Impact Assessment estimates the average costs per MRL adopted for existing substances and calculates a total cost for the residues programme as a whole at current prices. Ministers are invited to approve the Regulations.

12. Declaration

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: ...Bach

Date29th November 2005

LORD BACH
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REGULATORY IMPACT ASSESSMENT

ANNEX A

Trials Data

Costs associated with supporting MRLs for an 'average' pesticide active substance (use on grapes, carrots, apples, strawberry and lettuce)

Storage Stability Data	£12,000
Plant Metabolism Data	£50,000
Crop Residue Trials Data	£160,000
Sub Total	£222,000
Admin overheads (contract management, analysis and preparation of data) (+10%)	£22,200
Total	£244,200

Data provided for above uses can be used (under authorised extrapolation rules) to set MRLs on following crops

Carrots: parsley root, salsify, parsnip, horseradish.

Apples: quince, crab apples and pears.

Lettuce: spinach, watercress, witloof, lambs lettuce, herbs, frisee, radicchio, baby leaf brassica and mallow.

Therefore, above data supports 21 different MRLs.

Cost per MRL is £11,629.

We anticipate that MRLs will be set for approximately 450 pesticides, on approximately 170 foodstuffs. This would result in approximately 76,500 individual MRLs being set.

The majority of these will be set at the default limit of determination (effectively zero). This is because plant protection products are only used on a small proportion of the commodities subject to MRLs. Based on the 'average' pesticide listed above the total number of MRLs supported would be estimated at $(76,500 \times (21 \div 170)) = 9450$.

Total cost of the programme is approximately $(9450 \times £11629) = £110,000,000$.

This would be spread across the whole EC. The UK's share cannot be reliably estimated.

Lost imports

No estimates are available for this potential category of costs.

Produce Monitoring

The total estimated cost of pesticide residues monitoring by, or on behalf of farming, food manufacturing, importing or retailing companies at around £5m 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.

The Government surveillance programme has an annual recurring cost of £2m. Currently 60% (£1.2m) of the costs are met by industry and 40% (£0.8m) by government.

Total industry and government monitoring is approximately £7m.

Total costs

Non-recurring Costs		
	Trials data	£110,000,000
Recurring costs		
	Restricted/lost imports	(a)
	Monitoring costs	£7,000,000

(a) no quantitative data

All costs are 2003/04 prices.