

## GETTING THE BEST OUT OF DIRECTIVE 91/414/EEC

Brian Hicks, Editor of *Crop Protection Monthly*, describes an important recent conference and other European regulatory developments

Over 200 delegates attended the European Crop Protection Association (ECPA) Regulatory Conference, entitled *Review for the Future – Getting the Best out of Directive 91/414/EEC* held in Brussels 5–6 July 2001. Many top officials attended from the European Commission, 12 of the 15 member states and all the accession states, as well as industry registration specialists.

In opening the conference, ECPA's director general, Pierre Urech, said that the Pesticide Directive could not be proclaimed a total success, but that it had provided a modern science-based system that meets society's needs. He said that there had been "lots of joint learning and compromise" between many companies, countries and mindsets as a result of its implementation.

There appeared to be more consensus between industry and officials than at previous European regulatory conferences, helped no doubt by a flurry of decisions that have been taken in recent months. Most of those decisions were made at the meeting of the Standing Committee on Plant Health (SCPH) held in Stockholm, Sweden, on 29 June. Positive votes for Annex I listing were made for four new active substances (a.i.s), namely cyclanilide (Aventis), pymetrozine (Syngenta), acibenzolar (Syngenta) and pyraflufen (Nihon Nohyaku), to add to the seven already officially listed.

### Improved transparency and openness

More openness and transparency at the European Commission is apparent from the increasing amounts of published information accessible through the website for the Directorate-General (DG) Health and Consumer Protection ([http://europa.eu.int/comm/dgs/health\\_consumer/index\\_en.htm](http://europa.eu.int/comm/dgs/health_consumer/index_en.htm)). July was the tenth anniversary of the adoption of the European Pesticide Directive and the European Commission had to submit a report soon after the conference to the European Parliament on progress so far.

Robert J Coleman, director general of DG Health and Consumer Protection ("SANCO") told delegates that the Pesticide Directive had been a "complex creation", further complicated by the accession to the European Union (EU) of Austria, Finland and Sweden in 1995. Mr Coleman inherited responsibility for the directive in September 1999 when it was transferred to his directorate from agriculture. He said there was a general feeling in Europe that "food production had got too industrial" and this had led to ideas that an independent food authority was desirable.

### Agreement on European Food Authority

The European Council of Ministers agreed in June to the formation of the European Food Authority (EFA). Mr Coleman acknowledged that industry wanted a dedicated unit within the new authority to handle pesticides, but added that it would be up to EFA and its future director to decide. It will work in "as transparent a way as possible". The question of location has still not been decided and will become part of the general negotiations over locations of EU bodies. Finland is a candidate but industry would prefer somewhere else. A decision is expected by December and it will be operational by early 2002.

The European Food Authority will have some 250 staff, compared with 210 at the Medicines Agency. The Commission expects the agency to be robust, open and responsive to technical advice. EFA will have a mission of authority to maintain public confidence and will have its "own voice" on food issues. It will become an "authoritative risk communicator". A lack of resources currently prevents the Commission from analysing food safety data. EFA's main areas of focus will be in animal health and feed, plant health and human nutrition.

### Industry perspective on 91/414

Dr John Atkin, acting president of ECPA and chief operating officer of Syngenta AG, Basel, Switzerland, gave an industry perspective of the Pesticide Directive. He referred to some of the original objectives of reducing costs, speeding up approvals and improving the internal market. Although there have been shortcomings, ECPA members are now happier with the progress being made. However, political realities and differences between member states have made it difficult.

Dr Atkin said that it now typically takes 45,000 molecules to produce a new product from screening, up to 7 years to develop and 3 further years for regulatory clearance. Costs are up to EUR 170 million. Since 1991, ECPA members have spent some EUR 1 billion on the review programme alone. Acknowledging public concerns about pesticides, Dr Atkin said that industry's view was that pesticides should be used "as little as possible but as much as necessary".

A study commissioned by ECPA from the Scottish consultancy, Wood Mackenzie, Edinburgh, found that regulatory costs over the period 1993–99 have increased faster than sales and now exceed 10% of sales turnover in

the EU for member companies. By 2002, for every EUR 10 spent on R&D, an additional EUR 3 will be spent on regulatory costs. Some 320 a.i.s have been identified as not economically viable. ECPA estimates that from 2003–2006 decisions on over 60 a.i.s will need to be taken annually compared with about 30 today. It recommends a “step change” so that EFA can handle 50 dossiers annually. Dr. Atkin warned that any increase in costs could create an unsustainable business environment for the pesticide industry in the EU.

Jérôme Péribère, vice-president at Dow AgroSciences for Europe, told conference delegates that the benefits from “mutual recognition” between member states had not been realised. With 3–4 years required for Annex I listing, companies were bypassing the European system by applying directly for provisional registrations in member states. If it were only to take 1–2 years for listing, then mutual recognition could work effectively.

### Directive overlap with other legislation

There was considerable discussion during the conference about overlap with other European and international legislation such as the Water Framework Directive. This was touched upon by Robert Donkers of DG Environment in his presentation, as well as the costs and benefits of pesticides for society. He commented that that had been a big improvement in water quality of the last 20–30 years, but that it was vital to develop a strategy of sustainable use as a complement to the Pesticide Directive.

Dr Canice Nolan, Head of the Pesticides Sector at SANCO, discussed the review programme for older pesticides and said that “problematical substances” would be removed by July 2003. There would be implications for MRLs and the European legislation on this needed to be updated as did “linkages” with other legislation. The Commission expects the review programme to be completed by 2006, but ECPA believes that 2008 would be more realistic.

Of the first list of 90 pesticide a.i.s for review, some 11 have so far been officially approved for Annex I listing. Of the second list of 149, some 64 have been notified, so 85 will go from the market by July 2003. Of the third list of 402, 166 have been notified, so 236 will disappear by July 2003. Of the fourth list of 190, notification will be made in the next year.

### Public interest group perspectives

Dr Ute Meyer, co-ordinator for the non-governmental organisation, Pesticide Action Network (PAN) Europe, argued for greater participation of public interest groups in the regulatory process and greater transparency. She argued for opening up Commission review meetings to NGO observers. PAN represents over 600 public interest groups in over 60 countries (<http://www.pan-international.org>).

Another NGO speaker was Beate Ketzlitz, food policy

adviser to the European Consumers Association (BEUC). BEUC represents 32 consumer associations in 22 countries. She commented on the wide variations in pesticide monitoring programmes in EU states. She argued that the way decisions were made in Europe must be more readily understood by consumers and made more open. Ms Ketzlitz said that review of minimum residue limits (MRLs) for organophosphorus insecticides had to be a priority, especially for baby and infant food.

### Decision-making on right track

Dr Goffredo Del Bino, Head of Division, Plant Health (at SANCO) said that 91/414 had set the precedent of putting health and environment above production. He said that Europe now has a harmonised process which is effective and credible. Decision-making was slow from 1993–99, but is now on the right track. Dr Del Bino said that transparency had improved, but with appropriate respect for proprietary data. He said that the Commission report to the European Parliament would propose amendments to 91/414/EEC. These would include harmonised fees for new a.i.s, clear rules for parallel imports, data protection and compensation, data access and transparency, GMOs, co-formulants, minor uses and comparative assessments.

### Concerns of generic producers

Many generic pesticide producers are worried about the EU re-registration scheme since their products may not be permitted if there are insufficient data to support them alone or as part of a task force. Several European companies are now dropping supplies from manufacturers in Asia and Latin America as they often have inadequate or no data to support product registrations. A delegate from the Belgian office of the Indian company, Excel Industries, raised the question of data compensation. Mr Del Bino said that the Commission was developing guidelines through a working group, but that these do not have the weight of law behind them at present. The generic companies will no doubt be watching the progress of the proposed directive amendments with close interest.

### International harmonisation project

Moves are underway to bring more international harmonisation to pesticide regulatory processes. The European Commission has recently launched a pilot project (“Cornelia”) for the parallel evaluation by European and US authorities of a new a.i. The aim of the project is to identify the similarities and differences between US and EU data requirements, data evaluation and regulatory processes using a concrete test case, the new Aventis maize herbicide, foramsulfuron. The rapporteur is Germany. If successful, the initiative could lead to improved international co-operation in sharing the long and laborious work of pesticides evaluation.