Session 5B

Beyond 91/414 – What will the New Regulation mean in Practice?

Chairman & Session Organiser:	Dr Kevin Doughty *Bayer CropScience, Monheim, Germany*
Platform Papers:	5B-1 to 5B-4

The Commission perspective on the new Regulation

L Törnqvist
European Commission, DG SANCO, Unit E3/Chemicals, Pesticides and Contaminants, 1049Brussels, Belgium

Introduction

The Commission proposal for the new Regulation was launched on 12 July 2006, and it has been under discussion in the European Council and Parliament since then. The current status of these discussions will be presented at the October IPPC Congress.

The main objectives of the Commission proposal are as follows: to protect health and the environment; to provide for a common market; to speed up decision-making; and to increase transparency. The proposal relies on existing structures and the experience gained from applying Directive 91/414.

The proposal

To achieve high protection of human and animal health and the environment, the following aspects are considered important: detailed criteria for approval of active substances; identification of certain approved active substances as candidates for substitution; comparative assessment of plant protection products containing candidates for substitution; extension of the scope to safeners, synergists and co-formulants; record-keeping by farmers and informing neighbours about spraying events; a stronger obligation to apply integrated pest management; official controls; and prohibition of unnecessary vertebrate testing.

The following provisions were introduced to further progress towards a common market: division of the EU into 3 zones; examination of applications by one MS on behalf of the other MS within the same zone; compulsory mutual recognition of authorisations by MS in the same zone; and no national provisional authorisations.

To increase transparency, new rules were proposed on access to information and confidentiality, and on providing relevant information to neighbours.

Stimulation of innovation is anticipated by introducing deadlines for the approval of new substances. Zonal mutual recognition will provide for quicker access to a bigger market.

Major issues currently under discussion

Criteria for Annex I inclusion

During work done under Directive 91/414/EEC, the need for clearer criteria for Annex I inclusion was identified. The criteria that are now proposed are intended both to ensure a high level of protection, and to facilitate decision-making. The human health criteria are based on the following: ADI, AOEL, ARfD, CMR category 1 and 2, and the potential for endocrine disruption. The environmental criteria are based on persistence, bio-accumulation (including whether the substance is very persistent and very bioaccumulating), and toxicity.

Substitution and comparative assessment

The proposal describes that candidates for substitution are identified at EU level and the comparative assessment is carried out at Member State level.

Substitution may be applied if end-points such as ADI, ARfD and AOEL are significantly higher for the substitute than for the candidate. Further criteria refer to PBT properties. More general criteria also refer to 'other reasons for being a candidate'. Finally, the substitution of non-active isomers is foreseen. These criteria were discussed in Council and also in a special workshop on comparative assessment held in May 2007. Further details on the proposal for comparative assessment will be presented in the IPPC Congress in October 2007.

National provisional authorisations (NPAs)
This possibility is removed in the proposed Regulation. Authorisation will only be possible after a full, European-level evaluation of the substance. This will harmonise the availability of products in Member States. The deadlines for approval and authorisation that will be imposed will make it possible for companies to put plant protection products on the market within two years of dossier submission. However, it is clear from the Council discussions that most Member States wish to keep the option of granting NPAs – at least for a transition period.

Zonal mutual recognition
The proposal divides the Union into three zones in which obligatory mutual recognition will apply: the only exception is that additional restrictions for worker protection will be possible at Member State level. This proposal also proved controversial during discussions in Council: four zones were proposed, along with additional restrictions according to agricultural and environmental conditions, with no obligatory recognition of decisions, and voluntary mutual recognition between zones.

Discussion in the European Parliament
The Lead Committee for this legislation is Environment, Public Health and Food Safety, and an opinion is expected in September. Other committees involved are: Agriculture and Rural Development (AGRI); Industry, Research and Energy (ITRE); and Internal Market and Consumer Protection (IMCO). The Plenary Opinion is expected for 25-27 September 2007.

AGRI voted on 12 April 2007. The main points for amendment it proposed were rules regarding parallel trade, 10-year Annex I inclusion for candidates for substitution: a review cycle of 10 years; national provisional authorisations; zonal authorisations valid in the whole zone – but with restrictions, if justified; voluntary mutual recognition across zones; the establishment of a fund for minor uses; data protection extended by up to five years in connexion with minor uses and renewal or review of authorisations for any use; specific rules for data sharing; and that criteria for approval should become criteria for substitution.

ITRE voted on 3 May 2007. Their main points for amendment were: on low-risk products; mutual recognition within a zone, but with the possibility of restrictions; establishing a fund for minor uses; and data protection extended if linked to minor uses.

The main points for amendment proposed by IMCO were: rules regarding parallel trade; 10 years Annex I listing for substitution candidates; voluntary mutual recognition with other zones; data protection extended for minor uses by up to five years; and data protection for five years for renewal or review of authorisation.

A Member State view on the new Council regulation intended to replace Directive 91/414/EC

P J Chapman
Pesticides Safety Directorate, Mallard House, Kings Pool, 3 Peasholme Green, York, YO1 7PX, UK
Email: peter.chapman@psd.defra.gsi.gov.uk

Introduction

Since the implementation of Council Directive 91/414/EC in July 1993, there have been a number of significant events that have influenced the way plant protection products (PPPs) are regulated. In addition, the public generally wish to see tighter controls over their potential exposure to PPPs. The EU has increased in size from 12 to 27 Member States since 1993. This has had implications for how we work together to achieve a harmonized approach and to create an environment in which the workloads involved in the registration of PPPs can be shared between Member States. The original expectation that mutual recognition of authorisations would lead to a fully harmonized approach has not been realized to date. In addition, a number of food safety-related incidents have occurred, leading to the decision at Community level to separate the functions of risk assessment and risk management. The practical outcome of this was the establishment of the European Food Safety Authority (EFSA). Against this background of change, it became clear that a new regulatory framework was needed for the approval of active substances and the authorization of PPPs. The draft regulation consolidates the principles of maintaining human, animal and environmental safety as set out in Directive 91/414, and it will strengthen regulatory controls in a number of respects.

Extension of scope

The draft regulation now provides for the approval of safeners and synergists, with a review of existing safeners and synergists to be initiated within five years of the regulation coming into force. For co-formulants, the draft regulation provides for the establishment of a list of unacceptable substances and preparations. Adjuvants that do not contain unacceptable co-formulants are not included in the scope of the new regulation.

Introduction of the concept of basic substances and low risk substances

As part of the overall strategy to reduce dependence on pesticides, there is desire to encourage the use of substances that are likely to present a lower risk in terms of exposure. The draft regulation sets criteria for identifying such substances.

Provisional authorisation

The original Commission draft envisaged that provisional authorisations (which are permitted under Council Directive 91/414/EC) would no longer be allowed under the new regulation. The draft regulation sets a timescale for the approval (equivalent to Annex I listing) of an active substance of two years, starting from the time the dossier is declared complete. The German presidency has proposed a compromise text allowing for provisional authorisation for up to three years, if it becomes obvious that the decision on approval of a particular active substance will take more than two and a half years. At this point it is not clear how such a procedure could work in practice, bearing in mind that additional time is allowed for further information to be submitted during both the evaluation phase and the peer review phase. An alternative solution may be to allow either a single non-renewable period of provisional authorisation as the normal procedure, or, allow three year provisional

authorisation for a transitional period, until it could be established that the procedure might reliably deliver decisions on approval within the anticipated two to three year time scale. The average time from completeness check to decision on Annex I inclusion is currently in excess of four and a half years.

Mutual recognition and zonal authorization

One of the principal objectives of Directive 91/414 was to achieve harmonization by the mutual recognition of PPP authorizations between Member States. In practice, mutual recognition has not happened to any great extent. There have been a number of reasons for this: firstly, the delay in getting active substances included on Annex I; secondly, the fact that only a limited number of uses were considered in relation to the inclusion; thirdly, different models are used for the risk assessment e.g. operator exposure; and fourthly, Member States apply different risk mitigation measures according to local conditions. In an attempt to minimize these differences between Member States, the draft regulation proposes that the EU be divided into three zones, and that mutual recognition is compulsory within a zone. One issue arising is that where member states are in bordering zones where agronomic conditions are the same. The German presidency compromise text attempts to cover this situation by allowing mutual recognition between such countries. Current experience has shown that mutual recognition of evaluations - rather than of authorizations - can be achieved successfully if individual Member States simply evaluate the additional data relevant to their own national situation. Efforts are being made to further harmonise risk evaluation models in order to minimize differences between Member States. There may be a case for allowing a transitional period for implementing zonal authorizations to give current efforts to harmonize risk assessment time to take effect.

Comparative assessment and substitution

The draft regulation introduces the principle of identifying active substances as candidates for substitution on the basis of toxicity to humans or environmental risk. Approval of such substances would be limited to seven years. Authorisation of PPPs containing such active substances would only be allowed on the basis of comparative assessment with other PPPs and non-chemical methods at Member State level. The need for resistance management will be taken into consideration.

Hazard cut-off criteria

The draft regulation applies specific criteria to active substances classified as CMR 1or 2, and to suspected endocrine disruptors. Additional criteria are set for POPs, PBTs and vPvBs. From a technical perspective, the UK has always advocated a risk-based approach based on actual exposure. However, there is clearly now significant pressure from within the EU to apply hazard-based criteria at active substance level.

Data protection and data compensation

The draft regulation allows 10 years' data protection for test and study reports for the active substance and PPPs for a period of 10 years starting at the first authorization. The compromise text allows for an extension of up to three years where minor use authorizations are added to the registered uses.

Parallel trade

The original draft of the regulation did not include any reference to controlling parallel imports. This is an area of concern for many Member States, including the UK. We support the German presidency in putting forward a compromise text to address this omission.

Beyond 91/414 – what will the new Regulation mean in practice? The challenge to industry and the impact on innovation

E W Jones
European Crop Protection Association, 6 Avenue E van Nieuwenhuyse, B-1160 Brussels, Belgium
Email: euros.jones@ecpa.eu

The implementation of the review programme put in place by Directive 91/414/EEC has led to the removal of many active substances from the market – with many more substances likely to be lost as the third and fourth stages of the review programme are completed.

The introduction of approval criteria (or rather rejection criteria based on intrinsic properties) as part of the new proposal for a Regulation will inevitably lead to the loss of a number of other solutions.

The challenge to the crop protection industry will be to continue to meet farmers' needs by developing new and innovative products that meet the more stringent standards set out in the legislation. An important question is whether these new standards leave enough scope for innovation: the innovative industry has argued that the proposal leaves less scope, highlighting their belief that the new measures will have a significant impact on R&D spending in chemical crop protection.

There is currently a trend for the major R&D companies to move some of their R&D spending away from investment in chemical R&D towards spending in seeds and GM crops. Chemical crop protection may be seen by some companies as a 'cash cow' to support extended investment in GM R&D. With increasing legislative challenges and hurdles in Europe, a number of companies may well be tempted to rely on the old chemistry they manage to keep on the market and to channel their investment in discovery R&D away from chemical crop protection.

But which new elements of the proposal are the major concerns? There are three in particular that will impact on future R&D spending:

- The introduction of cut-off (rejection) criteria based on the intrinsic properties of active substances;
- The application of comparative assessment and regulatory substitution;
- Changes to the rules on data protection.

The introduction of cut-off (rejection) criteria

The cut-off criteria put forward by the Commission include substances that are considered to be POPs (**P**ersistent **O**rganic **P**olluters under the Stockholm Convention), PBT (using EU criteria for **P**ersistence, **B**io-accumulation and **T**oxicity) or endocrine disruptors (with as yet undefined criteria), as well as substances that are classified as CMR-1 or CMR-2 (**C**arcinogens, **M**utagens or as being toxic to **R**eproduction). While these cut-off criteria may reduce uncertainty by giving clear decision-making triggers for industry and

regulators, they do very clearly increase the hurdles industry will need to jump in order to stay on the market in future. In fact, some uncertainty remains, given the fact that the classification of substances is an on-going activity that is not coupled with the review process, and many substances could be classified (or re-classified) in future, as CMR-2 or endocrine disrupting substances.

The introduction of such criteria could also lead to the loss of many additional substances. While the Commission have argued that this will be less than 10% of substances, ECPA have estimated that the cumulative effect of the cut-off criteria could lead to losses as great as 30% of the substances that are currently on the market.

The application of comparative assessment and regulatory substitution
Comparative assessment is a politically-driven system for removing certain products when better alternatives become available. ECPA does not totally reject the use of comparative assessment, if it can be used as a more practical alternative to the cut-off criteria mentioned above. But it is clear that the application of comparative assessment will lead to greater uncertainty - with regulatory substitution decisions being based on the views of individual experts. The Commission has made it clear in their proposal that resistance management needs to be taken into account – they are therefore unlikely to be recommending the substitution of an identified product where only one alternative exists.

But uncertainty remains as to the best way of applying comparative assessment. One key concern would be if substitution were carried out on a crop-by-crop basis. If we have adequate alternatives for cereals but not for carrots, it would be a disaster if the product was substituted for cereals. The loss of the cereals market would have a major impact on the notifier. And it would be likely to make the marketing of the product unviable if it was only available for a minor crop such as carrots – thereby impacting the availability of minor crop solutions for farmers.

Changes to the rules on data protection
Data protection will continue to play a role in ensuring that notifying companies receive a return on the investment they make in the authorisation, and in particular, the re-authorisation of active substances and products. The current proposal limits data protection to studies on new products. The absence of data protection for substance defence will severely impact a company's willingness to defend off-patent active substances; i.e. why should a company invest in the defence of an active substance if other companies benefit directly from their investment in the data? Notifying companies need to have the encouragement to support and defend active substances – in order to keep a broad range of products available for farmers.

Conclusion
While Directive 91/414/EEC has led to the loss of many active substances, the proposal for a new Regulation puts forward additional measures that are likely to further limit the availability of crop protection solutions for farmers. Changes to the legislation are currently being considered by both the European Parliament and the Agriculture Council (made up of the 27 EU Agriculture Ministers). While Parliament is looking to further restrict the number of crop protection solutions, the responsibility for ensuring the availability of the necessary products will lie with the Agriculture Council.

The impact of European pesticide regulation on product availability for crops

C M Knott
Consultant, 55 Church Street, Werrington, Peterborough, Cambridgeshire, PE4 6QU, UK
Email: cathy.knott@btinternet.com

Directive 91/414/EEC: impact of the review programme on pesticide availability

Of the 625 'existing' active substances (a.s.) in Lists 1, 2 and 3 of the Review, 56% were not supported, mainly because of the cost to crop protection companies. The greatest impact from losing unsupported pesticides was on minor uses in horticultural crops. Derogations for 'Essential Uses' of 66 a.s. in 23 Member States (MS) were granted by the Commission until the end of 2007, to allow time for the development of alternatives. Losses also resulted from the failure of supported pesticides to achieve Annex 1 inclusion, and there were 'Essential Use' derogations for 19 a.s. in this category. However, after January 2006, no 'Essential Uses' were permitted for pesticides that failed to achieve Annex 1 inclusion, for example the herbicides diuron and trifluralin. There may also be significant losses of List 3 supported actives by the end of the review.

An a.s. can achieve Annex 1 inclusion, but then go on to fail re-registration at MS level. Isoproturon, a widely-used wheat herbicide, is Annex 1 listed, but it will be phased out in the UK because of groundwater issues. During the product re-registration phase, a.s. dose rates and the number of applications may have to be restricted, with potential implications for efficacy.

Potential impact of the proposed regulation (revision of 91/414/EEC)

Zonal authorisations (three zones) are under discussion. Some crops could benefit from greater flexibility across zones. The availability of PPPs for minor crops/uses may improve through two processes: **Mutual Recognition**, where products containing Annex 1-listed active substances can be registered for the same crop/use combination in another EU MS in the same zone; and **Extensions of authorisation** for PPPs to a minor use on a crop that is not widely grown in a particular Member State, or to a widely-grown crop to meet an exceptional need.

Comparative assessment and substitution is proposed at MS level, even though growers are in a better position to do this. Economic or practical disadvantages and the occurrence of resistance will be taken into account, but further losses will inevitably result, especially for minor crops. It is not clear whether a candidate for substitution will be withdrawn from all uses, or whether a case could be made for certain crops if there were no alternatives. The fewer a.s. available, the greater the resistance risk. If a new active is substituted for use in wheat, manufacture of the substituted a.s. is unlikely to continue for minor markets.

The new regulation will complement the wider 'Thematic Strategy', which includes the **Water Framework Directive**. Several new and existing a.s. on Annex 1 have water-related issues, and review reports advise MS to mitigate for these and other factors during re-registration. This may preclude registration in MS where there are water concerns. The available mitigation measures (nozzles and buffer zones etc.) differ between MS.

Impact on EU crops and ultimately, the consumer

The impact cannot be quantified in terms of yield and quality until 'Essential Uses' expire

and we know whether alternative solutions have been found. However, the cost of crop production will increase where cheaper, older a.s. are removed from the market. The number of 'Essential Use' requests shows the extent of the impact of the Review. The loss of one a.s. can mean the loss of a large number of uses, and can cause major difficulties for minor crops if there are very few (or no) alternatives. The most important unsupported losses were: the insecticide chlorfenvinphos - used for control of 'flies' in 20 vegetables (brassica, allium and umbelliferous crops) and essential in 6 MS; and the herbicides prometryn, cyanazine and metoxuron. Those not included in Annex 1 were: the nematicide aldicarb (essential in 8 MS for 12 crops), and the herbicides simazine (for a wide range of 13 crops) and atrazine (for maize and forestry). The loss of OP insecticides for pests (fruit fly and scale insects) in Southern Europe (fenthion in 5 MS; methidathion in 5 MS) will affect vines, citrus and olives.

The Review has had less impact on major crops because a wide selection of active substances is usually authorised, but there are challenges because of resistance (e.g. black-grass, *Septoria tritici* in wheat, pollen beetle in oilseed rape) and pesticides with new modes of action continue to be needed.

The search for solutions – minor crops

EU Steering and Technical Groups on Minor Uses were set up to obtain as many solutions to minor use needs as possible and to increase coordination between MS (residues and efficacy trials). Extrapolation projects to explore the scope for extending residues data to cover a wider range of crops are in progress. The most important gaps identified by Northern MS were for the control of 'flies': (71 MS/crop combinations); and for weed control in umbellifers (24) and alliums (17). Southern MS also identified 'flies' and weeds as targets. There are also national initiatives – e.g. the UK Horticulture Development Council residues database (with the potential for data sharing), and the UK Pesticides Safety Directorate Minor Use Network. The cost of finding alternatives will be considerable. Residues data will be needed but efficacy trials would be an unnecessary expense. There are differences in government support for minor uses between EU Member states. In the UK, the cost is mainly borne by growers through their levy bodies. Beyond the EU, some other countries have useful solutions – for example the US IR-4 Project, which is funded mainly by USDA agencies, provides new pest control solutions for US growers of speciality crops. In the US, crop protection companies are granted three years of additional data protection where minor uses are included on the product label. A similar proposal for the new EU regulation is now included in the latest draft text.

Prospects for the future

Inadequate data protection under 91/414 is an issue for crop protection companies and may inhibit pesticide development for the EU – there are other large markets. EU pesticide development will continue to focus on wheat. However, horticultural crops are of higher value than wheat and there is a greater incentive for growers to pay for pesticides because of the risk of crop rejection if quality is unacceptable. We can expect few new herbicides for broad-leaved crops, although GM herbicide-tolerance traits could simplify weed control. There is more optimism for new fungicides and insecticides.

Growers require a regulatory framework that allows provision of adequate solutions for major and minor crops.