

## **Costs of pesticide re-registration: implications for Mediterranean agriculture** – cross reference to presentation by Kostas Markakis

The annual conference, being held in Cyprus, focussed in part on the needs of farmers in southern Europe. Unlike the north, where fungal diseases are encouraged by the cooler, wetter weather, the main problems for Mediterranean farmers come from insects, nematodes and mites.

### **Limited options**

There are relatively few available options for dealing with such pests. On the current list for re-registration, there are 24 insecticides, but only two nematocides and two aracicides. From an already small base, the loss of even one compound could be very significant. The problem is that these are mainly rather low volume products, of greater importance in southern Europe than in the larger northern European market. The incentive to develop new and improved products is therefore not as great, and the pipeline is simply not producing sufficient potential new active ingredients to replace those at risk.

### **The high hurdle of re-registration**

Re-registration is a long and costly process. Since Directive 91/414 came into force 15 years ago, only 21 insecticides, nematocides and aracicides have been put into Annex I, and there are only half a dozen compounds in the pipeline at present. Applications for 43 compounds are pending, with only 13 of these for new products. Not all will achieve registration and, in the meantime, more than 65% of previously available insecticides have been lost to the European market. The problem is that all compounds are assessed according to the same very stringent risk criteria, which have become tighter since approval was first granted. While health and safety is of course something which no-one wants to jeopardise, the assessment takes no account of the benefits of using the compounds, nor of the consequences if they are delisted.

### **The consequences for farmers and trade**

Some crops – citrus, water melons etc – can only be grown commercially in Mediterranean climates, so that the whole of Europe is supplied from this region. But southern farmers also dominate fruit and vegetable production in general. Three quarters of the 50 million tonnes of vegetables grown annually in Europe come from Mediterranean countries. For some vegetables – tomatoes and aubergines, for example – the figure is over 90%. Even in the case of types of fruit which we don't necessarily associate with warmer climates, the south dominates: over three quarters of apples are grown in Spain, Portugal, France, Italy and Greece.

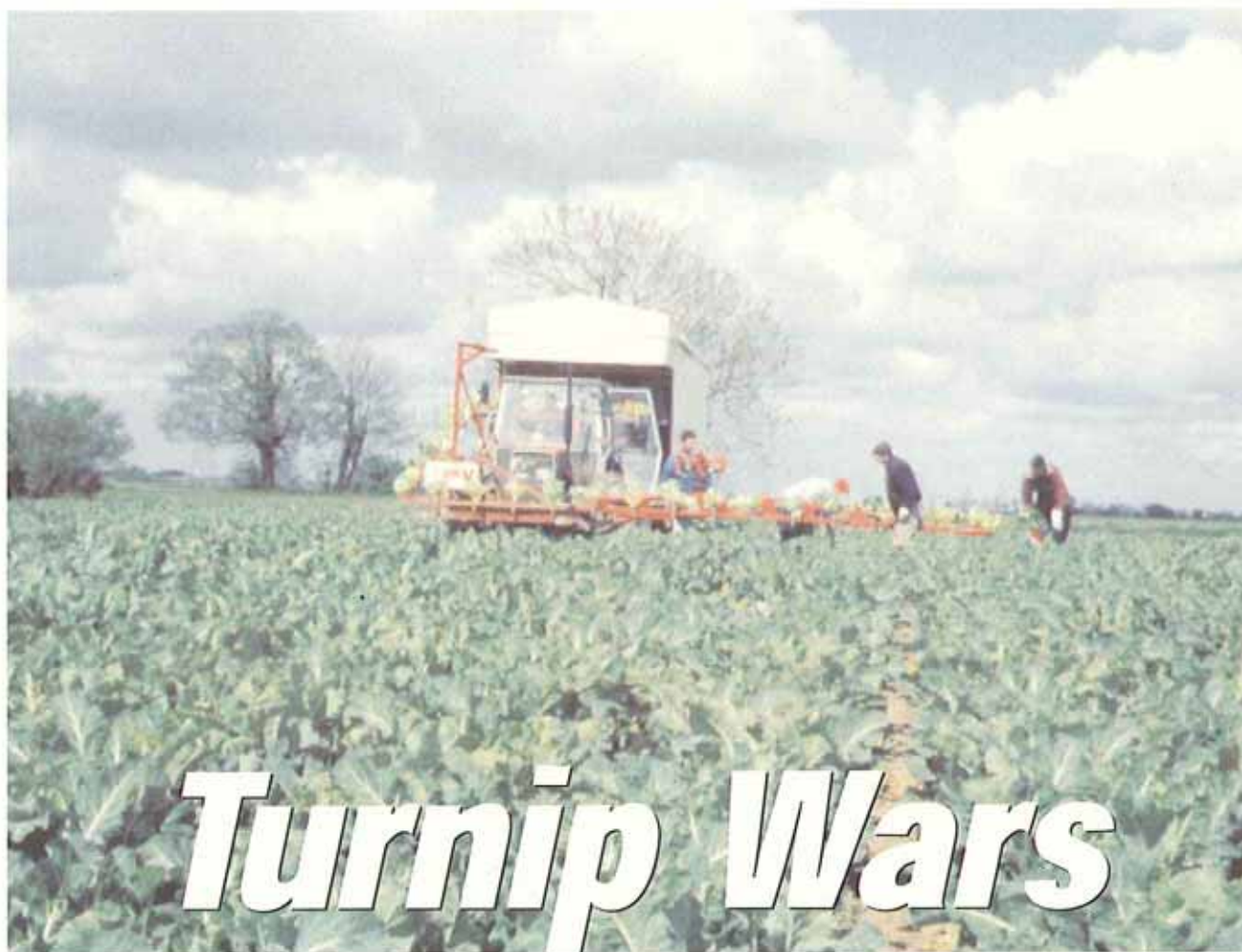
If important insecticides are lost, some crops may be more difficult to grow profitably, and more produce will need to be imported. Already, over five million tonnes of fruit and vegetables are imported annually, and reach consumers across the whole of Europe. Foreign growers already have an

advantage in having more plant protection products available to them. Imports are subject to random checks, but if no residues are detected, we never know what treatment was used in the field. Neither do we know what residues there are on produce which escapes testing. As EU regulations tighten, the balance of advantage falls more and more towards imports.

### **Mutual recognition procedures**

It seems important that this situation be addressed rather than continue to drift towards a position where farming in the Mediterranean region is put seriously at risk. One possibility is for more use to be made of mutual recognition procedures to enable Member States to give emergency approval of delisted products, to bridge the gap until new, safer compounds can be registered. In parallel, if more work is focussed on the areas of concern presented by delisted active ingredients, it may be possible to re-register them in a way which satisfies the needs of farmers and the criteria of the regulatory authorities.





*This year half the white turnips consumed in this country are likely to be imported because of restrictions on the pesticides available to UK growers. Alwyn Thompson unravels the regulatory minefield*

**F**or the foreseeable future the planned, large-scale commercial production of most high-quality field vegetables in the UK will depend on the availability of appropriate synthetic insecticides. This reality was echoed in last month's report of the Policy Commission on the Future of Farming & Food.

Pest control has generally been so good since the post-Second World War introduction of synthetic insecticides that many consumers today fail to appreciate the huge losses in the availability and quality of food that would occur were effective insecticides not available.

With significant changes in recent years to the safety standards applied under the legislation affecting the UK use of the organophosphorus and carbamate groups of 'anticholinesterase' insecticides, threats to the availability in growers' armouries of key 'actives' have burgeoned. In particular the UK field vegetable industry now faces problems, the size of which conceivably jeopardises the future existence of some sectors.

#### THE ROLE OF OPS AND CARBAMATES

OP pesticides (largely insecticides but also including some fungicides) have been used to excellent effect for more than 40 years, providing well-characterised, cost-effective treatments in a wide range of world crops. The carbamates are more recent but have performed equally well.

Since 1997 the use of OPs has declined. This trend is likely to continue as their use is better targeted, manufacturers rationalise commercial strategies and increasing legislation takes effect. However they continue to play a major role in crop protection and still have a vital 24% of the world insecticide market. Carbamate-based products have a further 16%. The primary uses of OPs are on horticultural crops, especially field vegetables where the products are used extensively in IPM programmes. Without access to OP products, major problems confronting growers in the planned production of high quality crops would include:

- cabbage root fly on leafy brassicas, swedes and turnips
- aphids on a wide range of field vegetables
- thrips on leeks and peas
- pests of sweetcorn.

Without carbamates, likely problems would include nematodes, aphids, slugs and cabbage stem weevil.

#### RESIDUE LEVELS

Since 1986 in the UK all pesticides have been subject to regulations requiring them to be registered in order for them to be advertised, stored, sold, supplied and used. These regulations include the 1985 Food & Environment Protection Act, the 1986 Control of Pesticides Regulations, the European Council Directive 91/414, the 1995 Plant Protection Products Regulations, the Council Directives on Maximum Residue Limits and the UK MRLs Regulations.

MRLs (which are not safety limits for pesticide products), are set on the basis of supervised field trials using pesticide applications in accordance with Good Agricultural Practice (GAP). This ensures that where pesticides are used in accordance with product label recommendations MRLs are unlikely to be exceeded thus minimising the exposure of consumers to harmful or unnecessary intakes of pesticides. Harmonisation of MRLs in the EU began in 1975. Since then a number of EC MRL



Directives has been published with implementation through national legislation.

Recently the EC has reviewed the way MRLs are set and as a result will be proposing changes to simplify the process in order to provide greater uniformity and clarity across member states.

## ACTIVES UNDER THREAT

The relatively recent focus of public attention on possible health and environmental hazards associated with the use of OP products in general, contributed to the UK Government initiating a specific review of anti-cholinesterase pesticidal actives in 1998.

Some of these actives were withdrawn from the market by approval-holders at an early stage; others were unsupported by approval-holders in 1999 when data was due to be submitted to the UK regulatory authority (the Pesticides Safety Directorate). As a result products with the following actives were withdrawn by the end of December 2001:

*carbaryl, carbofuran, chlorfenvinphos, diazinon, disulfoton, ethiofencarb, etrimfos, fenitrothion, heptenophos, mephosfolan, methomyl, phosalone, propoxyr, pyrazophos, quinalphos, thiometon, trichlorfon.*

An extension of approval, until July 2003, was allowed subsequently for the use of chlorfenvinphos on swedes and turnips.

Since 1999, the UK review has been progressed to complete the human health (by early 2002) and environmental (by early 2003) assessments of those actives which were supported, namely:

*aldicarb, azamethiphos, bendiocarb, benfuracarb, carbosulfan, chlorpyrifos, chlorpyrifos-methyl, dichlorvos, dimethoate, ethephon, ethoprophos, fosphiazate, malathion, methiocarb, oxamyl, phorate, pirimicarb, pirimiphos-methyl, thiodicarb, tolclofos methyl, triazamate.*

As a result of this review some approvals may be revoked or restricted. It is likely that not all current approvals will continue and this will have serious implications for UK growers within the next two years.

## THE EUROPEAN REVIEW

There is also an on-going European Union review, established through Directive 91/414 and subsequent regulations. Most OP and carbamate actives were included in the second stage for which dossiers will be submitted this year. Although some actives of importance to UK field vegetable growers are included in the list of actives being supported it is probable that various products, possibly including some with currently-supported actives, will be withdrawn from the market – again with serious implications for UK growers.

Draft Assessment Reports on actives being reviewed are due to be completed by October 2003, after which they will be considered by Commission/Member States Working Groups and the Standing Committee on Plant Health.

Notifications for those actives being supported in the third and fourth stages of the EU review programme will be required before July 2003. To date more than 360 pesticides are set to be withdrawn from the market across the EU as a result of manufacturers choosing not to support re-evaluations in the review. It is



## RESULTS OF THE 1999 PESTICIDE USAGE SURVEY

|                  |                                      |           |
|------------------|--------------------------------------|-----------|
| aldicarb         | alliums                              | 2,700ha   |
|                  | carrots                              | 7,800ha   |
| carbofuran       | brassicas                            | 1,500ha   |
|                  | root crucifers                       | 2,800ha   |
| chlorfenvinphos  | root crucifers                       | 7,700ha   |
| chlorpyrifos     | alliums                              | 2,700ha   |
|                  | brassicas                            | 2,700ha   |
| demeton-S-methyl | brassicas                            | 10,200ha  |
| dimethoate       | brassicas                            | 49,900ha  |
|                  | alliums, root crucifers and sweetcom | 1-2,000ha |
| disulfoton       | brassicas                            | 3,400ha   |
|                  | carrots                              | 1,200ha   |
| heptenophos      | brassicas                            | 1,400ha   |
| pirimicarb       | brassicas                            | 27,300ha  |
|                  | carrots, salads and sweetcom         | 2-8,000ha |
|                  | legumes                              | 28,100ha  |

conceivable that this number will rise to as many as 500 as a result of further withdrawals and failure to achieve the necessary authorisations through the review programme.

Currently the picture in the UK is not as severe as might be expected because only a proportion of the 360 or so actives not supported so far are approved in pesticide products in the UK.

## MINOR USES & SOLAS

The agrochemical industry is facing ever-increasing regulatory hurdles with its associated costs and product-development costs. In addition with the general downturn in agrochemical sales and prices and with consequently fewer products in development, the industry must increasingly target products based on new chemistry towards large,

commercially-sustainable markets. These do not include any UK horticultural crops alone but in terms of global agriculture, comprise of 'minor uses' for products.

In due course the development of insecticide products based on new chemistry will have some impact on UK horticulture as approvals become extended to minor use situations. However for the foreseeable future, UK horticulture will continue to depend on a limited range of chemistry and its associated products, to be used alone and increasingly in IPM programmes. It will be vital for the continued production of many horticultural crops in the UK at reasonable (rather than much-increased) costs to consumers that key insecticide products based on OP and carbamate insecticides are available.

It is also important that cognisance is given to the well-proven possibility that, were products from both groups of chemistry to become widely *unavailable*, new secondary pest problems, currently well controlled, might emerge. There is also apprehension that, with a much-reduced choice of chemistry available to growers, the pressure for the selection of resistant strains would increase – thus further increasing the magnitude of the crop protection problems.

Agrochemicals companies alone will be unable to support the availability of minor use products to field vegetable growers in the UK and it is clear that implementation of a highly co-ordinated programme of work is required without delay.

There is an urgent need for growers in the sector to work in a co-ordinated manner with the agrochemicals companies, the regulators, consumer organisations, retailers, educationists, central Government and others involved in the food chain, to support the future longer-term availability of key products. The Specific Off Label Approvals (SOLA) scheme of the Horticultural Development Council is likely to be seminal in this regard but who has the capacity to undertake the overall co-ordination role effectively is not as clear as it needs to be.





*The control of cabbage root fly would be considerably affected if Ops were phased out. Problems which would increase include damage caused by cabbage root fly maggots to swede (top) and young plants.*

## ALTERNATIVE CONTROLS

Whereas the effective control of pests with biological agents in controlled environments is now widespread, major problems remain with field vegetables although there has been relative success (albeit often expensive) with some pests. For example the control of caterpillars with products based on the toxin of strains of *Bacillus thuringiensis*. Nevertheless commercial producers of biological control agents are actively reviewing market opportunities associated with field vegetable production in the UK. However the long research lead times plus the high costs of meeting regulatory requirements, seen to be unnecessarily restrictive in the UK compared with some other countries, militate against other than the major companies being involved and they, like the major agrochemicals companies, must aim primarily at the larger global markets.

As with the minor uses of chemical (including OP and carbamate) insecticides, there is need for the UK horticulture industry to present its case more effectively than at present if cost-effective, biological components



of pest control programmes for field vegetables are to become commercial realities.

Other methods of pest-control offering opportunities as components of integrated control programmes to produce the increasingly high quality, safe produce required by the market include a wide range of cultural operations and the use of resistant varieties. However the widespread adoption of non-traditional methods is likely to involve major changes in crop production practices and will only follow widespread demonstration of their effectiveness under a range of conditions, together with reassurance that further problems will not be generated.

It is generally accepted that all long-term alternatives to the use of insecticides are likely to be more technically challenging and, importantly, more expensive.

## THE CONSEQUENCES

With the UK Government proceeding with its own review of OP insecticides 'to address public fears about the safety of these materials', the use of some products has already been revoked in the UK ahead of

corresponding action in other Member States of the EU. This has resulted in UK growers facing the current and future growing seasons at a severe disadvantage to their continental competitors.

For example the competitive disadvantage of UK growers can be illustrated by the fact that French cauliflower producers have recourse to 32 active ingredients, those in Spain 28, but in the UK only 13 remain. As a part consequence of this, it has been forecast that from 2002, 50% of the white turnips consumed in the UK will be grown in France and Spain. There is obvious danger that similar situations will develop on other crops.

Similarly this year, some field brassica crops in the UK will lack adequate crop protection products and other field vegetables may well be in similar jeopardy.

## RESISTANCE RISK

Pest control on some crops – for example carrots – will certainly depend on insecticides within only one chemistry group (in this case pyrethroids), with the attendant enhanced risks of the development of resistance by the target insects. It also seems certain that 2002 will see a significant reduction in the areas of many minor crops (eg watercress) in the UK. To avoid gaps on retailers' shelves, the shortfall will need to be made up by imports possibly treated with pesticides no longer available to UK growers and which consumers may assume to be no longer available more widely.

## NEGATIVE IMAGE

Despite the introduction of Assured Produce Schemes, Producer protocols, environmental safety schemes and 'branded produce', there is a view that growers like farmers have a negative public image. The public image of farmers and growers as responsible producers of safe, nutritious food and guardians of the national landscape and environment has declined drastically to the extent that consumers, especially the urbanised ones, are unaware and, worse, uncaring of the issues facing many growers today.

For field vegetable growers, there is urgent need for a 'champion' to be identified to effectively enhance the public image of the sector and help ensure that consumers are fully aware and appreciative of the current problems faced by the sector – as well as their wide implications. ○

Based on a forum organised by the British Crop Protection Council including growers, regulators, researchers, crop consultants, advisers, consumers and representatives of the agrochemical and biological-control industries at HRI Wellesbourne last November. The idea was to debate the present situation and contribute to improved understanding of the threats and appropriate action. The invited speakers were:

Fred Tyler (consultant)  
Peter Chapman (PSD)  
Dr Bob Dutton (Dow AgroSciences)  
Julian Ives (Koppert UK)  
Dr Rosemary Collier (HRI)

The forum was chaired by the author of this article, Dr Alwyn Thompson (consultant).



# Perspectives

on crop protection &amp; crop science

A briefing for policymakers from the European Crop Protection Association

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## European minor use crops under threat

Farmers throughout Europe should have continued access to crop protection products for minor crops, as far as regulatory provisions and economic reality permit.

With the removal of many crop protection products used to treat minor crops, there is an increased risk of resistance to the products remaining on the market. The continued production of many fruits and vegetables in Europe is threatened by the lack of products to protect them from pests and diseases

### A problem for minor crops

Although there is a vast range of fruit and vegetables available in our supermarkets, many are considered as minor crops as the number of hectares grown is low compared to other crops. Some examples of minor use crops are lavender in France, chicory in Belgium, blackcurrants in the UK and herbs grown across the EU. But the production of some of these crops could be under threat in Europe as it is economically unviable to maintain registration and use of crop protection products in these limited niche markets (minor crops).

Due to this lack of crop protection tools, EU production of some agricultural crops could simply disappear with downstream consequences for growers, processors and consumers.

The European crop protection industry strongly supports and is willing to contribute to a simplified and streamlined regulatory process that adequately addresses minor uses. Streamlined procedures are required to ensure that suitable crop protection solutions are available to supply niche markets, without compromising existing measures to protect consumers, operators and the environment.

With the loss of many crop protection products, there is a risk that pests and disease will develop resistance to the few remaining products on the market. The consequence could be that pests and disease increasingly threaten production. Or it could be that farmers will resort to the illegal use of unregistered products.

### Time needed to develop alternatives

The current framework ensures that crop protection products for certain essential uses are preserved, particularly where there are no suitable alternatives. While over 320 active substances were taken off the market from July 2003, it has been shown that there is an essential need for certain of these active substances, due to the absence of adequate alternatives.

Certain plant protection products containing these active substances will be allowed to remain on the market until June 2007, allowing their use in specific crops. These temporary measures are granted where it can be shown that there is an absence of efficient alternatives and that the active substance does not have any harmful effect on human or animal health and no unacceptable influence on the environment.

These temporary measures allow more time for the development of alternatives. The crop protection industry supports these temporary measures and will contribute to identifying and implementing viable alternatives where feasible.

### Providing adequate data protection

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Investment in Research & Development is a cornerstone to the Commission's commitment to the Lisbon Strategy. The crop protection industry in Europe continues to innovate for safer and ever-effective products; however, limiting time periods on data protection as well as obliging companies to share data on existing active substances will inhibit companies' abilities to develop new products, get these products to market and compete on a level playing field.

Freshfel Europe - the European fresh produce association, principally representing importers, exporters, wholesalers and retailers of fresh fruits and vegetables on the European dimension - believes the fresh produce sector is particularly vulnerable with respect to data protection provisions for crop protection products. Freshfel, in its comments to the Commission, remarked: "Our sector relies upon numerous active substances whose use is limited to fruits and vegetables, many of which are minor crops. These active substances are incorporated in products sold in limited quantities and hence provide restricted financial return to manufacturers. Data protection provisions must be reinforced to guarantee data exclusivity for a longer period to encourage greater support of existing substances." /FONT>

#### Growing need to combat illegal uses

The European crop protection industry is committed to minimising illegal uses as far as possible, but will need the support of the EU institutions to meet this inevitable challenge. The industry will continue to work to ensure that crop protection products are only used in accordance with label instructions. However, all stakeholders, including EU and Member State regulatory authorities, need to work together to address this important issue.


#### Need for reform


The European crop protection industry supports the speedy development of a system to facilitate the mutual recognition of products for existing minor uses. With the right regulatory framework, crop protection products for all crops -- major and minor -- should continue to be available, without compromising environmental protection or consumer safety.

#### Pesticides Directive revision speeded up

The obvious vehicle for reform is the proposed revision of the Pesticides Directive. The European Commission DG SANCO will soon begin the Inter-Service consultation on the proposal to replace Directive 91/414/EEC, with a finally agreed proposal expected before the end of the year.

ECPA therefore has an important role to play in communicating clearly with the other Commission to ensure a regulatory framework that maintains a wide range of authorisations.

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資料 5

News release

MEPs warned new legislation will damage [back to list](#)  
local food production

**Brussels, 18 October** – Ahead of a crucial vote, the European Crop Protection Association today warned MEPs that the Environment Committee amendments have radically altered the Commission's original pesticide proposals with no understanding of their impact on the availability of fresh food in Europe.

The warning was made as MEPs prepare to consider these amendments at the Parliament's plenary session on 23 October where the main areas of concern will be the use reduction targets and the introduction of an extended list of hazard criteria for removing plant protection products from the market.

ECPA believes that these amendments do nothing to enhance public health or environmental safety, and are expected to have the opposite effect as they will result in the loss of tools which farmers need to grow fresh food which forms the basis of a healthy diet. This will inevitably lead to greater imports and price rises both of which have the unintended consequence of reducing controls on safety and access to affordable healthy food.

ECPA's Director General, Dr. Friedhelm Schmider underlined the severity of the potential impact: "At a time when the EU has recognised the constraints on production in global agriculture by relaxing set-a-side rules, the Environment Committee amendments will prevent farmers from using what they need to grow our food."

"Outsourcing food production to other parts of the world is not an acceptable option. We must maintain our consumer health standards which are the highest in the world, while allowing our farmers to be competitive. Agriculture needs plant protection products to continue to produce fresh fruits and vegetables and other raw materials that are processed into high value food which consumers buy everyday at a price they can afford."

"Without the use of safe plant protection products a 30-40% of the locally produced food enjoyed by millions of Europeans would be at risk - this is surely not what the voters expect from their MEPs."

"These amendments are clearly unworkable in practice because we need food. By introducing politically



motivated amendments, which reflect the narrow agendas of a few organisations, are not based on sound science and pay little attention to their impact, the Environment Committee is putting the Parliament's credibility on the line."

Dr Schmider told MEPs that they should instead rely on the overwhelming evidence from independent scientists, farmers and the agri-food industry which demonstrate the safety of these technologies.

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#### Notes to editor:

1. The two pieces of legislation referred to are: [Regulation concerning the placing of plant protection products on the market](#), and [Framework directive on sustainable use of pesticides](#).
2. For more information about the MEP postcard campaign profiling farmers from around Europe, please visit: <http://www.understandtheimpact.eu/>
3. Further information about use reduction targets: See ECPA's document called [Sustainable Use - View on Danish Use Reduction Model](#).
4. Further information about hazard (cut-off) criteria:

- The current evaluation system is based on a full safety assessment – evaluating all the properties of the plant protection products, taking into account the potential for exposure under actual conditions of use.

- Within the proposal to replace Directive 91/414/EEC, hazard criteria are proposed which would lead to the exclusion of many active substances. While an active substance may have certain undesirable properties, this does not mean that such properties will be reflected in the final product when used properly.

- The European Parliament has proposed additional cut-off criteria. The criteria adopted in the Environment Committee could lead to the loss of over 75% of active substances currently



available. Cut-off criteria proposed by ENVI have greatest impact on insecticides, where over 90% of substances currently on the market would be removed from the European market.

- The loss of many products will have a negative impact on environmental protection. Dependence on too few chemicals leads to resistance development and an increase in the use of the remaining products, which may raise specific environmental concerns.

- Such a hazard based system would not allow a full safety assessment of products and would therefore lead to the unnecessary loss of many important products.

5. The European Crop Protection Association (ECPA) is the pan-European voice of the crop protection industry. Its members include both national associations and companies throughout Europe, including Central and Eastern Europe.

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#### Foot notes:

[1] The Parliament will be voting on two reports:

- Report on the proposal for a directive for the sustainable use of pesticides (COM(2006)0373 – C6 0246/2006 – 2006/0132(COD)); (Rapporteur: Christa Klaß)
- Report on a Proposal for a regulation ; The placing of plant protection products on the market (COM(2006) 0388 – C6 0245/2006 – 2006/0136(COD)); Rapporteur: Hiltrid Breyer)

[2] See notes to editor giving further information about use reduction targets.

[3] See notes to editor giving further information about hazard criteria.



## News release

Parliament first reading on key pesticide legislation would inflict serious damage on Europe's food & farming, says ECPA [back to list](#)

**Brussels, 23 October** – Serious damage will be inflicted on Europe's food and farming industry, according to the European Crop Protection Association, if today's vote in the European Parliament on the authorisation regulation for plant protection products was to result in legislation.

MEPs were voting on a new regulation governing the availability of plant protection products in the EU. The outcome of the vote today shows that a majority of MEPs have chosen to support an approach which would result in the ban of plant protection products that have been proven safe.

According to the European Crop Protection Association, MEPs have ignored the overwhelming evidence that demonstrates the safety of these technologies, without which up to 40% of our food would be at risk from destruction by disease and pest pressure. The result means that without further amendment by the Agriculture Council, farmers will in many cases be left with few solutions to protect important crops from destruction.

ECPA's Director General, Dr. Friedhelm Schmider, said: "European consumers repeatedly say they want more, affordable, fresh fruit and vegetables that are produced locally. But MEPs today made it harder to meet that demand by denying farmers the tools they need to produce sufficient quantity at a price that is affordable to all.

This also puts at risk the EU agri-food industry, which is a global leader, and depends on agriculture's raw materials to maintain its productivity and competitiveness. The result will mean this industry, which employs 18 million people, will be forced to import more food from outside the EU at a time when export markets are contracting.

MEPs have chosen to ignore these consequences.. This will mean more expensive and more imported food, that are not produced to the standards we have in Europe."

ECPA will continue to work alongside the farmers and growers in the agri-food industry, co-legislators and the European Commission with the intention of



producing a final outcome that better meets the needs of European voters.

### ENDS ###

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allow a full safety assessment of products and would therefore lead to the unnecessary loss of many important products.

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