# EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) REGULATIONS 1997

I, Joe Walsh, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving further effect to Council Directive No 91/414/EEC of 15 July 19911 and for the purposes of giving effect to Commission Directive 96/46/EC of 16 July 19962 and Commission Directive 96/68/EC of 21 October 19963 hereby make the following Regulations:
1 O.J. No. L230/1 19/8/1991
2 O.J. No. L214/18 23/8/1996
3 O.J. No. L277/25 30/10/1996

REG 1

1. (1) These Regulations may be cited as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 1997.
(2) The European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1996 and these Regulations may be cited together as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997 and shall be construed together as one.
(3) These Regulations shall come into operation on the 3rd day of July 1997.

REG 2

Interpretation
2. (1) In these Regulations—
"the principal Regulations" means the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1996;
(2) In these Regulations, unless otherwise indicated—
( a ) a reference to a Regulation is a reference to a Regulation of these Regulations,
( b ) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,
( c ) a reference to a Schedule is a reference to a Schedule of the Principal Regulations as amended by these Regulations.
(3) The phrase "designated chemist" and the interpretation of the phrase that follows it, included in paragraph (1) of Regulation 2 of the principal Regulations, is hereby replaced by the following:

" "designated analyst" means any appropriately qualified officer of the Minister who is authorised in writing by the Minister for the purposes of these Regulations."
(4) The phrase "State Chemist" and the interpretation of the phrase that follows it, included in paragraph (1) of Regulation 2 of the principal Regulations, is hereby replaced by the following:
" " State Chemist" means the Head of the State Laboratory or a member of the staff of the State Laboratory authorised by the State Chemist in writing to perform functions assigned to the State Chemist under Regulation 34"
(5) A word or expression that is used in the Directive of 1991 or in any Commission Directive or Regulation of the European Communities mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned.

REG 3

Amendments
3. Regulation 30 of the Principal Regulations is hereby revoked and is replaced by the following:
"30 (1) Subject to paragraph (5), an authorised officer may at any reasonable time enter—
( a ) any place or premises in which he has reasonable grounds for believing that—
(i) a plant protection product is being manufactured, placed on the market, stored or used, or
(ii) a controlled product is being produced, placed on the market, processed, stored or used,
( b ) any railway wagon, vehicle, ship, vessel, aircraft, container or other thing in which he has reasonable grounds for believing that a plant protection product or a controlled product is being either transported, stored or used, or
( c ) any premises in which he has reasonable grounds for believing that there are any books, documents or records relating to any business whose activities consist of or include
(i) the manufacture, placing on the market, storage, transport or use of a plant protection product, or
(ii) the production, putting into circulation, processing or storage of any controlled product,
and there or at any other place—
(iii) make such examinations, tests and inspections, and
(iv) take samples in accordance with the methods described in the manual on the development and use of FAO specifications for plant protection products (Food and Agriculture Organisation of the United Nations, FAO Plant Production and Protection Paper 128, Fourth Edition), as updated from time to time, of any plant protection product which he finds in the course of his inspection and which he believes is or may be a plant protection product to which these

Regulations apply, and
(v) take samples in accordance with Commission Directive 79/700/EEC of 24 July 19794 or the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, recommended method of sampling for the determination of Pesticide Residues (Volume 2, Codex Alimentarius, Food and Agriculture Organisation of the United Nations, World Health Organisation, Rome, 1993), where relevant, and in accordance with other internationally accepted procedures in other cases, of any plant, plant product, soil, compost, or take samples from or of any other thing, which he finds in the course of an inspection and which he believes may have been treated or contaminated with a plant protection product to which the Regulations apply,
4 O.J. No. L207/26, 15/8/1979
as he may consider appropriate and provided the quantity which a sample taken pursuant to this Regulation comprises is reasonable.
(2) A person who has in any place, on any premises or in any railway wagon, vehicle, ship, vessel, aircraft, container or other thing a plant protection product to which these Regulations apply, or a controlled product, shall at all reasonable times
( a ) afford to an authorised officer such facilities and assistance as are reasonably necessary for an inspection and for the taking of samples pursuant to this Regulation,
( b ) give an authorised officer any information which he may reasonably require regarding the purchase, importation, storage, transportation, sale, supply or use of any such plant protection product or regarding the production, purchase, importation, processing, transport, storage, sale, supply or use of any controlled product, which is within the person's knowledge or procurement,
( c ) produce to an authorised officer any document relating to the raw materials used in the formulation of any plant protection product or relating to the production of any controlled product which the authorised officer may reasonably require and when produced permit the officer to inspect and take extracts from the document.
(3) In addition to the foregoing any person who carries on the business of manufacturing, formulating, packaging, processing or marketing a plant protection product for the purposes of the Directive of 1991 shall—
( a ) keep records of all transactions regarding the plant protection product,
( b ) produce at the request of an authorised officer any records, books or other documents relating to such business which are in his possession or under his control,
( c ) permit such an officer to inspect and take extracts from such records, books or other documents and give to the officer any information which is within his knowledge or under his control and which such officer may reasonably require in relation to any entries therein,
( d ) afford to any such an officer such facilities and assistance as are reasonably necessary for inspecting the stock of any plant protection product on any premises on which such person carries on

such a business,
( e ) give to such an officer any information he may reasonably require in relation to such transactions, including, in particular, information which he may reasonably require regarding any plant protection product specified by him.
(4) Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall
( a ) divide the sample into 3 parts, each of which he shall seal and mark,
( b ) give one part thereof to a designated analyst for analysis in accordance with paragraph (5),
( c ) leave with, or send by registered post to, the defendant or his agent, a second part thereof, and
( d ) retain the remaining part thereof for possible analysis by the State Chemist in accordance with Regulation 34.
(5) Where a designated analyst receives a sample from an authorised officer in pursuance of these Regulations, he shall make analyses thereof in accordance with—
( a ) a validated method of analysis and the Codex Alimentarius Guidelines on Good Laboratory Practice in Pesticide Residue Analysis (Volume 2, Codex Alimentarius, Food and Agriculture Organisation of the United Nations, World Health Organisation, Rome, 1993), as updated from time to time, in the case of residues in controlled products, and
( b ) the relevant CIPAC method (Collaborative International Pesticides Analytical Council Limited, Handbook Volume I, IA, IB, IC, IG, D, E and F), as updated from time to time, or the method included as part of the documentation approved in accordance with Regulation 8, as appropriate, in other cases.
(6) ( a ) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken pursuant to this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (4)) was left with, or sent by registered post to, the defendant or his agent.
( b ) In any proceedings for an offence under these Regulations, evidence of the presence of a plant protection product to which the Regulations apply, in or on equipment capable of use for application of the pesticide, shall be evidence, until the contrary is proved, of the use of the plant protection product by the owner or person in possession of the equipment.
( c ) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of a plant protection product to which the Regulations apply, in or on agricultural produce, in soil or compost or in or on surfaces or other materials which may have been treated with or exposed to the plant protection product, shall be evidence, until the contrary is proved, of the use of the plant protection product by the owner, occupier or person in possession, as the case may be.

( d ) In any proceedings for an offence under these Regulations, a certificate in the form set out in Part I of the Twelfth Schedule showing the results of an analysis shall, until the contrary is shown, be sufficient evidence of the facts certified to therein in relation to—

(i) the presence in a plant protection product of any active substance, impurity or formulating ingredient, and the level of any such presence, or

(ii) the presence of a residue of a plant protection product and the level of such residues in any controlled product, and

a document purporting to be such a certificate shall be deemed, until the contrary is shown, to be such a certificate.

( e ) In any proceedings for an offence under these Regulations, each of the documents referred to in subparagraphs (1) (c) (iv) and (v), and in subparagraphs (5) (a) and (b) may be proved by a production of a copy thereof purporting to have been published in the Official Journal of European Communities, by the Food and Agriculture Organisation of the United Nations, by the Collaborative International Pesticides Analytical Council Limited, or by the production of the document describing the method, certified by the officer in charge of the competent authority as being part of the documentation submitted in accordance with Regulation 8, as appropriate.

( f ) For the purpose of these Regulations, the presence of a plant protection product, to which these Regulations apply, on any premises (including any stores) where the business of marketing such a plant protection product is earned on, shall, until the contrary is shown, be sufficient evidence that the plant protection product in question is or was being placed on the market by the owner and by the occupier of such premises.

(7) If any person—

( a ) tampers with any plant protection product so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the plant protection product,

( b ) tampers with any controlled product so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the product sampled, or

( c ) tampers or interferes with any sample taken pursuant to these Regulations,

he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000 or to imprisonment for a term not exceeding 6 months or to both.

(8) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on him by these Regulations shall, if requested by any person affected, produce the certificate to that person.

(9) A designated analyst shall be furnished with a warrant of his appointment by the Minister to carry out analyses as required by these Regulations."

REG 4

4. The phrase "designated chemist" included in paragraph (2) of Regulation 34 of the principal Regulations, is hereby replaced by the phrase "designated analyst".

REG 5

5. Point 4 of Part A of Annex II, as set out in Part I of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"4 ANALYTICAL METHODS
Introduction
The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.
For analytical methods used for the generation of data as required in accordance with Annex HA, or for other purposes, applicants must provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the requirements defined for methods for post-registration control and monitoring purposes.
Descriptions of methods must be provided and include details of equipment, materials and conditions used.
As far as practicable methods provided must employ the simplest approach, involve the minimum cost, and require commonly available equipment.
For the purposes of point 6 of this Annex, the following applies:

ImpuritiesAny component other than the pure active substance which is present in the active substance as manufactured (including non-active isomers) originating from the manufacturing process or from degradation during storage, Relevant ImpuritiesImpurities of toxicological and/or ecotoxicological or environmental concern, Significant ImpuritiesImpurities with a content of ³= 1 g/kg in the active substance as manufactured, MetabolitesMetabolites include products resulting from degradation or reaction of the active substance, Relevant MetabolitesMetabolites of toxicological and/or ecotoxicological or environmental concern.
On request the following samples must be provided:
(i) analytical standards of the pure active substance,
(ii) samples of the active substance as manufactured,
(iii) analytical standards of relevant metabolites and all other components included in the residue definition,
(iv) if available, samples of reference substances for relevant impurities.
4.1 Methods for the analysis of the active substance as manufactured
For point 4.1 the following definitions apply:
(i) Specificity

Specificity is the ability of a method to distinguish between the analyte being measured and other substances

(ii) Linearity

Linearity is defined as the ability of the method, within a given range, to obtain an acceptable linear correlation between the results and the concentration of analyte in samples.

(iii) Accuracy

The accuracy of a method is defined as the degree to which the determined value of analyte in a sample corresponds to the accepted reference value (e.g. ISO 5725).

(iv) Precision

Precision is defined as the closeness of agreement between independent test results obtained under prescribed conditions.

Repeatability: Precision under repeatability conditions, i.e. conditions where independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time.

Reproducibility need not be determined for the active substance as manufactured (for definition of reproducibility see ISO 5725).

4.1.1 Methods, which must be described in full, must be provided for the determination of pure active substance in the active substance as manufactured as specified in the dossier submitted in support of inclusion in Annex 1. The applicability of existing CIPAC methods must be reported

4.1.2 Methods must also be provided for the determination of significant and/or relevant impurities and additives (e.g. stabilisers) in the active substance as manufactured.

4.1.3 Specificity, linearity, accuracy and repeatability

4.1.3.1 Specificity of methods submitted, must be demonstrated and reported. In addition the extent of interference by other substances present in the active substance as manufactured (e.g. isomers, impurities or additives), must be determined.

While interference's due to other components may be identified as systematic errors, in the assessment of the accuracy of methods proposed for the determination of pure active substance in the active substance as manufactured, an explanation must be provided for any interference occurring which contributes more than ± 3% to the total quantity determined. The degree of interference for methods for the determination of impurities must also be demonstrated.

4.1.3.2 The linearity of proposed methods over an appropriate range, must be determined and reported. For the determination of pure active substance, the calibration range must extend (by at least 20 %) the highest and lowest nominal content of the analyte in relevant analytical solutions. Duplicate calibration determinations must be made at 3 or more concentrations. Alternatively, 5 concentrations, each as single measurements, are acceptable. Reports submitted most include the equation of the calibration line and the correlation coefficient and representative and properly labelled documentation from the analysis, e.g. chromatograms.

4.1.3.3 Accuracy is required for methods for the determination of

pure active substance and significant and/or relevant impurities in the active substance as manufactured.

4.1.3.4 To determine repeatability with respect to the analysis of the pure active substance, a minimum of five determinations must, in principle, be made. The relative standard deviation (% RSD) must be reported. Outliers identified through an appropriate method (e.g. Dixons or Grubbs Test), may be discarded. Where outliers have been discarded, that fact must be clearly indicated. An explanation as to the reason for the occurrence of individual outliers, must be attempted.

4.2 Methods for the determination of residues

The methods reported must be capable of determining the active substance and where relevant metabolites. For each method and for each relevant representative matrix, the specificity, precision, recovery, and limit of determination must be experimentally determined and reported.

In principle, residue methods proposed should be multi-residue methods; a standard multi-residue method must be assessed and reported as to its suitability for residue determination. Where residue methods proposed are not multi-residue methods, or are not compatible with such methods, an alternative method must be proposed. Where this requirement results in an excessive number of methods for individual pesticides, a 'common moiety method' may be acceptable.

For this section the following definitions apply:

(i) Specificity

Specificity is the ability of a method to distinguish between the analyte being measured and other substances,

(ii) Precision

Precision is defined as the closeness of agreement between independent test results obtained under prescribed conditions.

Repeatability: Precision under repeatability conditions, i.e. conditions where independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time.

Reproducibility: As reproducibility as generally defined (e.g. in ISO 5725) is generally not practicable for residue analytical methods, reproducibility in the context of this Annex is defined as a validation of the repeatability of recovery, from representative matrices, at representative levels, by at least one laboratory which is independent from that which initially validated the study (this independent laboratory may be within the same company) (independent laboratory validation).

(iii) Recovery

The percentage determinable of the amount of active substance or relevant metabolite added to a sample of the appropriate matrix which previously contained no detectable level of the analyte.

(iv) Limit of determination

The limit of determination (often referred to as limit of quantification) is defined as the lowest concentration tested, at which an acceptable mean recovery is obtained (normally 70110% with

a relative standard deviation of preferably <= 20%; in certain justified cases lower or higher mean recovery rates as well as higher relative standard deviations may be acceptable).

4.2.1 Residues in and/or plants, plant products, foodstuffs (of plant and animal origin),feedingstuffs.

Methods submitted must be suitable for the determination of all components included in the residue definition, as submitted in accordance with provisions of point 6.1 and 6.2 of this Annex, in order to enable Member States to monitor compliance with established MRLs or to determine dislodgeable residues.

The specificity of the methods proposed must enable all components included in the residue definition to be determined, using an additional confirmatory method if appropriate.

The repeatability of methods proposed must be determined and reported. Replicate analytical portions for testing can be prepared from a common field treated sample, containing incurred residues. Alternatively the replicate analytical portions can be prepared from a common untreated sample with aliquots fortified at the required level(s).

The results from an independent laboratory validation must be reported.

The limit of determination including the individual and mean recovery levels obtained must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

4.2.2 Residues in soil

Methods for analysis of soil for parent compound and/or relevant metabolites must be submitted.

The specificity of the methods must be such as to enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

The repeatability, recovery and the limit of determination including the individual and mean recovery levels must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

The proposed limit of determination must not exceed a concentration which is of concern with regard to exposure of non-target organisms or because of phytotoxic effects. Normally the proposed limit of determination should not exceed 0.05 mg/kg.

4.2.3 Residues in water (including drinking water, ground water and surface water)

Methods for analysis of water for parent compound and/or relevant metabolites must be submitted.

The specificity of the methods must be such as to enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

The repeatability, recovery and the limit of determination including the individual and mean recovery levels must be determined and reported. The overall relative standard deviation, as well as the

relative standard deviation for each fortification level must be experimentally determined and reported.
For drinking water the proposed limit of determination must not exceed 0.1 µg/l. For surface water the proposed limit of determination must not exceed a concentration which has an impact on non-target organisms deemed to be unacceptable according to the requirements of Annex VI.
4.2.4 Residues in air
Methods for the analysis of air for the active substance and/or relevant metabolites formed during or shortly after application must be submitted unless it can be justified that exposure of operators, workers or bystanders is not likely to occur.
The specificity of the methods must be such as will enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.
The repeatability, recovery and the limit of determination including the individual and mean recovery levels must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.
The proposed limit of determination must take into account relevant health based limit values or relevant exposure levels.
4.2.5 Residues in body fluids and tissues
Where an active substance is classified as toxic or highly toxic, appropriate analytical methods must be submitted.
The specificity of the methods must enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.
The repeatability; recovery and the limit of determination including the individual and mean recovery levels must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported."

REG 6

6. Point 5 of Part A of Annex III, as set out in Part 2 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"5. ANALYTICAL METHODS
Introduction
The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.
For analytical methods used for the generation of data as required in accordance with Annex IIIA, or for other purposes, applicants must provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used.
As far as practicable methods provided must employ the simplest approach, involve the minimum cost, and require commonly available equipment.
For the purposes of point 5 of this Annex, the following applies:

ImpuritiesAny component other than the pure active substance which is present in the active substance as manufactured (including non-active isomers) originating from the manufacturing process or from degradation during storageRelevant ImpuritiesImpurities of toxicological and/or ecotoxicological or enviromental concern,MetabolitesMetabolites include products resulting from degradation or reaction of the active substance,Relevant MetabolitesMetabolites of toxicological and/or ecotoxicological or enviromental concern.
On request the following samples must be provided:
(i) samples of the preparation,
(ii) analytical standards of the pure active substance,
(iii) samples of the active substance as manufactured,
(iv) analytical standards of relevant metabolites and all other components included in the residue definition,
(v) if available, samples of reference substances for relevant impurities.
For definitions see Annex IIA, point 4.1 and 4.2.
5.1 Methods for the analysis of the preparation
5.1.1 Methods, which must be described in full, must be provided for the determination of the active substance in the preparation. In the case of a preparation containing more than one active substance a method capable of determining each, in the presence of the other, should be provided. If a combined method is not submitted, the technical reasons must be stated. The applicability of existing CIPAC methods must be reported.
5.1.2 Methods must also be provided for the determination in the preparation of relevant impurities, if the composition of the preparation is such that on the basis of theoretical consideration such impurities may be formed during manufacture or result from degradation during storage.
If required methods for the determination of formulants or constituents of formulants in the preparation must be submitted.
5.1.3 Specificity, linearity, accuracy and repeatability
5.1.3.1 Specificity of methods submitted, must be demonstrated and reported. In addition the extent of interference by other substances present in the preparation must be determined.
While interference's due to other components may be identified as systematic errors, in the assessment of the accuracy of methods proposed, an explanation must be provided for any interference occurring which contribute more than ± 3 % to the total quantity determined.
5.1.3.2 The linearity of proposed methods over an appropriate range, must be determined and reported. The calibration range must extend

(by at least 20 %) the highest and lowest nominal content of the analyte in relevant analytical solutions of the preparation. Duplicate calibration determinations must be made at 3 or more concentrations. Alternatively, 5 concentrations, each as single measurements, are acceptable. Reports submitted must include the equation of the calibration line and the correlation coefficient and representative and properly labelled documentation from the analysis, e.g. chromatograms.
5.1.3.3 Accuracy is normally only required for methods for the determination of pure active substance and relevant impurities in the preparation.
5.1.3.4 For the determination of repeatability, a minimum of five determinations must in principle be made. Relative standard deviation (% RSD) must be reported. Outliers identified through an appropriate method {e.g. Dixons or Grubbs Test), may be discarded. Where outliers have been discarded, that fact must be clearly indicated. An explanation as to the reason for the occurrence of individual outliers, must be attempted.
5.2 Analytical methods for the determination of residues
Analytical methods for the determination of residues must be submitted unless it is justified that the methods already submitted according to the requirements of Annex IIA, point 4.2 can be applied.
The same provisions as provided in Annex IIA, point 4.2 apply."

REG 7

7. Point 6 of Part A of Annex II, as set out in Part I of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"6. RESIDUES IN OR ON TREATED PRODUCTS. FOOD AND FEED
Introduction
(i) The information provided, taken together with that provided for one or more preparations containing the active substance, must be sufficient to permit an evaluation to be made as to the risks for man, arising from residues of the active substance and relevant metabolites, degradation and reaction products remaining in food. In addition, the information provided must be sufficient to:
· permit a decision to be made as to whether, or not, the active substance can be included in Annex I,
· specify appropriate conditions or restrictions to be associated with any inclusion in Annex 1.
(ii) A detailed description (specification) of the material used, as provided under point 11 must be provided.
(iii) Studies should be performed in accordance with the guidance on regulatory testing procedures for residues of plant protection products in food5 .
5 Guidance under development.
(iv) Where relevant, data should be analysed using appropriate

statistical methods. Full details of statistical analyses carried out should be reported.

(v) Stability of residues during storage

It may be necessary to perform studies on the stability of residues during storage. Provided samples are frozen within generally 24 hours after sampling and unless a compound is otherwise known to be volatile or labile, data are not normally required for samples extracted and analysed within 30 days from sampling (6 months in the case of radio labelled material).

Studies with non-radio labelled substances should be carried out with representative substrates and preferably on samples from treated crops or animals with incurred residues. Alternatively, if this is not possible, aliquots of prepared control samples should be spiked with a known amount of chemical before storage under normal storage conditions.

Where degradation during storage is significant (more than 30 %) it may be necessary to change the storage conditions or not to store the samples prior to analysis and it may be necessary to repeat studies where unsatisfactory storage conditions were used.

Detailed information with respect to sample preparation and the storage conditions (temperature and duration) of samples and extracts must be submitted. Storage stability data using sample extracts will also be required unless samples are analysed within 24 hours of extraction.

6.1 Metabolism, distribution and expression of residue in plants

Aim of the tests

The objectives of these studies are:

· to provide an estimate of total terminal residues in the relevant portions of crops at harvest following treatment as proposed,

· to identify the major components of the total terminal residue,

· to indicate the distribution of residues between relevant crop parts,

· to quantify the major components of the residue and to establish the efficiency of extraction procedures for these components,

· to provide a basis for a decision as to the definition of and basis for expression of the residue.

Circumstances in which required

These studies must always be performed unless it can be justified that no residues will remain on plants/plant products which are used as food or feeding stuffs.

Test conditions

Metabolism studies have to involve crops or categories of crops in which plant protection products containing the active substance in question would be used. If a wide range of uses in different crop categories or in the category fruits is envisaged, studies have to be earned out on at least three crops unless it can be justified that different metabolic pathways are unlikely to occur. In cases where use is envisaged in different categories of crops, the studies must be conducted in crops representative of the relevant categories. For this purpose crops can be considered as falling into one of

five categories: root vegetables, leafy crops, fruits, pulses and oil seeds, cereals. If studies are available for crops from three of these categories and the results indicate that the route of degradation is similar in all three categories then it is unlikely that any more studies will be needed unless it could be expected that a different metabolic pathway will occur. The metabolism studies must be designed such that the properties of the active substance and the intended method of application, are taken into account. An evaluation of the results obtained from the studies conducted must be submitted, having particular regard to the point and path of uptake (e.g. via leaves or roots), and on the distribution of residues between relevant parts of the crop at harvest (with particular emphasis on edible parts for man or animals). If the active substance or relevant metabolites are not taken up by the crop, this must be explained. Information on the mode of action and the physicochemical properties of the active substance may be helpful in assessing trials data.

6.2 Metabolism, distribution and expression of residue in livestock

Aim of tests

The objectives of these studies are:

· to identify the major components of the total terminal residue in edible animal products,

· to quantify the rate of degradation and excretion of the total residue in certain animal products (milk or eggs) and excreta,

· to indicate the distribution of residues between relevant edible animal products,

· to quantify the major components of the residue and to show the efficiency of extraction procedures for these components,

· to generate data from which a decision on the need for livestock feeding studies as provided for in point 6.4 can be made.

· to provide a basis for a decision as to the definition of and basis for expression of the residue.

Circumstances in which required

Metabolism studies on animals, such as lactating ruminants (e.g. goat or cow) or laying poultry, are only required when use of plant protection products containing the active substance may lead to significant residues in livestock feed (> 0.1 mg/kg of the total diet as received, except special cases e.g. active substances which accumulate). Where it becomes apparent that metabolic pathways differ significantly in the rat as compared to ruminants, a pig study must be conducted unless the expected intake by pigs is not significant

6.3 Residue trials

Aim of the tests

The objectives of these studies are:

· to quantify the highest likely residue levels in treated crops at harvest or out loading from store, following use in accordance with the proposed good agricultural practice (GAP), and

· to determine, when appropriate, the rate of decline of residues in and/or on crops.

Circumstances in which required

These studies must always be performed where the plant protection product will be applied to plants/plant products which are used as food or feeding stuffs or where residues from soil or other substrates can be taken up by such plants, except where extrapolation from adequate data on another crop is possible.
Residue trial data must be submitted as part of the Annex II dossiers, for those uses of plant protection products for which authorisation is sought at the same time as inclusion of the active substance in Annex I is sought.
Test conditions
Supervised trials reported should be of trials that correspond to proposed critical GAP. The test conditions must take into account the highest residues which may reasonably arise {e.g. maximum number of proposed applications, use of the maximum envisaged quantity, shortest pre-harvest intervals, withholding periods or storage periods) while being representative of the realistic worst case conditions in which the active substance would be used.
Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned for which its use is to be recommended.
When designing a supervised trial programme, factors such as climatic differences existing between production areas, differences in production methods (e.g. outdoor versus glasshouse uses), seasons of production, type of formulations etc. should normally be taken into account.
In general, for a comparable set of conditions, trials should be carried out over a minimum of two growing seasons. All exceptions should be fully justified.
The precise number of trials necessary is difficult to determine in advance of a preliminary evaluation of the trial results. Minimum data requirements only apply where comparability can be established between production areas, e.g. concerning climate, methods and growing seasons of production etc. Assuming all other variables (climate etc.) are comparable, a minimum of eight trials representative of the proposed growing area is required for major crops. For minor crops normally four trials representative of the proposed growing area are required.
Due to the inherently higher level of homogeneity in residues arising from post-harvest treatments or protected crops, trials from one growing season are generally acceptable. For post-harvest treatments, in principle a minimum of four trials are required, carried out preferably at different locations with different cultivators. A set of trials must be carried out for each application method and store type unless the worst case residue situation can be clearly identified.
The number of studies per growing season to be performed can be reduced if it can be justified that the residue levels in plants/plant products will be lower than the limit of determination.
Where a significant part of the consumable portion of the crop is

present at the time of application, half of the supervised residue trials reported should include data to show the effect of time on the level of residue present (residue decline studies) unless it can be justified that the consumable crop is not affected by the application of the plant protection product under the proposed conditions of use.

6.4 Livestock feeding studies

Aim of the tests

The objective of these studies is to determine the residue in products of animal origin which will result from residues in feeding stuffs or fodder crops.

Circumstances in which required

Feeding studies are only required:

· when significant residues (³ 0.1 mg/kg of the total diet as received, except special cases, such as active substances which accumulate) occur in crops or part of the crop {e.g. trimmings, waste) fed to animals, and

· when metabolism studies indicate that significant residues (0.01 mg/kg or above the limit of determination if this would be higher than 0.01 mg/kg) may occur in any edible animal tissue taking into account the residue levels in potential feeding stuffs obtained at the 1 ´ dose rate.

Where appropriate separate feeding studies for lactating ruminants and/or laying poultry should be submitted. Where it appears from the metabolism studies submitted in accordance with the provisions of point 6.2 that metabolic pathways differ significantly in the pig as compared to ruminants, a pig feeding study must be conducted unless the expected intake by pigs is not significant.

Test conditions

In general, the feed is administered in three dosages (expected residue level, 35 times, and 10 times the expected residue level). When setting the 1 ´ dose, a theoretical feed ration must be compiled.

6.5 Effects of Industrial processing and/or household preparations

Circumstances in which required The decision as to whether it is necessary to carry out processing studies will depend on:

· the importance of a processed product in the human or animal diet,

· the level of residue in the plant or plant product to be processed,

· the physicochemical properties of the active substance or relevant metabolites, and

· the possibility that degradation products of toxicological significance may be found after processing of the plant or plant product.

Processing studies are not normally necessary if no significant or no analytically determinable residues occur in the plant or plant product which would be processed, or if the total theoretical maximum daily intake (TMDI) is less than 10% of the ADI. In addition processing studies are not normally required for plants or

plant products which are mostly eaten raw except for those with inedible portions such as citrus, banana or kiwi fruit where data on the distribution of the residue in peel/pulp may be required. 'Significant residues' generally refer to residues above 0.1 mg/kg. If the pesticide concerned has a high acute toxicity and/or a low ADI, consideration must be given to conducting processing studies for determinable residues below 0.1 mg/kg.

Studies of the effects on the nature of the residue are not normally required where only simple physical operations, not involving a change in temperature of the plant or the plant product, are involved, such as washing, trimming or pressing.

6.5.1 Effects on the nature of the residue

Aim of the tests

The objective of these studies is to establish whether or not breakdown or reaction products arise from residues in the raw products during processing which may require a separate risk assessment.

Test conditions

Depending upon the level and chemical nature of the residue in the raw commodity, a set of representative hydrolysis situations (simulating the relevant processing operations) should be investigated, where appropriate. The effects of processes other than hydrolysis, may also have to be investigated, where the properties of the active substance or metabolites indicate that toxicologically significant degradation products may occur as a result of these processes. The studies are normally conducted with a radio labelled form of the active substance.

6.5.2 Effects on the residue levels

Aim of the tests

The main objectives of these studies are:

· to determine the quantitative distribution of residues in the various intermediate and end products, and to estimate relevant transfer factors, and

· to enable a more realistic estimate to be made of the dietary intake of residues.

Test conditions

Processing studies should represent household processing and/or actual industrial processes.

In the first instance it is usually only necessary to carry out a core set of "balance studies" representative of the common processes relevant to plants or plant products that contain significant residues. A justification must be provided for the selection made.

The technology to be used in processing studies should always correspond as closely as possible to the actual conditions that are normally used in practice. A balance sheet should be made in which the mass balance of residues in all intermediate and end products is investigated. In drawing up such a balance sheet any concentrations or reductions in residues in individual products can be recognised and the corresponding transfer factors can also be determined.

If the processed plant products play an important part in the diet, and if the "balance study" indicates that a significant transfer of residue into the processed products could occur, then three "follow up studies" to determine residue concentration or dilution factors must be carried out.

6.6 Residues in succeeding crops

Aim of the test

The objective of these studies is to permit an evaluation to be made as to the residue levels likely to occur in succeeding crops.

Circumstances in which required

Where data generated in accordance with Annex IIA point 7.1 or Annex IIIA point 9.1, shows that significant residues (10 % of the applied active substance total of unchanged active substance and relevant metabolites or degradation products) remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, and which could lead to residues above the limit of determination in succeeding crops at harvest, consideration must be given to the residue situation. This should include consideration of the nature of the residue in the succeeding crops and involve at least a theoretical estimation of the level of these residues. If the likelihood of residues in succeeding crops can not be excluded, metabolism and distribution studies should be carried out, if necessary followed by field trials.

Test conditions

If a theoretical estimation of residues in succeeding crops is carried out, full details of the estimations and a justification for the conclusions reached, must be provided.

Metabolism and distribution studies and field trials, if necessary, must be carried out on representative crops chosen to represent normal agricultural practice.

6.7 Proposed maximum residue levels (MRLs) and residue definition

A full justification for the proposed MRLs must be provided, including, where relevant, full details of the statistical analysis used.

When judging which compounds are to be included in the residue definition, account must be taken of the toxicological significance of the candidate compounds, the amounts likely to be present and the practicallity of the analytical methods proposed for post-registration control and monitoring purposes.

6.8 Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses

A full justification for the proposals must be provided.

6.9 Estimation of the potential and actual exposure through diet and other means

Consideration must be given to the calculation of realistic dietary intake levels. This may be done in a stepwise fashion leading to increasingly realistic predictions of intake. Where relevant, other sources of exposure such as residues arising from the use of medicines or veterinary drugs must be taken into account.

6.10 Summary and evaluation of residue behaviour
A summary and evaluation of all data presented under point 6 must be provided. It must be carried out and be presented in accordance with the guidance provided by the competent authority. It should include a detailed and critical assessment of the data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.
In particular the toxicological significance of any non-mammalian metabolites must be addressed.
A schematic diagram should be prepared of the metabolic pathway in plants and animals with a brief explanation of the distribution and chemical changes involved."

REG 8

8. Point 7 of Part A of Annex III, as set out in Part 2 of the First Schedule of the Principal Regulations, is amended by the insertion after "7.2 Data on Exposure" of the following:
"When measuring exposure to a plant protection product in the air within the breathing space of operators, bystanders or workers, the requirements for measuring procedures described in Annex IIA to Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work 6 have to be taken into account."
6 O.J. No. L 327/8 3/12/1980

REG 9

9. Point 8 of Part A of Annex III, as set out in Part 2 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
" 8. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED
Introduction
The provisions of Annex II, section 6, Introduction apply.
8.1 Metabolism, distribution and expression of residue in plants or livestock
Aim of the tests
The objectives of these studies are:
· to provide an estimate of total terminal residues in the relevant portion of crops at harvest following treatment as proposed,
· to quantify the rate of degradation and excretion of the total residue in certain animal products (milk or eggs) and excreta,
· to identify the major components of the total terminal residue in crops and in edible animal products respectively,
· to indicate the distribution of residues between relevant crop parts and between relevant edible animal products respectively,

· to quantify the major components of the residue and to show the efficiency of extraction procedures for these components,
· to generate data on the basis of which a decision can be made as to the need for livestock feeding studies as provided for in point 8.3,
· to provide a basis for a decision as to the definition of and basis for expression of the residue.

Circumstances in which required

Supplementary metabolism studies only need to be performed where it is not possible to extrapolate from data provided for the active substance in accordance with the requirements of Annex IIA, point 6.1 and 6.2. This might be the case for crops or for livestock for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I or where it could be expected that a different metabolism will occur.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex IIA, points 6.1 and 6.2, apply.

8.2 Residue trials

Aim of the tests

The objectives of these studies are:
· to quantify the highest likely residue levels in treated crops at harvest or out loading from store following use in accordance with the proposed good agricultural practice (GAP), and
· to determine, when appropriate, the rate of decline of residues in and/or on crops.

Circumstances in which required

Supplementary residue trials are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex IIA, point 6.3. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex 1.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex IIA, point 6.3 apply.

8.3 Livestock feeding studies

Aim of the tests

The objective of these studies is to determine residue levels in products of animal origin which will result from residues in feeding stuffs or fodder crops.

Circumstances in which required

Supplementary feeding studies for the purpose of assessing maximum residue levels for products of animal origin are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex IIA, point 6.4. This might be the case where additional fodder crops are to be

authorised which lead to an increased intake of residues by livestock for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex 1.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex HA, point 6.4 apply.

8.4 Effects of industrial processing and/or household preparations

Aim of the tests

The main objectives of these studies are:

· to establish whether or not breakdown or reaction products arise from residues in the raw products during processing which may require a separate risk assessment,

· to determine the quantitative distribution of residues in the various intermediate and end products, and to estimate transfer factors,

· to enable a more realistic estimate to be made of dietary intake of residues.

Circumstances in which required

Supplementary studies only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex HA, point 6.5. This might be the case for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex 1.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex IIA, point 6.5 apply.

8.5 Residues in succeeding crops

Aim of the test

The objective of these studies is to permit an evaluation to be made as to the residue levels likely to occur in succeeding crops.

Circumstances in which required

Supplementary studies are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex IIA, point 6.6. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex 1.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex IIA, point 6.6 apply.

8.6 Proposed maximum residue levels (MRLs) and residue definition

A full justification for the proposed MRLs must be provided, including, where relevant, full details of the statistical analysis used.

If the metabolism studies submitted in accordance with the provisions of point 8.1 indicate that the residue definition should be changed taking into account the actual residue definition and the necessary

judgement as outlined under the corresponding paragraph of Annex IIA, point 6.7, a re-evaluation of the active substance may be necessary.
8.7 Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses
A full justification for the proposals made must be provided.
8.8 Estimation of the potential and actual exposure through diet and other means
Consideration must be given to the calculation of realistic dietary intake levels. This may be done in a stepwise fashion leading to an increasingly realistic prediction of intake. Where relevant, other sources of exposure such as residues arising from the use of medicines or veterinary drugs have to be taken into account.
8.9 Summary and evaluation of residue behaviour
A summary and evaluation of all data presented under point 8 must be provided. It must be carried out and be presented in accordance with the guidance provided by the competent authority. It should include a detailed and critical assessment of the data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.
Where metabolism data have been submitted the toxicological significance of any non-mammalian metabolites must be addressed.
A schematic diagram should be prepared of the metabolic pathway in plants and animals with a brief explanation of the distribution and chemical changes involved if metabolism data have been submitted."

REG 10

10. The Twelfth Schedule as set out in the Principal Regulations is hereby revoked and replaced by the following:
Regulation 30 (6)
"TWELFTH SCHEDULE
CERTIFICATE OF RESULT OF ANALYSIS

Laboratory Reference Number.....Sample of.....received by the designated analyst on.....from.....Methods of analysis used.....
This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analysed under the provisions of the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997 and

that the results of the analysis are as follows:

.....
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.....

This certificate is issued under the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1997

Date.....Signed.....Designated Analyst.....Designated Analyst.....Designated Analyst"

Given under my Official Seal, this 3rd day of July, 1997

Joe Walsh

Minister for Agriculture, Food and Forestry

EXPLANATORY NOTE

These Regulations, amend the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1996 (S.I. No. 139 of 1994, S.I. No. 200 of 1995 and S.I. No. 159 of 1996).

The amendments, inter alia, specify the detailed requirements relating to analytical methods and relating to residues in and on agricultural produce, to be submitted in support of applications for authorisation for marketing and use of plant protection products.