

European ruling on generic pesticides

Intellectual Property lawyers from Addleshaw Booth & Co have set an important legal precedent in the European Court of Justice (EJC) to allow producers of generic pesticides to compete with the world's largest manufacturers. The firm was acting on behalf of Clayton Plant Protection Ltd. in a dispute brought by Monsanto plc who challenged a decision by the UK Pesticides Safety Directorate (PSD) which allowed Clayton to sell a glyphosate product essentially identical to Roundup. Monsanto had been seeking to extend their protection by submitting further unsolicited data to the PSD and claiming that generic producers had to match such data. The EJC ruling was that this unfairly stifled competition and that when an application is made for authorisation to market a generic product equivalent to a product already on the market, then it should rely only upon the same data that was submitted in support of the original application

Italian government forced to biotech compromise

The Italian government has retreated from its tough stance on biotechnology following a protest by influential scientists. It has agreed to field trials to assess the impact of GMOs. The government has been strongly influenced by the Green Party and possibly by the Roman Catholic Church. It has refused to implement the EU directive on biotechnology patenting and will not allow imports of genetically modified organisms, even when these are EU-approved. However, it is thought that these influences may now be on the wane. The centre-right alliance, which may shortly come to power, backed the scientists. Italy has only 46 biotechnology companies. Assobiotech, the industry association, says Italy now faces an opportunity of rare strategic importance.

SP dip containers under scrutiny

UK government advisors have raised concerns over containers for synthetic pyrethroid sheep dips. Organophosphate sheep dips were withdrawn for 10 months in the UK in 2000 while improved containers were developed. Now synthetic pyrethroids, which can be 1000 times more active, might be similarly regulated unless producers improve on the packaging. According to the Veterinary Products

Committee there are defects in the container design for these substances. Concerns are focusing on the ease of opening of the containers, spillage and the dip pooling cap. Exposure to organophosphates has been associated with chronic ill health, but there are fewer operator concerns over synthetic pyrethroid usage.

Brussels threatens action over Biocides Directive

Legal action could be taken by the European Commission against 11 member states if the 1998 Biocides Directive is not transposed into national law within two months. The law should have been in force by May 2000. Safety and environmental standards for products such as disinfectants and pesticides for non-agricultural use are set out by the Directive and a new procedure for the approval of biocide products was introduced. The Directive has already been transposed in Italy, Sweden, Denmark and Austria.

US pesticide re-assessment postponed

The deadline for the Environmental Protection Agency to withdraw from a proposed settlement in a lawsuit involving a schedule for pesticide reassessments has been extended from 2 March to 19 March 2001. On the last day of the Clinton administration, the EPA and the Natural Resources Defence Council entered into a consent decree that would impose additional deadlines on the EPA as it conducts pesticide safety reassessments under the Food Quality Protection Act of 1996. Before it can take effect, the settlement must be approved by a federal court in California.

EPA moving forward on pesticide review

The Environmental Protection Agency has re-assessed the safety of about half of the riskier pesticides that it planned to review under the federal food safety law of 1996. As of October 2000, the EPA had re-assessed 2275 of 5542 tolerances for group 1 pesticides, 424 of 1684 tolerances for group 2 pesticides and 521 of 880 group 3 pesticides. The EPA raised 183 tolerances, retained 1688, lowered 146, and revoked 1487. In group 1, of the 225 active ingredients reviewed 159 were for pesticides used on food and 66 were pesticides no longer used on food. By 2006,

the FQPA requires the EPA to have re-assessed 8961 pesticide tolerances.

UK government funds health investigation into OPs

The Ministry of Agriculture, Fisheries and Food announced in mid-March an extended research programme costing £1.4 M into the effects of organophosphates (OPs) on human health. Government funding of an analytical survey of health complaints by personnel involved in the dipping of sheep is also being undertaken. The all-party OP parliamentary group approved the announcement but criticised the time taken to have got to this stage. The OP Information Network, a campaign group, criticised the rejection of research proposals from independent researchers with extensive clinical experience of OP poisoning.

Halting diazinon

Despite an agreement between the Environmental Protection Agency and the manufacturer (Syngenta) to withdraw diazinon from home garden uses by 2004, six state attorneys general are pressing major retailers to immediately withdraw the herbicide. The attorneys general claim that the EPA's own assessment shows the product to be unsafe but Syngenta maintain that the product is safe and that the voluntary withdrawal was a commercial decision.

CPA calls for action to ensure pesticide tax stays away

Although the threatened pesticide tax was absent from the March UK budget, the Crop Protection Association (CPA) calls for pesticide manufacturers, farmers and distributors to pull together urgently to deliver the voluntary measures acceptable to the government. Agreement is expected soon between the industry and government on the environmental factors against which the industry will be measured. The first report is aimed to be back to the government by 1 October. Some measures can be implemented quickly such as promoting best practice, producing pesticide environmental data sheets and appointing a biodiversity officer for the industry. The pesticide stewardship consortium, representing the agrochemical and agricultural industries, are considering the 27 measures proposed as an alternative to the pesticide tax. The final protocol is

due to be agreed within 8 months leading to a pilot scheme within 1 year, on-farm uptake within 2 years and the involvement of 30% of arable land by 2006. A summary of the CPA measures can be downloaded from <http://www.cropprotection.org.uk/>

Rotterdam Convention

Export notification procedures drawn up in the Rotterdam Convention which cover export of hazardous chemicals and pesticides restricted or banned in the EU are being applied by Cefic (the European Chemical Industry Council) and the European Crop Protection Association (ECPA) on a voluntary basis. The Convention is expected to take two years to implement fully. Prior informed consent has to be secured before the materials are exported.

Signing the POPs treaty

The Persistent Organic Pollutants (POPs) Convention, agreed at Johannesburg in December 2000 will be signed was signed in May 2001 in Stockholm by more than 100 countries, including the USA. For more information on the POPs Convention see *Pesticide Outlook*, 2000, 11(3), 123.

Picoxystrobin receives its first registration

On 31 May 2001 Syngenta announced the first registration worldwide of its new broad-spectrum strobilurin fungicide, picoxystrobin. It has been granted registration in Germany for use on wheat, barley, oats and rye, and will be marketed as Acanto®. This is the first of a number of cereal fungicide registrations expected, largely in other European countries. Further information is available at <http://www.syngenta.com>. The next issue of *Pesticide Outlook* will contain an article on strobilurins, especially picoxystrobin.

EC lists substances requiring strict water environmental protection measures

The European Commission has developed a procedure that will enable the listing of priority substances (PS) for which far-reaching measures must be taken to protect aquatic environments. In addition, priority hazardous substances (PHS) will be listed for which even more stringent measures are required to protect these environments. A third list has been drafted of 11 substances for which classification as PS or PHS is uncertain. It is proposed that a formulation be drawn up within 2 years to regulate PS

emissions and establish water quality standards: these substances are alachlor, benzene, chlorfenvinphos, dichloromethane, 1,2-dichloroethane, diuron, isoproturon, nickel, simazine and trichloromethane. For PHS, emission control proposals must lead to a complete phasing out of discharges over a 20-year period: these substances are brominated diphenyl ether (only pentabromodiphenyl ether), cadmium, chloroalkanes, hexachlorobenzene, hexachlorobutadiene, hexachlorocyclohexane, mercury, nonyl phenols, polycyclic aromatic hydrocarbons, pentachlorobenzene and tributyl tin compounds. No decision has yet been made on the substances and substance groups that are under consideration as priority substances; these are anthracene, atrazine, chlorpyrifos, diethylhexylphthalate, endosulfan, lead, naphthalene, octyl phenols, pentachlorophenol, trichlorobenzene and trifluralin. These proposals will be considered by the European Parliament and the Board of Environmental Ministers over the next few months. An Expert Advisory Forum drawn up from all EU member states and the European chemical industry organisation Cefic will also be involved in the discussions.

MAFF is dead – long live DEFRA

Following the recent UK General Election, the functions of the former Ministry of Agriculture, Fisheries and Food (MAFF), including pesticide regulation, will be carried out by a new Department for Environment, Food & Rural Affairs (DEFRA). DEFRA also brings together the Environment Protection Group and the Wildlife and Countryside Directorate of the former Department of the Environment, Transport and the Regions (DETR) and responsibility for certain animal welfare issues and foxhunting from the Home Office. DEFRA will also sponsor a number of important non-Departmental Public Bodies, e.g. the Environment Agency, the Countryside Agency, Meat and Livestock Commission, Kew Gardens, English Nature, Food from Britain and the Royal Commission on Environmental Pollution. For further details on the web see <http://www.maff.gov.uk/> (this website will be reorganised shortly to reflect the recent changes).

Another name change

The Global Crop Protection Federation (GCPF), previously known as GIFAP, has changed its name again to CropLife International. It is styling itself as a global federation representing the plant science

industry – i.e. broadening its scope to include both crop protection and agricultural biotechnology. It is also dedicating itself to become more attuned and responsive to the issues and concerns of society.

Snippets

...replacement for gamma-HCH: Bayer product expected in two years

Bayer has a replacement for gamma-HCH. UK894 contains imidacloprid and beta-cyfluthrin for use against insects such as adult flea beetle, cabbage stem flea beetle and aphids on oilseed rape. Results have surpassed those of gamma-HCH. UK894 is already sold in some countries as Chinook.

...The European Commission have added the following active substances to Annex I of Directive 91/414/EEC on placing plant protection products on the market: amitrole, diquat, pyridate, thiabendazole, bentazone and fenhexamid.

...EPA abandons split biotech registration

The type of split pesticide registration, which permitted StarLink corn to be approved for animal feed but not for human use, has been eliminated as a regulatory option by the US Environmental Protection Agency. The decision was quickly endorsed by the US biotechnology industry. Research commissioned by the EPA has found that StarLink's Cry9C protein is eliminated from the corn by wet milling but not by dry milling.

...accelerated approval of pesticides in the Netherlands

The EU Commission called on the Netherlands to speed up their approval proceedings from generic pesticides and parallel imports. The commission initiated the second stage of a lawsuit for treaty infringement against the Netherlands. Approval of new pesticides already manufactured and marketed in other EU states can take up to 2 years in the Netherlands. The EU Commission considers 45 days a more appropriate period.

...European Union settles differences with China over intellectual property protection

China has reached an agreement with the European Union in which new members of the EU will benefit from the same intellectual property protection as the other member countries. China had previously refused to give protection to pharmaceutical and agrochemicals from Austria, Finland and Sweden which only joined the EU in 1995.