



BURGESS SALMON

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New legislation on genetically modified produce

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THE DEBATE OVER GENETICALLY MODIFIED organisms (GMOs) has been active for several years now. In 2005 the media regularly depicted protesters against GM trials. The debate may have largely subsided since then but it has risen again recently with news that scientists at Bristol and Liverpool universities have cracked the complete genetic code of wheat. GM hit the headlines again when an American newspaper quoted an unnamed British farmer, who claimed to be selling milk from a clone-derived animal. So what is the future of GMOs?

It is not only in the UK that GMOs have been back in the headlines. Following criticism that European legislation has hampered the progress of GMOs, the EC has recently made proposals that aim to radically change how food and feed producers and biotechnology and agri-chemical companies access the vast potential of GM science. The EC intends to pass the baton to individual member states to clarify the support they intend to give the GM cultivation industry, but will the changes be a help or a hindrance?

EXISTING GM LEGISLATION

A GMO is an organism, such as a plant or animal, whose genetic characteristics have been artificially modified to give it a new property. To ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in complete safety, the EU has established a legal framework regulating genetically modified food and feed in the EU.

DELIBERATE RELEASE DIRECTIVE

Directive 2001/18/EC (the Deliberate Release Directive) pursues the global objective of ensuring high-level protection of human health and the environment when releasing GMOs into the environment through the adoption of the precautionary principle.

The Deliberate Release Directive provides that the introduction of GMOs into the environment be carried out according to a step-by-step principle. This means that the containment of a GMO is gradually reduced and the scale of the release gradually increased only where the evaluation of the earlier stages of the process confirm that it is safe to do so in terms of the protection of human health and the environment.

Despite the gradual introduction of vertical legislation on GMOs, such as Regulation (EC) No 1829/2003 (the Food and Feed Regulation) and Regulation EC 1830/2003 (the Traceability and Labelling Regulation), the Deliberate Release Directive remains a point of reference in its provisions on environmental risk assessment for the purpose of placing GMOs on the market, as well as their risk management, labelling and monitoring.

FOOD AND FEED REGULATION

The Food and Feed Regulation provides a harmonised procedure for the scientific assessment and authorisation of GMOs. The authorisation procedure is administered by the European Food Safety Authority (EFSA). It provides for a uniform and transparent EC procedure for all marketing applications of GMOs and their derivatives.

A single application for a GMO and all of its uses may be filed under the Food and Feed Regulation, provided that one of its uses concerns food or feed. The Food and Feed Regulation also lays down specific labelling requirements for GM food and feed. However, in terms of environmental risk assessment, it relies on the provisions of the horizontal Deliberate Release Directive.

Both the Deliberate Release Directive and the Food and Feed Regulation provide for the pre-marketing authorisation of GMOs and establish the scientific standards for the assessment of potential risks to human health and the environment.

TRACEABILITY AND LABELLING REGULATION

After an authorised GMO is available on the market, the Traceability and Labelling Regulation provides a harmonised EU system for identifying GM products throughout the supply chain. Each GM product is given a nine-character unique identifier, which is stored on the Organisation for Economic Co-operation and Development's BioTrack database.

The separate area of law concerning the contained use of GMOs in laboratories is not covered in this article.

NEED FOR CHANGE

Since the adoption of the Food and Feed Regulation six years ago, seven member

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states have prohibited or restricted the cultivation of GMOs in their territories. This has been done in a several ways, including through the introduction of safeguard measures on individual authorised GMOs and the general prohibition of GM seeds. On four different occasions, the Council of the EU (the Council) has rejected all proposals by the European Commission (the Commission) to repeal national safeguard measures on GMO cultivation, even though EU scientific assessments had concluded that these national measures were not based on new or additional scientific information and were not legally justified.

Member state prohibitions and restrictions under the Food and Feed Regulation have therefore clogged up Commission and Council desks. As a result, there has been call for a change. Has the need for change been triggered by the desire to promote the benefits of GM (as it should do) or to remove the clutter on the desks of European civil servants (as is suspected)?

GM POLICY OVERHAUL

In September 2009 the Commission president José Manuel Barroso laid down the guidelines for a new policy on GM crop cultivation. The policy was used to highlight the principle of subsidiarity, namely that the EU shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by member states. GM legislation is seen as an example of an imbalance between the EU framework on GMOs and the need to take account of the divergent opinions of 27 member states on such an emotive subject. In other words, the EC has recognised that member states may be in a better position than Brussels to carry out their own impact assessments to justify their decisions about the cultivation of GMOs in their territories at national, regional or local levels.

An official Commission communication containing a proposal package was made on 13 July 2010. Once it receives approval, member states will have the freedom to decide whether to allow, restrict or ban the cultivation of any particular GM product in their territory. The decision by the relevant member state is one of the stages in the step-by-step process governed by the Deliberate Release Directive. It is worth emphasising that the existing EFSA

authorisation process, one of the earlier stages in the directive's process, will remain unaffected.

This move is designed to support the implementation of a faster authorisation process because it will no longer be hampered by dealing with the log-jams created by member states who oppose GMOs. Instead, those member states will be able to ban the cultivation of GMOs in their territory.

Britain is one of Europe's most vigorous cheerleaders for the expansion of GM crops. Along with Spain and the Netherlands, it has lobbied the Commission to overturn the

co-existence of GMOs with conventional and organic farming.

Further research and development of the GM industry has shown that the Co-existence Recommendation puts unnecessarily heavy restraints on member states and does not maximise what measures are available under Article 26a. The EC has therefore revised the Co-existence Recommendation to give greater flexibility to member states in the cultivation of GMO.

The cultivation of GMOs in the EU has massive implications for agricultural production and its central administration.

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restrictions in the current GM legislative system, and has committed hundreds of millions of pounds of public money to agricultural research around the world. There is certainly the appetite in this country to embrace the overhaul, but have the correct changes been made?

LEGISLATIVE CHANGES

Revision of Co-existence Recommendation

Article 26a of the Deliberate Release Directive provides that member states may take appropriate measures to avoid the unintended presence of GMOs in alternative products. This particularly applies to avoiding the presence of GMOs in alternative produce, such as conventional or organic crops.

In an attempt to support member states in the process of developing national measures to avoid the presence of GMOs, in 2003 the Commission published Recommendation 2010/C200/01 (the Co-existence Recommendation). This legislation provides guidance for the development of national strategies and best practice to ensure the

Obviously, the possibility of the unintended presence of GM crops in non-GM products must be minimised to ensure that consumers and producers can choose what types of produce are bought and sold on the market.

To provide European producers and consumers with a choice between GM food and non-GM food, there should not only be a traceability and labelling system that functions properly but also an agricultural sector that can provide the different types of products without cross-contamination. This is the objective of the revised Co-existence Recommendation.

Opt-out clause

The Commission has proposed Regulation 2010/0208 to introduce a new article into the Deliberate Release Directive. The proposed Article 26b allows member states to invoke grounds to restrict or prohibit cultivation of all GMOs that have been authorised for cultivation in the EU. Any such restriction or banning measures

brought in by member states will be subject to the following conditions.

Risk to health and environment is not a legitimate ground for a ban

Member states already have the ability to take an authorised GM product off the market under the existing legal framework if they have serious grounds to consider that it is likely to constitute a serious risk to health and environment. The member state can invoke the special procedures of the safeguard clause in Article 23 of the Deliberate Release Directive or the emergency measure in Article 34 of the Food and Feed Regulation.

Consequently, the proposed Article 26b stipulates that member states cannot invoke the protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures. This condition aims to contain the authorisation system within the realm of the EC and EFSA.

Conformity with treaties

The measures under article 26b also have to have regard to:

- 1) the principle of non-discrimination between domestic and foreign products;
- 2) the provisions on quantitative restrictions of trade between member states; and
- 3) the international obligations of the EU and with those established by the World Trade Organisation (WTO).

Article 26b relates to member states' greater freedom in relation to GMO cultivation only. The importation and marketing of GMOs will continue unchanged.

Ongoing environmental and socio-economic changes

As well as the changes that are already underway, the EC and the EFSA are working with member states on the particular areas for improvement of the implementation of the GMO legislation identified by the 2008 Environment Council conclusions. The update of the EFSA guidelines for environmental

risk assessment is ongoing and covers the specific areas requested by the Council. EFSA is expected to finish the guidelines in the last quarter of 2010, in time for a further round of discussions with member states.

In parallel with these updates, the Commission will provide a report on the socio-economic implications of GMOs based on information provided by member states by the end of 2010.

ENVIRONMENTAL LIABILITY DIRECTIVE AND LIABILITY COVER FOR GMOs

Analysing GM legislation on its own does not provide the full picture. It is worth briefly commenting on the relationship between the Deliberate Release Directive and Directive 2004/35/EC (the Environmental Liability Directive).

The Environmental Liability Directive's fundamental principle is that the cost of damaging the environment is met by those who cause the damage. In other words, the polluter pays principle.

Following a lengthy and controversial debate about the lack of specific liability for any harm caused by GMOs in the GM legal framework, liability for environmental damage from the environmental release of GMOs is specifically covered by the Environmental Liability Directive. The Deliberate Release Directive is contained within Annex III of the Environmental Liability Directive, which confers strict liability for environmental damage caused by the release of GMOs.

As a result, insurance for environmental damage caused by GMOs is generally not available. This is obviously a concern to operators in the GM industry, and it is customary to see liability from damage caused by GMOs specifically excluded from general third party liability policies. However, the Environmental Liability Directive gives member states the option of adopting a 'permit' or 'state-of-the-art' defence.

A permit defence is applicable where the operator was neither at fault nor negligent and the environmental damage was caused by an emission or event expressly

authorised by, and fully in accordance with, the conditions of a permit.

A state-of-the-art defence is applicable where the operator was not at fault or negligent and the environmental damage was caused by an emission, event or any method of use of a product that the operator demonstrates was not considered likely to cause environmental damage, according to the state of scientific and technical knowledge at the time the emission occurred.

These defences have been incorporated into the relevant UK domestic regulations but have not been made available in Wales.

CONCLUSION

The new EC proposal package is intended to paint a more certain political picture for biotechnology companies with limited access to the EU cultivation market and food and feed producers with a limited choice of GM products.

Instead, the proposals have sparked a wave of criticism, with biotech companies fearing that the measures could jeopardise the existing fragile internal market, undermine farmers' choice of technology and increase distortions of competition among them. The proposed changes have also raised concerns that legal disputes between farmers, crop companies and national authorities will be on the increase.

It is difficult to see how the proposed changes to the law are going to implement the political objectives behind them. It will be some time before a clearer route to the GM cultivation market emerges. However, if the potential economic benefits of GM cultivation are enjoyed in enthusiastic member states, such as the UK and Spain, we may see neighbouring countries lowering their restrictions and insurance companies reviewing their policies.

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