

AgChemForum

Brian Hicks, editor of *Crop Protection Monthly*, reports on an ambitious new programme of pesticide conferences organised by IBC Global Conferences Ltd. as its first AgChemForum at London's Barbican Centre from 12-15 March 2001 (www.agchemforum.com)

Introduction

Delegates could choose from three different conferences each day covering a wide range of themes. These comprised "E-crop protection", GMOs, biological pesticides, regulatory issues (maintaining markets, international developments) and scientific topics (discovery, residues, formulation, contract research). This report is a selection from the three days of conferences.

Reducing the European paper mountain

In the E-Crop Protection conference, Michael Gross of Hewlett Packard Consulting, Germany, reviewed progress with regulatory dossier submission using Computer Aided Dossier and Data Supply (CADDY). The first ideas for CADDY were discussed in early 1995 and a meeting was later held between the European Crop Protection Association, industry representatives and the European Commission. There was a "clear need to get rid of a lot of paper", as dossiers typically have 30,000–100,000 pages.

The development of CADDY is progressing, but there have been problems across Europe with differences in hardware between authorities; some still want to stick with paper, while others have computer monitors which are too small or have too low resolution.

Some 53 contracts for CADDY retrieval software and help-desk support had been concluded by the end of 2000, including 563 client licences. Some 43 contracts are in Europe, eight in North America, one in Japan and one in India. Support from North America has declined somewhat, as other systems are also being supported there, including HTML, PDF and Word. Companies tend to have their own individual approach to structuring dossiers which all differ in some respects, although many have systems with interfaces to CADDY.

In March this year, the Standing Committee on Plant Health (SCOPH) of the European Commission stated that dossiers submitted should be electronic wherever possible. Mr Gross estimates that some 40–50 CADDY dossiers are available today and that at least 15 CADDY submissions have been made to the UK's Pesticide Safety Directorate. Industry sources reckon that paper requirements in dossier preparation have been halved through the use of CADDY and that EUR 60,000 per dossier are now typically saved in copying costs.

Improvements in the CADDY system are being planned, including the addition of hyperlinks and data tables. A CADDY survey of 30 reviewers in six European member state

authorities was conducted last year. As a consequence, a user meeting will be held in Brussels later this year to address the issues raised and provide more training and support.

Contract Research Organisations (CROs)

There has been significant growth in contracting out research services in recent years, especially in relation to the European review programme for older pesticides according to directive EEC/91/414. Graham Hughes (Technomark Consulting Services) chaired this session and discussed conventional services contracted for on an "ad hoc" basis. He presented the case for more strategic partnerships between companies and CROs and made analogies with the motor and electronics industries.

His theme was further developed by Stephen Shires (FMC Europe, Brussels), who also discussed outsourcing work in genomics. Outsourcing can speed up the entry of new products with earlier profit generation outweighing any additional costs. He commented that there is a need to balance the extent of the CRO partnership with maintaining independence and retaining the "act of discovery" in-house.

Discussion amongst delegates suggested that contracting out could benefit any organisation, from small "virtual" companies to integrated giants. In large companies, the internal politics are crucial and "partnership" contracting requires stability and top management commitment for benefits to arise.

Presentations on contracting out regulatory affairs were made by John Street (Syngenta UK) and Terry Roberts (JSC International, UK). Dr Street discussed the criteria for choosing a CRO and the practicalities of handling and monitoring the work. He emphasised the practical importance of briefing and clearly defining scope for flexibility in decisions about dossier assembly and presentation to authorities. Dr Roberts emphasised the wide industry perspective and extensive contacts that a consultant or CRO can bring. He expects contracting out of regulatory work to increase, especially in Latin America and Japan as OECD standards are more widely adopted.

Potential for biological pesticides

In the opening talk of this conference session, Len Copping, consultant and author of the *Biopesticide Manual*, reviewed the status of this growing range of products – those derived from micro-organisms (bacterial, fungal and viral) are currently the major segment.

Advantages of biopesticides are their specific activity against a single pest type as found with certain bacteria against fireblight, nematodes specific to particular soil insects and *Microsporidium* against locust species. Long residual activity is frequently found, but this may be accompanied by an apparent slow start to activity, sometimes perceived as a disadvantage by farmers.

Except for Bt products, biopesticides are focussed in niche markets, mainly horticultural, where there are clear and specific needs not met by chemical or other means. Delegate discussions highlighted the dilemma posed by the specificity of biopesticides, which inevitably limits market potential. Development is mainly being pioneered by small specialist companies.

Development costs of biopesticides in the USA are relatively low, as discussed by Fred Betz (Eden Bioscience, USA). There is a relatively informal and "tiered" approach to data requirements. If the first level safety data (simple toxicity and ecology studies) show benign effect to all but the target pest, further data requirements are limited accordingly. Alison Hamer (JSC International, UK) described how EU protocols are derived from directive 91/414/EEC, with initial data required according to Annexes II and IIIB, not much different from conventional agrochemicals. The European situation is further complicated by variations in requirements of member states and lacks the homogeneity of the US system.

Biopesticide R&D is continuing to attract investment, despite the lack of returns so far. There are now 29 companies in the USA which have become members of the US Biopesticide Industry Alliance compared with 12 when it was founded last year. Some 200 biopesticides are registered in the US, nearly all of which are exempt from residue tolerance requirements. Of these 65 are microbials (including 17 Bt variants and 39 bacteria) and 129 are biologicals.

Dr Stephen Lisansky of CPL Scientific Consultants reflected somewhat gloomily on the commercial prospects, drawing on his 20 years experience in the sector. He estimates the global market at manufacturer level at US\$300-350 million, about 1% of the crop protection market, with Bt products accounting for 70%.

There was discussion on the need for the industry in Europe to have more dialogue with the European Commission and national governments to study the simplification of biopesticide registration and release these products from the strait-jacket of the current system.

IBC Global Conferences Ltd. is part of the Informa Group. According to Christina Jackson, conference director, a second AgChemForum will be held next year, although probably at a new venue. For proceedings and further information, contact IBC (Tel: +44 (0)20 7453 5404 Fax: +44 (0)20 7453 5422 E-mail: babita.bahal@informa.com).

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