SESSION 6A

HARMONISATION OF MRLS IN THE EU – TIMESCALES, CHALLENGES AND SOLUTIONS

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Harmonisation of MRLs in Europe – perspectives of the new MRL regulation

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ABSTRACT

In March 2005 a Regulation on MRL setting for pesticides in or on food and feed of plant and animal origin was published. The status of current legislation and MRL setting, the scope of the new Regulation and the plans of the European Commission (EC) for developing the new Regulation are presented.

INTRODUCTION

Maximum residue limits valid in all Member States (MS) of the European Union are fixed up to now on the basis of four different Directives. These Directives shall be replaced by a uniform law, a Regulation. This Regulation was published on 16th March 2005 in the Official Journal, the Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. The publication is a consequence of the regulation on the general food law, i.e. Regulation (EC) No 178/2002.

This Regulation entered into force on 5th April 2005 with the exception of chapters II, III and V. Chapter II (Procedure for application of MRLs), chapter III (MRLs applicable to products of plant and animal origin) and chapter V (Official controls, reports and sanctions) will enter into force from six months from the publication of the last of the Regulations establishing Annexes I, II, III and IV. Annex I shall be first established within three months from the entry into force of this Regulation and the Annexes II, III and IV shall be first established within 12 months from the entry into force of this Regulation.

THE EXISTING DIRECTIVES

In the EC, a procedure for setting MRL for pesticide residues existed since 1976. In that year Directive 76/895/EEC was published. For the first time MRLs were set for fruit and vegetables. Unanimous majority was needed in the Council for setting or changing an MRL in that Directive. MRLs set in the framework of that Directive are not absolute values. MSs are allowed to deviate from the values, setting on a national level higher or lower limits, but imports from other MSs should not be hampered. Taking this into account these levels are primary a trade tool. That Directive was amended a few times until 1990. In that year Directive 90/642/EEC was published and from that point of time onwards no new active substance was added; a couple of active substances were deleted and in a very few cases MRLs were changed.

In 1986, two Directives were published at the same time, i.e. Directive 86/362EEC on the fixing of maximum levels for pesticide residues in and on cereals and Directive 86/363/EEC on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin. 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 followed in 1990. The later covers more crops than the Directive from 1976 as beneath fruit and vegetables also some agricultural crops, hops and tea are covered. In all three cases a qualified majority in the Council was needed for an amendment of these Directives. The values given are absolute ones, i.e. Member States have to adopt them in their national laws and regulations without any deviation.

All Directives have the same order. After the legal text, an Annex I follows describing the crops to which the MRLs apply. In Annex II the fixed values are mentioned.

Until 1997 these Directives were amended a few times in the Council – about once per year. In that year some fundamental changes were introduced into all four Directives. These were primarily necessary to avoid trade problems between MSs by introducing a conciliation procedure. One of the main changes was the clarification that MRLs also belong to same product used as feed for livestock animals. Another important point was changing the procedure; MRLs are fixed by a Commission Directive instead of a Council Directive. Starting in 1997 MRLs were changed several times a year by Commission Directives needing a qualified majority in the Standing Committee (today Standing Committee on the Food Chain and Animal Health (SCFCAH)). Last but not least some additional changes took place taking note of some other Directives and handling same provisions in the same way within the four Directives.

THE NEW REGULATION

The new Regulation consists of 36 introductory notes (i.e. the "whereas"), 50 Articles divided into 10 chapters and seven annexes that are foreseen to be published at later stages.

Main changes

The main changes are:

- In future, the European Food Safety Authority (EFSA) will play a major role in the work of MRL setting.
- Food and feed shall only be placed on the market if they are in line with the MRLs set in the framework of the Regulation (Article 18(1)). Deviations are only possible in exceptional cases according to Directives 91/414/EEC and 2000/29/EC (Article 18(4)).
- All combinations active substance/product are covered from the beginning by a default value of 0.01 mg/kg (Article 18(1)).
- Provisional MRLs on the basis of Article 4(1) f of Directive 91/414/EEC will no longer be set. The provision in Directive 91/414/EEC was changed by Article 48(2) of the Regulation but unfortunately no time-limits for adoption and publication by MSs were introduced.
- Without a suitable MRL – if the default value is not adequate – and provided that Article 4(1) f of Directive 91/414/EEC will be changed in the MSs, a use may not be authorised.
- For setting or changing of an MRL, it is necessary to submit an application (Article 6).

Also the European Parliament adds some important changes.

- The protection of consumers was of high importance for the European Parliament especially in cases of high intake and high vulnerability (like children and the unborn) (Article 14(2)).

- The same applies to the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available (Article 14(2)).
- The possibility given to the MSs to name the retailers, traders or producers concerned, where MRLs are exceeded (Article 30(3)). This provision should be carefully read in connection with the provisions of Regulation (EC) No 882/2004.

Throughout the Regulation animal health is also of importance. This appears to go beyond the requirements of Directive 91/414/EEC. Concerning the scope of the regulation, it is important that this Regulation shall apply without prejudice to Directives 98/8/EC (biocides), 2002/32/EC (undesirable substances in animal feed) and Regulation (EEC) No 2377/90 (veterinary medicine). For this reason, MRLs for active substances in plant protection products belonging also to one of the other groups mentioned before will be covered by this Regulation.

One point hasn't changed in comparison to the existing Directives. In case of information that pesticide residues may endanger human or animal health, immediate action may be taken on the basis of Article 53 and 54 of Regulation (EC) No 178/2002.

Products to which the MRLs apply

Crops and group of products to which harmonised MRLs apply will be covered by Annex I. This Annex shall be first established within three months from the entry into force of the Regulation, i.e. 4th July 2005. The list may be revised when appropriate, normally at the request of a MS (Article 4). In the meantime a proposal was send to the MSs but not yet adopted.

MRL setting in future

The Regulation will have three Annexes for fixed MRLs. They will deviate between permanent and temporary MRLs and active substances where MRLs are not required.

The provisions to be fulfilled for active substance for which no MRLs are required are also in force since 5th April 2005 (Article 5). These active substances should be listed in Annex IV which shall be first established within twelfth months from the entry into force of the Regulation, i.e. 4th April 2006. In decision making the following should be taken into account:

- the use of the active substance,
- the scientific and technical knowledge,
- the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals, and
- the results of any evaluations and decisions to modify the uses of plant protection products.

The chapters II and III are not yet in force. They describe how MRLs will be set in future. The procedure involves the MSs, the EC and EFSA.

Under normal circumstances an application for setting MRL will be made together with the application for authorisation of a plant protection product. Nevertheless, the number of applicants is much broader. These are:

- applicants according to Directive 91/414/EEC,
- all parties demonstrating, through adequate evidence, a legitimate interest in health, including civil society organisations,
- commercially interested parties such as manufacturers, growers, importers and producers of products covered by Annex, and
- Member states.

This opens the possibility to Non-Governmental Organisations (NGOs) to submit an application.

The application should contain:

- the name and address of the applicant,
- a presentation of the application dossier (including a summary of the application, the main substantive arguments, an index of the documentation, and the description of the Good Agricultural Practice),
- a comprehensive overview of relevant concerns raised in the available scientific literature about the plant protection product and/or its residue,
- the data listed in Annexes II and III to Directive 91/414/EEC relating to residue behaviour including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories.

These requirements cannot be fulfilled by every applicant. It is possible to request further data within a time-limit set by the MS.

A copy of the application is sent to the EC and EFSA. After finalising the assessment taking into account publicly available data (e.g. Draft Assessment Reports, JMPR evaluations) either by a MS in case of an application for authorisation of a plant protection product or by a rapporteur MS in case of an application for an import tolerance the assessment report is send to the EC. They will inform the other MSs and send all the data to EFSA. EFSA will acknowledge the receipt of the application to the applicant, the evaluating MS and the EC. Within three months, or in exceptional cases, within 6 months EFSA shall submit a reasoned opinion to the applicant, the MSs and the EC. The participation of EFSA is not necessary when MRLs are changed due to the fact that an authorisation is withdrawn.

The reasoned opinion shall contain:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes,
- the anticipated LOD for the pesticide/product combination,
- an assessment of the risks of the acceptable daily intake or acute reference dose being exceeded as a result of the modification of the MRL; the contribution to the intake due to the residues in the product for which the MRLs was requested, and
- any other element relevant to the risk assessment.

It is foreseen that EFSA publishes its reasoned opinion. It should be noted that the decision taken by EFSA may be reviewed by the Commission on its own initiative or in response to a request from a MS or from any person directly and individually concerned (Article 13).

Within three months, the EC shall present a proposal for a Regulation to the MSs. It is possible to request further data which then shall be sent to EFSA and the MSs. Decision making by the EC shall take into account (Article 14(2);

- the scientific and technical knowledge,
- the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available,
- the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals,
- the results of any evaluations and decisions to modify the uses of plant protection products,
- a CXL or a GAP implemented in a third country for the legal use of an active substance in that country, and
- other legitimate factors relevant to the matter under consideration.

To complete the timeframe the proposal made by the EC if acceptable to the MSs must be notified to the World Trade Organisation before final voting in the SCFCAH and publication.

As stated above for every combination active substance/crop a default value is set at the beginning. If the evaluation process shows that this value cannot be reached by standard methods of analysis a realistic value can be published in Annex V of the Regulation (Article 18(1)). Additionally the rules concerning residues in processed products may be not sufficient. It is possible to establish specific concentration and dilution factors in a separate list, i.e. Annex VI (Article 20(2)). Additionally a specific list for fumigants (Annex VII, Article 18(3)) shall be established. This list is necessary to define an exemption from the MRLs set. MRLs may be exceeded immediately after fumigation. and storage is defined as putting on the market.

Inclusion of existing MRLs into the Regulation

MRLs set in the framework of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC shall be transferred into Annex II of the Regulation which should be first established within 12 months from the entry into force of the Regulation, i.e. 4th April 2006. Those MRLs have to fulfil the criteria of Article 14(2) (see above).

MRLs set in the past by the MSs and which are necessary to cover national authorisations shall be included into Annex III of the Regulation. This includes also the remaining MRLs set in Directive 76/895/EEC. Also, this Annex should be first established within 12 months from the entry into force of the Regulation they have to fulfil the criteria of Article 14(2).

Before publication of the Regulation MSs agreed on a format to send their national MRLs to the Commission which had to be done until end of March 2005. The EC added the Codex MRLs. The notifications were combined and send to EFSA. On request of the EC, MSs have to submit further data like use pattern, residue trials data etc. EFSA should submit a reasoned statement especially concerning the risk to consumers. At the beginning, the Annex III will be rather extensive until active substances were included in Annex I of Directive 91/414/EEC and the MRLs were re-evaluated in order to transfer them into Annex II. Later on the Annex III will contain only a limited number of temporary MRLs for certain circumstances on the basis of monitoring data (Article 16)

- in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Article 8(4) of Directive 91/414/EEC (like aldrin, dieldrin, DDT),
- where the products concerned constitute a minor component of the diet of consumers, and do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals,
- for honey,
- for herbal infusions,
- where essential uses of plant protection products have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC, or
- where new products, product groups and/or parts of products have been included in Annex I, and one or more MSs so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated, provided that no unacceptable safety concerns for the consumer have been identified.

These MRLs have time-limits for their inclusion in Annex III and the limits depend on the situation exceeding in no case 10 years.

Further measures

As in the past the EC as well as the MSs have to set up programs to enforce the MRLs set. Laboratories analysing samples have to participate in Community proficiency tests. The annual report will no longer be prepared by the Food and Veterinary Office in Dublin but will become a duty of EFSA.

Financial contribution up to 100 % by the EC may be made to the following supporting measures:

- A consolidated database for Community legislation on MRLs of pesticide residues being publicly available.
- Community proficiency tests.
- Studies and other measures necessary for the preparation and development of legislation and of technical guidelines on pesticide residues, aimed, in particular, at developing and using methods of assessing aggregate, cumulative and synergistic effects.
- Studies necessary for estimating the exposure of consumers and animals to pesticide residues.
- Studies necessary to support control laboratories where analytical methods are not capable of controlling the MRLs established.

In addition to the database available to the public, a database with some more information will be set up for EC and MSs.

FUTURE DEVELOPMENTS

A first proposal for Annex I was presented by the EC in March 2005. This proposal was rather disappointing due to the following reasons:

a) In contrary to the discussions in the Council, the EC started not with existing list of crops and group of crops but with a complete list leaving out just fodder crops. The problem is connected to the default value of 0.01 mg/kg valid immediately for all food and feed items.
b) In a few instances, the existing crop grouping was changed which may cause difficulties with group MRLs based in the past on extrapolation. The future of the existing extrapolation model is questionable.
c) A statement of the Legal Service of the Commission concerning a judgement of the European Court of Justice on grape leaves was missing (European Court of Justice, 2004). Due to this judgement, the EC tried to close all groups of crops by mentioning as many crops as possible belonging to group of crops. Nevertheless, a position "others" (other crops belonging to a certain group of crops) will be necessary in future.

Proposals concerning Annexes II, III and IV are not yet available. The filling of these annexes is one of the key issues during the next months. MSs sent in their national MRLs. These values were combined and the combined values were sent to EFSA in summer 2005 for assessment. The time frame given can only be met with a pragmatic approach, i.e. to evaluate consumer risk first on the basis of MRLs. Where no risk for consumers could be predicted the MRLs should be set taken into account that the values have to be re-evaluated when the active substance is included in Annex I of Directive 91/414/EEC. The problems with the remaining active substances leave enough work for MSs and EFSA to be done by until March 2006. A decision hasn't yet been taken on such an approach.

An additional problem is the complete entering into force 6 month after publication of the last Regulation setting up Annexes I, II, III and IV. The authorisation of plant protection products is a continuous work and therefore MRLs derived by MSs during the next months will not be covered by the new Annexes. EC promised that once the proposals for Annex III have been established and indicative vote has taken place they will request MSs to send in a second lot of national MRLs in order to change the Regulation/the Annex III immediately. Nevertheless, a certain gap of MRLs could be expected. It might be that the problem is even bigger as a connection between Annex I of this Regulation and the national MRLs exists.

Unfortunately, a problem is incorporated in the provisions concerning MRLs under certain circumstances in Article 16 (Annex III). The provision that temporary MRLs may be set on the basis of monitoring data is in contradiction to the provision that an authorisation may only be granted, when an appropriate MRL is fixed in the Regulation.

Work on Annexes V, VI and VII hasn't yet started. It can be predicted that a first proposal on Annex V ("realistic LOQs") and Annex VII ("fumigants") will be published shortly after publication of Annexes II, III and IV as some of the data are still mentioned in the existing Directives. A first proposal concerning Annex VI with the concentration and dilution factors will need some time as somebody has to analyse the Draft Assessment Reports and the MRL proposals of the MS submitted in the past. Enforcement laboratories (food and feed) are waiting on this Annex as they expect more legal certainty in their decision making.

Although the timeframe set out in the Regulation is rather ambitious, no discussion took place so far on any procedural questions like uniform application forms or strengthening the work. EC announced in the past that they are not able to increase the number of meetings of the Working Group Pesticide Residues (where the decisions are prepared) and that they will take the opportunity for voting whenever the SCFCAH will meet.

MSs are also awaiting a reasoned statement of the Legal Service on the question how to proceed with Article 48(2). This article changes Article 4(1) f of Directive 91/414/EEC and the change is in force since 5th April 2005. Unfortunately, no time-limit was set to adopt this change by MSs. It might be that the amendment of Directive 91/414/EEC has to be awaited.

REFERENCES

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Council Directive of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (86/362/EEC), OJ L 221, 7.8.1986, p. 37.

Council Directive of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin (86/363/EEC), OJ L 221, 7.8.1986, p. 43.

Council Directive of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (90/642/EEC), OJ L350 of 14.11.1990, p. 71.

Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC), OJ L 230 of 19.8.1991. p.1.

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Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community, OJ L 169 of 10.7.2000, p. 1.

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Import tolerances – EC maximum residue levels and the implications for trade with countries outside the European Union

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ABSTRACT

The current system for establishing EC MRLs does not make adequate provision for legitimate pesticide uses outside of the EU. The new MRLs Regulation will tighten the statutory control of pesticide residues in food. Hence, if specific import tolerances are not set, significant trade problems could arise when residues in imported produce are found to exceed a default limit of 0.01mg/kg. PSD has developed a scheme to allow import tolerance applications to be evaluated efficiently, so that appropriate MRLs can be established.

INTRODUCTION

Maximum Residue Levels (MRLs) are specific limits for pesticide residues in food commodities, established by national, regional or international authorities or organisations. They are intended to ensure that pesticides are being used in accordance with good agricultural practices and that resulting residues are not harmful to consumers. In many cases, MRLs are statutory and give relevant authorities the power to block or seize produce found to exceed the relevant level or levels.

Within the European Union (EU), harmonised statutory community MRLs (EC MRLs) are the remit of the European Commission. An established mechanism of scientific evaluation and discussion is used to propose EC MRLs appropriate to authorised pesticide uses within the EU. Levels agreed by all Member States are currently set in EC Directives. These are applicable to the whole Community and must be transposed into national laws in all Member States. However, little consideration has been given to setting EC MRLs based on different agricultural practices outside the EU, for crops not grown within the EU, or for pesticides not authorised in the EU. Such MRLs are referred to as import tolerances.

THE IMPICATIONS OF EC MRLS FOR IMPORTS

Regulation (EC) No 396/2005 (MRLs Regulation; European Parliament and Council, 2005) establishes EC MRLs directly applicable to all Member States and will replace all existing MRL Directives. The MRLs Regulation has already been published and is intended to come into force towards the end of 2006. Importantly, the MRLs Regulation will set MRLs for all pesticides; many of which were not previously covered by statutory limits. Where a particular pesticide use has not been assessed, the MRLs Regulation will establish a default MRL of 0.01mg/kg. This represents the quantification limit for most pesticides, indicating that no residues are allowed.

There is an established system for setting harmonised EC MRLs for authorised uses within the EU and this system will continue with the new MRLs Regulation. The system allows the Member State authority responsible for the particular pesticide (Rapporteur) to include information on use on imported crops in their proposals for MRLs. However, Rapporteurs are not obliged to do this and there are often procedural and resource difficulties. Hence, to date, only a few EC import tolerances (effectively EC MRLs) have been considered and these have been set on an *ad hoc* basis.

For pesticides that do not yet have EC MRLs, there has also been the option of setting national import tolerances. This is not a harmonised system and even where Member States have chosen to do this, it is often a lengthy process and the resulting levels may not be recognised in other Member States. Increasingly though, as harmonised EC MRLs are being set for more and more pesticides, there are fewer opportunities for Member States to set their own levels. Furthermore, when the new Regulation comes into force, the option for setting national MRLs or import tolerances will be removed.

It is clear then, that unless import tolerances have been specifically assessed and appropriate levels set in the MRLs Regulation, a default level of 0.01mg/kg will apply. This is likely to have serious implications for trade of the relevant commodities.

PESTICIDES FOR WHICH IMPORT TOLERANCES MIGHT BE NEEDED

New pesticides or ones already reviewed

For new pesticides or existing ones that have already completed the rigorous review programme under Directive 91/414/EEC (the Authorisations Directive; European Council, 1991), an extensive dossier of toxicology, metabolism and other relevant data will already have been evaluated and peer reviewed in the European framework. These data have been used to demonstrate that at least one use of the pesticide is acceptable under strict scientific criteria. Hence, a positive decision has already been taken to include the pesticide in Annex I to the Authorisations Directive.

However, before further uses of these pesticides can be authorised or re-registered in Member States, a further dossier of residues trials and other data relevant to the specific use must also be evaluated. Once these dossiers have been generated, submitted and evaluated to support the authorisation, the process for establishing EC MRLs is relatively straightforward and requires little input from the applicant. This is because the Member State authorisation is used as the basis for setting the relevant EC MRL and all that remains is the peer review process and agreement amongst all Member States.

For uses of these pesticides outside Europe though, the situation is less straightforward. To support an import tolerance application, a dossier of residues trials and other relevant data must be generated to the same standards as for uses within the EU. Ordinarily, this dossier would be submitted to the Rapporteur, who would then be responsible for evaluating the data. If acceptable, they would propose an EC import tolerance to be peer reviewed and agreed by all Member States, in the same way as EC MRLs. However, the Rapporteur Member State may be unable or unwilling to evaluate the supporting dossier.

Pesticides yet to be reviewed

There are many existing pesticides within the EU review programme, for which acceptability has not yet been decided. In other words, a decision has not yet been taken regarding inclusion of the pesticide in Annex I to the Authorisations Directive. For most of these pesticides, there are no EC MRLs at present and any national MRLs take precedence in the relevant Member States.

However, the new MRL Regulation will establish an Annex of temporary EC MRLs for these pesticides, based on the existing national MRLs. It is accepted that national MRLs established in the past do not necessarily meet the current requirements for EC MRLs, established by the Authorisations Directive. Hence, the intention is that these temporary EC MRLs will gradually be replaced by definitive EC MRLs, as decisions on acceptability of the relevant pesticides are made under the Authorisations Directive.

For uses of these pesticides outside Europe, it may be that a national MRL or import tolerance in at least one Member State already covers the use. If so, no further data should be required at this stage, even if supporting data to current EU standards are not available. If no national MRL covers the use though, a national import tolerance is urgently required in order to establish a temporary EC MRL in the new Regulation. The data requirements, timetables and ability to set or amend national MRLs would depend on which Member State the application was made to (European Commission, 1999a).

Ultimately though, definitive EC MRLs will be set for these pesticides also. Hence, import tolerances will need to be supported by dossiers to current EU standards, once decisions on acceptability of these pesticides are made under the Authorisations Directive.

Unsupported pesticides

For some pesticides, a decision has already been taken for non-inclusion in Annex I to the Authorisations Directive. This could be because there was no notifier willing to support the EU review of the pesticide. Alternatively, it could be that following evaluation of the supporting dossier, the pesticide was found not to meet the strict inclusion criteria. Either way, the decision means that authorisations will not be allowed to continue in the EU and EC MRLs supporting EU uses will therefore eventually be set to the limit of quantification (LOQ).

However, these pesticides may still be supported in markets outside the EU and the decision for non-inclusion may have been unrelated to residues in food or consumer safety. Hence, there is no scientific reason why an import tolerance could not be supported, although there are likely to be several procedural difficulties.

Firstly, unlike pesticides included in Annex I to the Authorisations Directive, there may be an absence of or deficiency in supporting data in the major areas of toxicology and metabolism. Realistically, only manufacturers or Approval Holders of the pesticide would have access to or be willing to generate data to fill these data gaps. These data would be in addition to the residues trials and other data relevant to the specific use. Secondly, because the pesticide is no longer supported in the EU, there may be no Rapporteur Member State. This may cause difficulties as to who is responsible or willing to undertake the scientific evaluation of a dossier supporting an import tolerance application.

THE ROLE OF INSTITUTIONS IN ESTABLISHING IMPORT TOLERANCES

The European Food Safety Authority

The new MRLs Regulation states that the European Food Safety Authority (EFSA) is to be responsible for establishing EC Import Tolerances. However, in the short term, EFSA does not have the resources to evaluate extensive dossiers of supporting data from applicants for import tolerances. There has also been no guidance from EFSA as to the data that will be required to support EC import tolerances. However, the consistent opinion of Member States is that the scientific standards for MRLs based on uses both inside and outside of the EU should be the same.

Initially at least, EFSA's role is more likely to be one of independent reviewer, rather than evaluator. This means that the job of evaluating supporting data for import tolerance applications will fall to the Member States. Thus, the process will mirror that adopted for evaluating EC MRLs or applications for Annex I listing under Directive 91/414/EEC. Again in the short term at least, it is possible that EFSA will choose to implement their role as reviewer of import tolerance proposals on request only. In other words, only reviewing and commenting on those evaluations regarded as controversial or problematic, at the request of the European Commission.

Whatever the process adopted, it is clear that relevant import tolerances must already have been established when the MRLs Regulation comes into force. If this is not done, default levels of 0.01mg/kg will be established for the relevant pesticide/commodity combinations.

Competent authorities in member states

Although not confirmed by EFSA, it seems logical that designated Member State competent authorities, who currently have the expertise and experience of data evaluation, will act as Rapporteurs for import tolerances also. However, existing Rapporteurs may not have the additional resources to evaluate import tolerances or may not be able to meet evaluation deadlines. For the unsupported pesticides for which there are currently no Rapporteurs, it is possible that EFSA will assign Rapporteurs, in the same way as the European Commission has assigned Rapporteurs for existing pesticides under the review programme. However, again, assigned Rapporteurs may not have the additional resources or may not be able to meet deadlines.

A more efficient process may be for applicants with import tolerance requests to choose a Rapporteur, in the same way as notifiers choose Rapporteurs for new pesticides. Whichever system is used to decide Rapporteurs for import tolerances, it must ensure that available applications to the required standards are processed in time to meet the deadlines set by the new MRLs Regulation.

UK Pesticides Safety Directorate

Pesticides Safety Directorate (PSD) is the competent authority for pesticides in the UK. Until recently, PSD did not set or propose import tolerances, as there was no mechanism for recovering the evaluation costs. For uses within the EU, the same data are used to support an authorisation and to propose the relevant MRL. For import tolerances though, there is no EU evaluation of data to support an authorisation and so the evaluation cost must be met separately. A scheme was therefore developed that now allows PSD to charge a fee to applicants for the necessary evaluation work associated with import tolerances. This model for charging is now recognised in the new MRLs Regulation and may allow authorities in other Member States to overcome resource difficulties associated with import tolerance requests.

Although data requirements and evaluation guidelines have not yet been provided by EFSA, PSD have developed their own data requirements and guidance and published these on their website (http://www.pesticides.gov.uk/applicant_guide.asp?id=1239). These are based on the relevant requirements for authorisations in the EU (European Commission, 1999b) and PSD will evaluate import tolerance applications to the same standards laid down in the Authorisations Directive. This is because most Member States have made it clear that the same standards must apply to MRLs and import tolerances. Hence, PSD's opinion is that if it's evaluations are to be accepted by other Member States, they must comply with these same standards.

For processing purposes, PSD has categorised import tolerance applications according to the amount of data needed to be evaluated. This broadly corresponds to the status of the pesticide under the Authorisations Directive:

Category 1 – Requiring a full human health evaluation. This is any import tolerance that requires a toxicological evaluation in order to establish an acceptable daily intake (ADI) and if relevant, an acute reference dose (ARfD). This would generally be pesticides not authorised in the EU or those not supported under the EU review programme. Metabolism (plant and possibly livestock), residues trials data and consumer risk evaluations would also be required.

Category 2 – Metabolism (plant and possibly livestock) and residues trials data evaluation. This would include any active substance for which an ADI (and ARfD if relevant) was already established, but an evaluation of appropriate plant metabolism data was required in order to establish or confirm a crop residue definition (and/or animal residue definition, if relevant). This would generally be active substances authorised in the EU, but on crop groups unrelated to the imported crop. Residues trials data and consumer risk evaluations would also be required.

Category 3 – Residues trials data evaluation. This would include any active substance for which toxicology and plant (and possibly livestock) metabolism endpoints were already established. This would generally be pesticides already authorised on related crops in the EU. Only evaluation of residues trials data and consumer risk for the proposed crop would be required.

A standard fee for each category is derived from average estimates of the work involved. Targets of 6-14 weeks are also given for completion of the evaluation stage. These targets ensure a prompt response to the applicant as to the outcome of PSD's evaluation.

For pesticides where there are not yet EC MRLs, PSD can establish the proposed import tolerance as a temporary national MRL. This would be an interim measure only until such time as a harmonised EC import tolerance was established. This gives some flexibility, as existing UK evaluations can be used to support import tolerances in the absence of relevant endpoints agreed at EU level. However, PSD does not dictate the timetable for setting harmonised MRLs and it is likely that EC import tolerances will only be considered when EC MRLs for the relevant pesticide are already being discussed.

SUMMARY

The system for setting harmonised MRLs for the EU is well established and is a good mechanism for ensuring that MRLs are appropriate for the use of pesticides within the Community. Although poorly representing uses outside of the EU, this has not been a major problem to date, as many pesticides do not have EC MRLs. The new MRLs Regulation will however strengthen the role of MRLs and close off existing loopholes which have benefited importers until now. Although the need to establish import tolerances in the new Regulation is recognised, the EU has been slow to develop the necessary procedures and guidelines and it has been left to Member State authorities to adopt national procedures. PSD has led the way in developing a scheme intended to meet the requirements for harmonised import tolerances. However, it remains uncertain as to whether applicants, Member States and the EU institutions can set appropriate levels in legislation in time to prevent significant trade difficulties.

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The impact of the new EU MRL legislation on retailers

Retailers' representative

No paper included as final confirmation of speaker awaited.

Harmonizing pesticide clearances for minor crops

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ABSTRACT

Horticultural and other speciality crops present unique challenges in pest management. These crops are inherently unattractive to registrants in seeking pesticide labels, due to small market potential, geographic diversity, and the economic risks. While major grain and other agronomic crops are relatively few in number, these crops are financially and biologically attractive for commercial pesticide development. This paper summarises the key factors in the successful harmonization of pesticides in the U.S. and North America via the IR-4 project. Several public and private sector partnerships have contributed to the productivity of the IR-4 Project, from which more than 8,300 tolerances have been granted. These tolerances account for 42 percent of all Maximum Residue Limits (MRLs) issued by the U. S. Environmental Protection Agency since 1963 for use in U.S. agriculture. One key has been the use of Crop Groups and Representative Crops within a group to generate harmonized residue data from which MRLs can be extended to several other crops. As an example of the crop grouping scheme, herbicide trials were conducted with two representative crops (carrot and radish) in six regions that represented 98% of the U.S. production. From this work, MRLs were established so that clethodim could be labelled in these crops and 12 others with similar edible parts and biological traits in the Root Crops Group. More recently, harmonization work with Canada and Mexico has been highly productive, with shared protocols and lead roles designated in petition reviews.

INTRODUCTION

Since weed, disease, and insect pests impose more costs or losses on crops than any other component in field production, pesticides are essential to produce adequate food and fibre for modern-day industrial societies. Pest control products are fundamental in integrated pest management (IPM) and crop production programs. However, the challenge is to find economically efficient and safe ways to develop and sustain pesticides, particularly for specialty crops. The stakeholders and challenges involved in pesticide development include public stakeholders interested in food safety and confidence, growers who require timely availability of

pesticides, registrants needing adequate economic incentives to expand registrations, and workable transparent procedures for regulatory agencies. The overall goal is to establish efficient strategies and tactics for developing transparent research data for food safety.

Major crops such as wheat, maize, sorghums, soybean, cotton, peanut, and rice are grown on a vast number of hectares (ha) and provide major food stuffs for consumers and ample agricultural markets to justify product development by registrants. In these agronomic crops, where profit margins are slim, pest management represents a high portion of production costs and producers are highly responsive to tactics that will reduce costs and risks (Smith *et al.*, 2002). However, far fewer products are available for specialty crops although more than 50 vegetable crops are of major economic importance and dietary diversity. Another 200 specialty food crops are commonly grown and an additional 600 other crops are of economic importance in the U.S. Quality and cosmetic appearance are pervasive issues in specialty crops to assure that market grade standards are met.

Some of the challenges in pesticide clearance for speciality crops include the large number and diversity of these crops, smaller agricultural markets and economies, higher financial risks, and the more diverse production practices and environmental conditions. However, these specialty crops are essential for dietary health and provide important economic returns (Smith and Anciso, 2005). For example, in the 18 western states in the U.S. specialty crops make up 44 percent of all cash crop receipts.

HARMONIZATIONS FOR PESTICIDE DEVELOPMENT

Experiences in the U.S. indicate that at least three components are required for effective harmonization. First, harmonization of crop nomenclature is essential to assure consistent use of crop names and avoid ambiguities. Botanical nomenclature should be established, considering the large number of speciality crops (exceeding 1,000 worldwide), tendencies to use colloquial names, and other factors. Standardization of names is not a particular problem but must be clearly designated and can be handled by some cross indices of several common names and final reference to scientific names. A brief review of crop nomenclature indicates very little difference between North American Free Trade Agreement (NAFTA) and EU countries. For example, most agriculturalists recognize that alfalfa and lucerne both refer to *Medicago sativa* L. but other names may include mielga and sickle medic.

A second sequential component for efficient harmonization for Maximum Residue Limits (MRLs) involves Crop Groupings. Crop groups have been used quite effectively for several decades in the U.S. with no problems and are periodically reviewed and expanded. Crop groups are discussed in more detail below.

Finally, some common agreement is essential in the design of protocols and generation of reliable data in deriving acceptable MRLs. While it is beyond the scope of this paper to cover the harmonization factors in generating residue samples of raw agricultural commodities (RACs), field test guidelines are well-defined and have been time-proven by the U. S. Environmental Protection Agency (US EPA). These guidelines couple a strong food safety rationale with pragmatic design of field trials. For example, field trials must be located in the geographic regions that represent 98% of the national production of a commodity. Guidelines

and other field-test criteria are readily available (EPA web page, 2005) and "the Green Book" (Markle *et al.*, 1998).

U.S. HARMONIZATION EXPERIENCES WITH THE IR-4 PROGRAM

The Interregional Project Number 4 (IR-4), established in 1963, has grown into a federally funded program headquartered at Rutgers University in New Jersey. IR-4 consists of voluntary partnerships that involve the IR-4 Headquarters and Regional Offices, USEPA, nearly 50 Land Grant universities, U. S. Department of Agriculture (USDA), all major registrants operating in the U.S., and numerous grower organizations. The primary goal is to coordinate priorities and activities to obtain pesticide tolerances, and ultimately labels, for specialty crops. Project Clearance Requests (PCRs) may be submitted to IR-4 by University, extension, or grower stakeholders at any time. PCRs are reviewed by IR-4 and then by partners at annual regional and national planning meetings where projects are prioritized (as an A, B, or C project) for implementation. Proposed projects are coordinated with USEPA and registrants before work is initiated. Good Laboratory Practices (GLP) protocols are developed for field and laboratory residue work, which are implemented by the IR-4 regional offices, with the field work usually preformed by University or USDA co-operators.

Funding for specialty crop clearances is provided from multiple sources. The IR-4 Program received $US 11.2 million in federal funds (FY 05), of which 74% was dispersed to support regional field and laboratory programs. Universities, USDA, grower groups, registrants, and others provided another $US 17.3 million directly or as in-kind contributions, primarily to conduct GLP field work and residue analyses. Basic toxicology, metabolism, and environmental exposures (such as dietary, soil, and water) are commonly handled by the registrant in their initial registration submission and are generally not part of the IR-4/speciality crop research process. As a measure of performance, since 1963 more than 8,300 pesticide tolerances have resulted from IR-4 activities, which account for 42% of all tolerances granted by USEPA over the past 40 years. A high degree of trust and open communication have made these achievements possible, particularly benefiting consumers and the food marketing industries. IR-4 has been a highly successful partnership for stakeholders and fostered several new initiatives, including early clearances for reduced risk pesticides, research grants for bio-pesticides, a methyl bromide replacement program, and other special projects.

CROP GROUPS

The task of establishing MRLs for conventional or biological pesticide labels for the more than 800 minor food and fibre crops in the U.S. would be an insurmountable task! The Crop Group scheme was initially establish by the USEPA in 1962, with revisions and additions in 1983 and 1995, and generally follows the Codex Alimentarius Commission Classification of foods and animal feeds. The USEPA classification has been expanded to 20 Groups and is in the process of being expanded with NAFTA and as an international project.

Crop groups enable researchers and regulatory people to be more efficient and inclusive in pesticide reviews. Crops are grouped together based on several criteria, such as similar edible parts, plant growth characteristics, botanical relationships, economic importance, and use of the

raw commodity. The number of crops within a crop group may be as few as eight, as in Crop Group 8 - Pome Fruits, to as many as 52, as in Crop Group 6 - Vegetable Legumes. IR-4 and USEPA are now in the process of updating the crop group program for more inclusive coverage of crops and regulatory efficiency.

Subgroups may be established within a crop group to address unique features and provide additional efficiencies. Within a crop group or sub-group, representative crops are designated to serve as surrogates in developing MRLs for the whole group or a subgroup. Emphasis is placed on maximizing potentials for residues. For example, Crop group 8 for cucurbits includes several muskmelons but the representative crop for muskmelons is cantaloupe (*Cucumis melo*, var. *cantalupensis*) since this melon has a finely ridged rough surface which could result in higher retention of a pesticide than a smooth-surfaced melon. Crops with somewhat different botanical traits are not sub-grouped. For example, crop group 14 for tree nuts includes pistachio but this crop is not in the same sub-group as walnut and pecan since pistachio shells readily dehisce and split which could result in higher residues on the edible portion, as compared to other nut crops.

HARMONIZED PROTOCOLS

Centrally-established protocols are followed at each location so that all residue samples are generated, stored, and handled in a comparable manner. Field trials are conducted under GLP guidelines. Pesticide treatments include maximum anticipated rates, shortest pre-harvest intervals (PHIs), and other factors. All samples from a national trial are analyzed by a common lab. The resultant samples generate pesticide analytes which IR-4 uses in preparing a tolerance petition to US EPA to establish MRLs for the raw agricultural product. Quality assurance and adherence to GPL standards are documented in a two-tiered system which involves both IR-4 audits at co-operator field sites and laboratories while work is in progress and additional audits by US EPA.

Once residue trials are completed and MRLs are generated for representative crops the registrant may extend the pesticide label for use on any or all crops within the sub-group or group. Crop Group 1B, involving Root Vegetables, is used as an example here to show how the crop group and representative crop concept has operated in generating MRLs for several other crops. In the U.S., carrots are produced on 40,000 ha, 76% of which is for fresh markets, and makes up an estimated 0.32% of the human diet (Markle *et al.*, 1998). Radish make up 0.003% of the U.S. diet and are grown on 18,000 ha, with 67% grown in Florida. These two crops serve as surrogates for establishing MRLs on several other crops in a root crop sub-group. Since grassy weeds imposed significant losses in root crops, University and grower representatives submitted a PCR, requesting labelling of clethodim (Select or Cletodime) as a post-emergence herbicide. Basic toxicology and environmental work had already been completed by the registrant and clethodim was already cleared for post-emergence use in cotton, soybean, peanut, and lucerne.

To generate residue data to establish an MRL, trials were conducted with the two representative crops. Eight carrot and four radish trials were conducted in regions of the U.S. which represented 96% of the total production (as outlined by Markle *et al.*, 1998). With residue data from the raw agricultural commodities from more than 50 samples, a petition was prepared by IR-4. After intensive review, US EPA established an MRL of 1.0 ppm for the 1B Vegetable Crop Group. The registrant then expanded the clethodim label so that the herbicide could

potentially be used in the production of carrot, radish, and 12 other minor crops, including beet-table (4,200 ha), burdock (< 100 ha), celeriac (300 ha), chicory (350 ha), ginseng (590 ha), horseradish (1,100 ha), oriental radish (140 ha), and parsnip (2,100 ha). Although sugar beet is included in the Root Crop group, this crop is not included in the sub-group with carrot since sugar beets are produced on a much larger scale. While the registrant may have eventually cleared clethodim for the 40,000 ha of carrot, labelling for the other minor crops in this group would not have occurred due the expense of registration, nominal production of these crops, and other priorities for the company. Although there are no data on the extent of post emergence use of clethodim in root crops, growers now have an alterative to solely depending on a soil-applied herbicide and avoiding yield and quality losses in these short-season crops.

HARMONIZATION WITH OTHER COUNTRIES

Several initiatives between the U.S., Canada, and Mexico merit some review and may have implications for EU partners. IR-4, Agriculture and Agri-Food Canada (AAFC), and Health Canada started cooperative work, which has lead to several achievements. With this past cooperation and NAFTA programs, today joint field studies are launched, data are shared between agencies, registrants may submit concurrent data packages, and an agency in one country may assume a lead role in the review process. Despite its critics, NAFTA has clearly improved trade, clarified import expectations, and enhanced the use of objective criteria for regulatory reviews.

Several cooperative efforts between the U.S. and the EU have enhanced trade. For example, the USDA maintains a rather complete listing of the MRLs for nearly all pesticides, by country and commodities (USDA, 2005).

Under NAFTA provisions, the U. S. and Canada formally established a Technical Working Group on Pesticides (TWG) for bilateral pesticide regulations. Regulatory work loads are now shared. More recently Mexico has participated in the program since considerable southern/early season production is exported to the U.S. and to Canada. Both countries participate in the annual U. S. Food Use Workshops, where regulatory representatives, liaison representatives from the registrant firms, and other stakeholder participate in reviewing needs and setting priorities for cross-border interests. NAFTA and the TWG have resulted in greater market access for all partners, use of lower risk pesticides, more efficient reviews and advanced awareness, and coordinated use of residue data in regulatory decisions. Somewhat related, these TWG partners work together on the United Nations Globally Harmonized System of Classification and Labelling of Chemicals(GHS) program, which seeks common criteria and communication to reduce multiplicative testing.

More recently, an International Crop Grouping Project has been launched by IR-4 and US EPA that involves crop and regulatory experts to focus on common needs, with representation from the EU and the European Commission and Codex Commission on Pesticide Residues. After an initial meeting in October, 2002, Dr. Hong Chen (hchen@aesop.rutgers.edu) in the IR-4 office has continued to coordinate efforts to enhance to crop group concept with goal of more global harmony, trade, and enhanced regulatory efficiency. International cooperation in pesticide safety and harmonization is anticipated in the of Country of Origin Laws (COOL) and added ability to track RAC and processed foods from sites of origin to end use points of sale.

IMPLICATIONS FOR THE FUTURE

Clearly, coordinated strategies and involvement of multiple stakeholders, as demonstrated by the IR-4 program and crop groupings scheme, have proven to be both effective and efficient in obtaining pesticide registrations. Further, program coordination with NAFTA partners has been implemented with good success, indicating that cross-border projects and shared reviews are productive and can work well for all parties.

The issue of harmonized MRLs is vital to global agriculture and can positively impact trade and consumers for North and South America, the EU, Japan, and others. Outreach initiatives on MRL issues with trading partners is a key component for the future (Ewart, 2005).

New chemistries will continue to evolve, especially to replace old products. Development of reduced risk pesticides will continue to enhance pest management programs in the large hectarage agronomic crops. However, cooperative/harmonized programs will be essential to bring these benefits to the smaller speciality crops.

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MRLs extrapolation proposal within miscellaneous fruits

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ABSTRACT

As a result of the European review programme for existing active substances regulated by Directive 91/414/EEC, the number of plant protection products (PPP) currently authorized for crops in Europe has decreased significantly. This situation may be particularly alarming for minor crops where frequently few PPP are registered and, in the majority of cases, there are no harmonized Maximum Residue Limits (MRLs) established or they are fixed in the limit of quantification (LOQ). The system for setting MRLs for minor crops is frequently based on simple extrapolation from values already set in similar major crops according with European guidelines. However the suggested extrapolation system is not evident for all the vegetable groups, this is the case in the group of miscellaneous fruits. Field trials have been performed in kaki trees with PPP containing captan, fenitrothion and trichlorfon that are authorized in Spain in different crops of this group. MRLs have been calculated and a critical study on possible extrapolation of these results to other crops within this group is discussed.

INTRODUCTION

It is clearly not practicable to carry out supervised trials on all of the many varieties of crops, on all the crop species on which a pesticide may need to be used or under a wide range of climatic conditions and cultivation techniques. The system for setting MRLs is frequently based on simple extrapolations from results fixed on similar major crops following the European guideline of extrapolations (European Commission, 2001).

The majority of significant residues at harvest result from applications when the edible part of the plant is already present. Pesticide residues occurring in crops at harvest depend on two factors (Bates, 1990): 1) the initial deposit, its distribution and coverage and 2) its disappearance after application, both apparent through dilution by crop growth, and real, through the effects of various physical, chemical and biological activities. There are some factors which affect the initial deposit: formulation, rate of application, equipment, increment of growth or weight increase for crops in the last few days or weeks before harvest, the surface area of vegetable per unit weight, the nature of the surface area and finally meteorological conditions that can influence the growth and ripening of the crop. On the surface of the plant the deposit is exposed to a variety of environmental conditions and may be lost by rainfall, volatility, oxidation, hydrolysis or photo degradation. Within the plant, metabolism is the mechanism for reducing the concentration of the pesticide. Chemical and physical characteristics of the active substances are important to predict the behaviour of the deposit. Some authors have studied all these factors and proposed models to predict initial deposit and dissipation of the residue (Bates, 1990, Holland *et al.*, 1996, Hyder & Travis,

2003). However these models have not been applied or are limited only to the prediction of residues to optimise differences in application.

Eight field trials have been performed in two consecutive years in kaki (*Diospyros kaki* L.f.) according with European guidelines (European Commission, 2000a), an important minor crop in Spain representative of miscellaneous fruits. PPPs containing captan, fenitrothion and trichlorfon have authorized uses in different crops of this group (Fernández-Cruz *et al.*, 2004, 2005a, 2005b). Residue levels at different times have been analysed with methods developed and validated according to European requirements (European Commission 2000a, 2000b) and conducted under GLP. Dissipation curves, half-lives of elimination and MRLs have been calculated. The aim of this study is to propose the extrapolation of these results to other crops of the group, in a case-by-case basis, as suggested in the guideline.

MATHERIALS AND METHODS

A bibliographic/literature search has been done in scientific databases to compare our results in kaki with results obtained with captan, fenitrothion and trichlorfon in other crops. Mean residue values at each time have been analysed by non linear least squares regression with the program STATGRAPHICS *Plus* 4.1 Version and fitting data to a regression line with the following equation: $\ln C_t = \ln C_0 - kt$; where C_t is the estimated concentration at a time t, C_0 is the estimated maximum initial concentration at time 0, K is the slope of dissipation. The half-life of the residue was calculated with the equation $t_{½} = \ln 2/k$.

To study statistically significant differences between intercepts and slopes, regression lines have been analysed with the program STATGRAPHICS *Plus* by the "comparison of regression lines analysis" with the analysis of variance (ANOVA).

RESULTS AND DISCUSSION

To propose extrapolations to other crops within the groups, the agricultural practices (GAPs) and climatic conditions should be similar. In these conditions, only characteristics of the crop (growth or weight increment, ratio surface/weight, surface nature and interception of the spray by the crop) will affect the initial deposit.

The main Spanish fruits in the miscellaneous fruit group are fig, avocado, kaki, cherimola, pomegranate, kiwi, mango, pineapple, prickly pear and banana. These crops are not botanically related. The ratios surface/weight of avocado, kaki, cherimoya, pomegranate, mango and banana are similar. However the nature of the peel is different. The kaki's peel is thin and smooth whereas the other ones are thick and hard. The growth of these fruits is unknown but should not be very high in the last 15 days before harvest. The interception of the spray should be similar in the trees avocado, cherimoya, mango and kaki. These crops are produced in Spain mainly in Andalucía, Canarias and Comunidad Valenciana. The majority are harvested between the end of summer and the autumn except banana crop that is collected during the whole year. Therefore, climatic conditions could be considered similar between these crops. With respect to the other fruits of the group, except pineapple, the surface and weight is lowest and the initial deposit is expected to be higher.

For captan, no studies of dissipation in other crops have been found in the literature. Residue levels obtained in field-treated kaki trees with a single application of captan 50 % [WP], 150 g a.s. /hl showed that dissipation curve of captan could not be calculated as no elimination was observed in 7 days (Fernández-Cruz *et al.*, 2005b). The initial deposit obtained in kaki with captan was lowest than that expected. It should be 1.6 times less than trichlorfon and 2 times higher than fenitrothion. Physico-chemical properties indicated that captan is less liposoluble and more volatile than fenitrothion. Captan is easily hydrolysed at basic pH whereas fenitrothion is stable to the hydrolysis. Residue levels of captan should have been higher than those of fenitrothion and undergo a higher dissipation. However this was not the case. It is not possible with these data, and as no other data of dissipation of this substance were found in the literature, to propose any extrapolation.

Figure 1 represents the median results (n=4) from four different sites obtained each in greenhouse or field-treated bananas with trichlorfon 80 % [SP], 320 g a.s/hl (Otazo, 1998) and the median results (n=8) obtained from four different field-sites kakis treated in two consecutive years with trichlorfon 80 % [SP], 240 g s.a./hl (Fernández-Cruz *et al.*, 2005b). R-square of regression lines were 0.92 and 0.96 for kaki and banana, respectively. The eliminations half-lives calculated from slopes were 5.3, 5.9 and 6.7 days for field-banana, field kaki and greenhouse-banana, respectively. The statistical analysis, to compare the regression lines of banana with kaki, indicated that there are not statistically significant differences between the slopes. Trichlorfon is capable of penetration into the flesh in a high proportion (14 to 70 % from 2-3 hours to 10 days after treatment) (Fernández-Cruz *et al.*, 2005b). Other studies with fenitrothion in kaki (Fernández-Cruz *et al.* 2004) and malathion and fenitrothion (Saénz *et al.*, 1995), organophosphorus insecticides show a low penetration of these compounds. The dose applied in bananas was 25% higher than in kaki. In this case, residue results can be assumed to be comparable (European Commission, 2001). However initial deposits were lowest in banana with statistically significant differences at $p<0.01$ found for the intercepts in field-treated bananas. It seems that the thickness and roughness of the peel is essential for the penetration of the residue and in the case of the banana it is more exposed to climatic conditions. Trichlorfon is highly soluble in water, highly volatile, and quickly hydrolyzed by high temperatures. The MRL in force for trichlorfon is 0.5 mg/kg for the whole group of miscellaneous fruits. The natural logarithm of 0.5 is –0.693. From figure 1, a PHI of 28 days should be proposed for residues under the MRL in force.

With these data, it could be considered that residue levels in kaki fruits will be higher than in avocado, cherimoya, pomegranate, mango and banana, where peels are thick and hard. From results obtained in kaki fruits, a MRL of 5 mg/kg for a PHI of 10 days could be proposed for these fruits. However, due to the high capability of penetration of trichlorfon and the poor data, it should be advisable to perform residue trials specially, in the most consumed avocado.

Median results from some studies of dissipation of fenitrothion in bananas (Otazo *et al.*, 1998), apricots (Cabras *et al.*, 1997), oranges and clementines (Montemurro *et al.*, 2005) and our results in kaki are represented in Figure 2. In the study of Cabras *et al.* (1997), fenitrothion 23.15%, microencapsulated liquid was applied at a dose of 198 g a.s./hl in an apricot plot divided in 4 equal blocks. Four different sites of greenhouse or field bananas were treated with fenitrothion 50% EC, 75 g a.s./hl (Otazo *et al.*, 1998). Clementines and oranges were treated in two consecutive crop seasons with fenitrothion 47.5 % emulsifiable concentrate, 85.5 g a.s./hl and with fenitrothion 23.15%, microencapsulated liquid, 81 g a.s./hl. Montemurro *et al. (2005)* show a similar behaviour for the two formulations with high medium levels (n=3) of fenitrothion for 50 and 75 days after the treatment, respectively. The

long persistence of fenitrothion cannot be attributed, in this case, to the slow release from microcapsules but to physico-chemical characteristics of the active substance and the waxy surface of the citrus plants that protect fenitrothion from the chemical degradation and volatilisation. In our study in kaki, a preparation of fenitrothion 50 % EC, 75 g/hl was applied in four different sites in two consecutive years (n=8). The doses applied in bananas, kaki, oranges and clementines can be considered comparable, whereas the dose in apricot plots was 2.6 times higher than in kaki. The statistical analysis of the regression lines showed that the intercepts in greenhouse and field banana were significantly different at $p<0.01$ compared with the intercept in kaki. From these results it can be concluded that initial deposits of fenitrothion are not related to the dose in apricot and banana. Data obtained in orange did not fit well with a regression line and statistical analysis could not be performed. R-square of regression lines were 0.87, 0.93, 0.94 and 0.98 for clementine, kaki, banana and apricot, respectively. The eliminations half-lives calculated from slopes were 6.9, 7.8, 8.5, 12.2 and 40 days for apricot, field-banana, kaki, greenhouse-banana and clementine, respectively. The statistical analysis, to compare the regression lines with kaki, indicated that there are not statistically significant differences among the slopes of apricot, banana and kaki. Fenitrothion is very persistent, especially in citrus fruits, however in this group the MRL in force is 2 mg/kg (ln 2=0.693) enough to ensure that residue levels in these fruits will not exceed the MRL (Figure 2). In another study in apples, residues were also very persistent remaining for 50 days (from a C_o of 0.95 mg/kg to 0.26 mg/kg) with a $t_{½}$ of 35 days (Saenz *et al.* 1995).

The MRL in force for fenitrothion in the miscellaneous fruits group is 0.5 mg/kg. Data obtained in kaki fruits with fenitrothion indicated that a MRL should be fixed in 1 mg/kg for a PHI of 15 days. Considering all these results a MRL of 1 mg/kg (ln 1=0) with a PHI of 20 days could be proposed in avocado, cherimoya, pomegranate and banana. However, as there is not experience of dissipation of residues in these fruits, as initial deposits are not related to the dose and due to the high persistence observed in some fruits, it should be advisable to conduct almost another field residue trial in another fruit of the group.

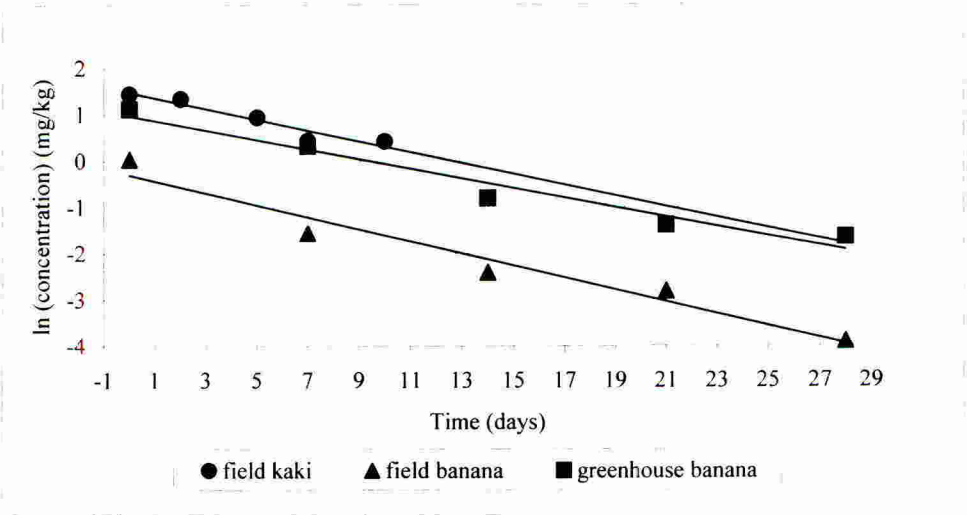

Figure 1. Trichlorfon dissipation in kaki and banana

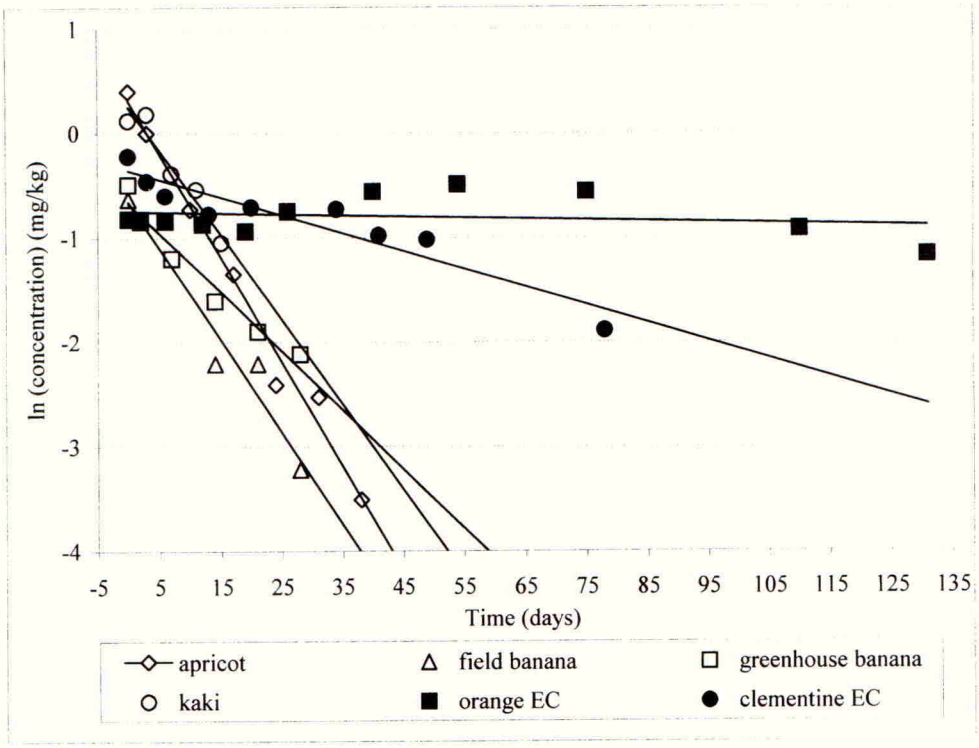

Figure 2. Fenitrothion dissipation in different fruits

CONCLUSIONS

From this study, it can be concluded, that it is not always possible to anticipate the initial deposit of a substance and its dissipation. It is necessary to know the dissipation of the residue in different crops to understand the behaviour of the compound and propose the extrapolation of results to other crops.

Some authors have performed field trial studies in different crops of the same groups and with different active substances to validate the extrapolation systems (Ripley *et al.*, 2003; Reynolds *et al.*, 2005). Both authors conclude that the extrapolation of the residue levels for the majority of the combinations studied is not valid and that it is not possible to recommend the extrapolation from similar crops without investigate before the dissipation curves.

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