Editorial: The future of plant biotechnology

New regulations and their impact on start-up companies

The last BIO 2002 conference in Toronto had more than 15,000 participants. The impression gained was the overwhelming developments in the pharmaceutical sector which was very exciting for those participating.

The success stories in the global plant biotechnology sector are also incredible. The US government predicts farmers will sharply boost their plantings of genetically improved plants (GIP) this year, despite international debate on biotechnology food. Farmers are expected to plant more than 79 million acres (40 million hectares) of genetically improved corn and soybeans in 2002, a 13 per cent increase from last year. There are also positive signals from other parts of the world. Indian farmers have finally got the official go-ahead for planting insect-resistant cotton. In Brazil it is expected that after years of having to smuggle seeds from Argentina, genetically improved crops will be authorised. In China more than 5 million subsidiary farmers are using insect-resistant plants successfully.

The adoption of genetically modified (GM) crop varieties worldwide by farmers in both developed and less developed nations is the result of the economic, crop quality and environmental benefits that these crops provide. The adoption rate has increased every year since their first introduction, and will continue to do so as more countries come to appreciate the benefits that the tool of modern biotechnology provides in developing crop varieties that meet their specific needs.

The debate in Europe on the application of plant biotechnology, however, is dominated by two major developments. On the one side most of the risk scenarios that were the basis of consumer concerns have been disproved. On the other side these facts and the positive practical experiences gained are unfortunately not being considered at the political level when drafting new regulations.

Although environmental activists are still concerned by the threat to the monarch butterfly by insect-resistant Bt-corn, data show that the amount of monarchs in the USA is, in fact, increasing this year – despite the growing use of Bt-plants by farmers. The US Environmental Protection Agency (EPA) renewed the registration and approved the growth of this biotechnology crop for another five years.

The broad consultation process initiated by G8 and organised by the OECD in 2000 confirmed that food with ingredients from genetically improved plants is not more dangerous than its conventional counterparts. Similar results were given in a report published at the end of 2001 by EU Commissioner Philippe Busquin, which analysed all the risk assessment studies funded by the Commission since 1986.

What regulation is in place?

The Deliberate Release Directive 90/220/EC was revised in April 2002 (now named 2001/18/EC). In addition, several other regulations covering the labelling of products are in place. The Novel Food Regulation (258/97/EC) agreed on in 1997 is due for revision very shortly and a discussion paper on its implementation and options for change is expected from the Commission imminently.

In addition two new regulations are under discussion in the EU: please see Geraldine Schofield's paper in this issue covering the authorisation of GM food and feed and the other on traceability and labelling. The Commission's proposal has addressed key issues

that are necessary to provide a clear regulatory framework guaranteeing safety for consumers and practicability for the industry. The Commission has proposed:

- legal recognition of accidental traces of genetically modified organisms (GMOs) in non-GM or other crops, also called adventitious presence (AP);

- establishment of a more comprehensive, centralised and transparent regulatory procedure for the safety assessment and approval for commercialisation of GMOs.

Both issues are of key importance to make a safe and practical GMO regime possible. Nonetheless, companies are seriously concerned about specific requirements on labelling in the proposed regulations that cannot be supported through scientifically verifiable testing methodologies. Whereas the former Novel Food Regulation foresaw labelling only in the cases where the application of genetic engineering could be detected by analytical methods, the new labelling provisions will cover all food ingredients, including sugar or plant oil where neither DNA nor protein can be detected. Not only are these proposals impractical, because they cannot be verified by the authorities responsible for implementation, but they also place all operators in a legally uncertain position.

At the same time the existing simplified procedures for the authorisation of food (the only procedures that have made an authorisation possible in the last five years!) will be withdrawn, monitoring will become obligatory, and approval will be time limited.

De facto moratorium

The increasing gap between GM products (not) authorised in Europe and authorised for the market in other parts of the world, especially the USA, increases the uncertainties in the market. More than 50,000,000 ha of transgenic plants have been used worldwide this year. In comparison, in Europe farmers had less than 15,000 ha of plants. In total we now have had experience of more than 170,000,000 ha worldwide over the last six years. But although the Novel Food Regulation has existed since 1997, not a single GM product besides those accepted as substantially equivalent has been authorised under this regulation. And no product was authorised under the Deliberate Release Directive since 1998 due to political opposition to the technology by six member states, including France.

What impact will the existing moratorium and the two new EU regulations (discussed above) have on start-ups working with plant biotechnology and on plant breeders? The simple answer is that both the old and new regulations will have an impact not only on multinational companies but especially on small and medium size companies. Plant breeders in particular, usually small to medium size enterprises, are facing a dilemma: the positive experiences in other parts of the world clearly indicate that there are obvious advantages of the new varieties for the farmer. However, will this approach to gaining increased consumer confidence by strengthening the regulatory framework lead to a situation in which the regulatory burdens are simply too high to be managed by a company of this size?

Negative signals from politics are also bad for the developments of new enterprises. The limited venture capital market is focusing its attention on markets with a high return of investment. In a situation of uncertainty regarding the public acceptance and the non-application of existing laws, predictions on the size and the timing of the return of investment, however, are extremely difficult.

The second question is 'What can be done to ensure the future development of plant biotechnology is not blocked?' Research projects very strongly indicate that there are several interesting product areas: the substitution of chemical processes by plants (renewable materials), the (reduced) application of more environmentally friendly

herbicides, the synthesis of substances beneficial for the health of the consumer (functional food), the reduction of allergens and the production of pharmaceuticals in plants. All these potentials have, however, a chance of being successful in the European market only if the legal framework is manageable, and if the application of genetic engineering is not discriminated against any longer.

Over the past few years the 'gold rush' of new start-up companies working in the pharmaceutical sector has been impressive. Ten years ago, for example, no one in Germany would seriously have considered that this country would be a leader in this sector and have one of the largest numbers of entrepreneurs in Europe, so strong was the rejection of this technology – resulting in a delay of more than ten years of the production of recombinant insulin by Hoechst. Today some 85 pharmaceuticals made from GMOs are available on the market and 360 new companies have been set up. This dynamic development can also take place in the plant biotechnology sector. All we need is a comprehensive policy as became the case in the pharma sector after some years of intense public debate.

The European Commission made an important step forward towards such a leadership. In March 2002 the Barcelona Summit of the Head of States supported the EU Commission's ideas of a European Life Science Strategy aimed at the improvement of the general framework for the development of a European biotechnology industry. The strategy paper was actually a follow-up to the Council's decision two years before to become the number one in knowledge base technologies in the world by 2010.

Such a strategy, however, can only be successful if it is accompanied by additional activities in the individual member states. The Germany Industry Association (DIB), for example, requested an additional, compulsory national biotechnology strategy. The idea was agreed on in principle by both large parties, the Christian Democrats and the Social Democrats.

Such national biotechnology strategies will help to attract the necessary human and financial resources and industrial capacities to further develop plant biotechnology and to increase the European competitiveness and meet society's needs in parallel.

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