EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF CULTIVATION OF GMOS UNDER DIRECTIVE 2001/18/EC AND REGULATION (EC) No 1829/2003, AND THE PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS UNDER DIRECTIVE 2001/18/EC

Final Report: Executive Summary

EPEC

European Policy Evaluation Consortium (EPEC)
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EXECUTIVE SUMMARY

This is the executive summary of the final report of an evaluation undertaken by the EPEC consortium for the European Commission.

The project was formally titled the Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003 and the placing on the market of GMOs as or in products under Directive 2001/18/EC. It focused on the legislative framework governing the cultivation of GMOs in the EU. The work was led by GHK Consulting. Support to GHK was provided by Technopolis and a panel of experts.

The research and consultations were carried out during 2009 and the main text of the report was finalised in May 2010. Some supplementary analysis was conducted later to reflect on the various proposals made by the Commission in July 2010 relating to the legislative framework covered by the study.

The evaluation has addressed a set of detailed questions through analysis supported by a wide-ranging consultation exercise

The terms of reference of the evaluation required examination of the core components of the system that deal with risk assessment, management and communication. They also specified that a number of specific issues be considered. These included the objectives and scope of the legislation; the interplay of the two authorisation procedures; Part B provisions on field trials; national measures; inspections and controls of the presence of unauthorised GM material; national safeguard / emergency measures; issues of confidentiality and data protection; the effect of zero–tolerance policy on unauthorised seeds and the interplay between the environmental risk assessment of herbicide tolerant GMOs under Directive 2001/18/EC and the ERA for the use of the respective herbicides under Directive 91/414/EC.

The evaluation began with a phase of desk research that provided a definition of the legislative framework and an outline of the current situation and a detailed schedule of issues to be explored. This was followed by a consultative exercise that engaged with governments, industry, NGOs and other interests across the EU. Detailed questionnaires were sent to authorities in all 27 EU Member State, the European Food Safety Authority (EFSA), biotechnology companies, environmental NGOs, farming groups, trade associations, and research institutes. An online e-survey was open up to all interested organisations in Europe. In-depth interviews were conducted with officials from nine Member State chosen for their experience in one or more of the following: appraising ERAs under the Regulation; dealing with applications for cultivation; hosting field trials; GMO cultivation; and safeguard measures. Interviews were conducted with notifiers, EFSA, NGOs, as well as farming and other industry associations.

The legislative framework as it operates today is not meeting needs or expectations, or its own objectives

This evaluation was asked to consider, in effect, whether the legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003 and marketing of their other uses under 2001/18/EC is fit for purpose. The empirical evidence is clear – as currently implemented, it is not. The system is not working as envisaged and is not, in aggregate, meeting its objectives. Dissatisfaction and frustration are widespread. At time of adoption the Directive and Regulation constituted an attempt at a new and improved legislative framework governing what had proven to be a difficult area of EU policy. Yet, from the time these instruments came into force until

March 2010 the EU did not adopt a single decision, positive or negative, on an application to cultivate a GMO. The 'dysfunction' in the system arises as a consequence of a complex set of factors, both external and internal to the authorisation process. The external socio-political environment undoubtedly affects the way actors engage with and use the process. The EU operates an approval system based on a science-based safety assessment for products that many in Europe, including Member State governments, object to on socio-economic and ethical grounds. And while extensive efforts have been made to ensure that the appraisal systems are rigorous, they struggle to accommodate the particular assumptions, perceptions of risk and local concerns of different actors The resulting frustration triggers objections, which result in requests for further analysis, which increases the workload on the system, which in a world of finite resource leads to more delays, which further increases frustration.

Adjustments to the authorisation process and its financing could provide helpful improvement to the system's performance but more fundamental, and difficult, reforms are needed if qualified majority votes are to be a realistic prospect

There are options available that would fine-tune (through changes in procedure and process) and lubricate (through greater resources) the authorisation machinery. These changes are worthwhile: each could make a small contribution towards creating a system that is more efficient, time-limited and transparent. Yet none directly addresses the gap between the scope of some actors' concerns with GMO products and the scope of the EU's authorisation process as set out in the legislation. The challenge is to identify options that can provide the desired flexibilities and freedoms and command the confidence of those involved, without distorting the authorisation process. Reforms that resulted in a multitude of different and supplementary Member State approval mechanisms are unlikely to improve the efficiency, transparency and certainty of the system. The Commission's proposals of July 2010, which present options to allow more choice to Member States in deciding whether to cultivate GMOs, are an attempt to meet that challenge.

Conclusions have been reached on the specific questions from the terms of reference

The objectives: The legislation's stated objectives remain consistent with the needs of society but there is some disagreement about whether they are sufficient. There is a view amongst some Member States that socio-economic factors should have a more prominent place in the framework. A more pressing issue is that the objectives are not being met in the way intended by the legislation. The environment and human health are being protected from potential adverse risks of GMO cultivation not by a timely, efficient process that screens out of 'unsafe' products, but instead by the absence of decisions on applications.

The scope: Pressure to update the legislation's scope arises as innovations lead researchers and industry to adopt new techniques. Some of those already available create new challenges for the regulatory system because there is no recombinant DNA in the product placed on the market. The rate of innovation in biotechnology is unlikely to slow and ensuring that legislation remains relevant is likely to be an ongoing challenge, especially if the focus is on the techniques used rather than the characteristics of

the final products and the traits they express. There is a case for considering the principles that should define the scope of the legislation in the future.

The biotech industry is against expansion of scope to new techniques. Expansion of scope without improvements to the system's efficiency would, in effect, automatically bar any products produced with those techniques from the EU market. But some consultees are concerned about the potential impacts of the products derived from new techniques.

Procedures for risk assessment: The risk assessment procedures as implemented are not efficient, time-limited or fully transparent. There is a mismatch between some consultees' expectations and the current process. In particular there is disagreement over (i) its 'resolution' (the extent to which it considers the diversity of agro-ecological environments and non-target species within Europe and thus addresses specific concerns of a particular Member State or region) and (ii) coverage of management and mitigation options. Some Member States are looking for more explicit consideration of socio-economic factors.

Involving risk managers from Member States in the determination of these boundaries and assumptions, and asking them to formally accept the guidance could help to align otherwise diverse Member States concerns and the EFSA-mediated process under the Regulation. The current problems could be relieved by measures that: accelerate learning through communication and dialogue amongst notifiers, Member States and EFSA; streamline the process and promote engagement through system reforms; address the scale and flow of financial resources in the system; and improve predictability and efficiency through greater harmonisation of practice among Member States and notifiers.

The existence of two separate procedures for GMO cultivation authorisations and the application of the "one-door-one-key" principle under the Regulation: The existence of two separate procedures by which GMOs can be authorised for cultivation has caused few problems. Notifiers have switched to the Regulation but the principles established in the Directive, especially in its Annexes, are integral to the legislative framework for GMO cultivation. Where use of the alternative channels has emerged as an issue it has mainly been in the context of procedural aspects such as the scope for dialogue between notifiers and those appraising the risk assessment; and emergency and safeguard measures.

Interplay between the environmental risk assessment (ERA) of herbicide tolerant GMOs under Directive 2001/18/EC and the ERA for the use of the respective herbicides under Directive 91/414/EC: A herbicide used on a Genetically Modified Herbicide Tolerant (GMHT)crop is assessed differently from the same herbicide on non-GMHT crops and conventional crops. This creates a level of confusion and introduces uncertainties into the risk assessment of GMHT plants. There has been no agreement on a common approach and there are inconsistencies in the

way MSs have dealt with applications for GMHT plants. There is a need for a more coherent approach to the risk assessment of GMHT plants. Better coordination is necessary between the applicable legislative frameworks as well as between the authorities managing the processes.

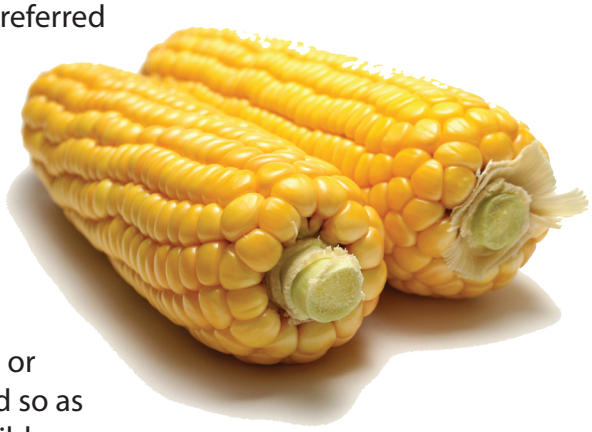
The success of the Part B provisions in fulfilling the legislation's objectives, impacts of their implementation on risk assessment and authorisation procedures: Field trial applications are becoming more concentrated in fewer Member States. The annual number of trials has declined since 2006. Some notifiers believed this is due to increasing difficulties in obtaining approvals and completing field trials. Some Member States would like to see further harmonisation of the design, conduct and analysis of field trials of GMOs for eventual commercial use. The quantity and quality of field trials being conducted impacts on cultivation applications. A lack of authorisations for cultivation reduces the incentive to invest in research, and thus the demand for further field trials. Remedies lie mostly outside the legislative framework but there is potential to tackle the issues by encouraging more independent research, promoting efforts to avoid field trial destruction and promoting the development of guidelines on field trial design and delivery. Better data on trends in EU field trial activity would also be helpful.

The current provisions for the risk management of GMO marketing and their implementation: The evaluation has considered both the institutional decision-making and the practical risk management issues associated with GMO cultivation.

The decision-making aspects of the current framework, as implemented, are not efficient, transparent or sustainable. Member States have proven unable to reach a qualified majority on any of the draft Decisions put forward, and the Commission has itself has only recently issued a final Decision on an application active for 13 years where the choice was not resolved by the Council, namely the Amflora potato. Views amongst Member States are polarised and voting patterns suggest little prospect of a qualified majority emerging under current rules.

There are some process and procedural remedies available that could address current concerns about aspects of the defined process. But many of the causal factors behind the blockages in decision-making lie 'upstream' in the risk assessment process or 'beyond' the scope of the authorisation procedure as currently defined. Member State voting is believed to reflect in part objections to the technology that have a socio-economic or ethical basis and which thus have no voice in a science-based assessment of safety.

Where there is appetite for reform it is for carefully designed, limited changes that address these specific issues rather than whoesale change of the overall system. Many consultees preferred to avoid the uncertainties associated with opening up the current legislation, arguing for reforms that use existing legislation or which are designed so as to restrict the possible scope of any changes to current law.



The first preference of industry consultees was for the existing legislative framework to be implemented as drafted rather than for it to be amended. The evidence

suggests that, with no sign of a shift in Member State voting patterns in prospect, this would require use of Commission powers of decision (in the absence of a qualified majority of Member States for or against authorisation) on applications that have received a favourable scientific assessment and would also see continued use of national safeguard measures by Member States that do not wish to see domestic cultivation of EU-authorised GMOs.

The evaluation concludes that reform of 'upstream' processes, while helpful, is unlikely to be sufficient to remove the blockages and there is a case for examining targeted changes to the rules that govern the decision-making process.

There is scope to introduce new flexibility into the decision-making mechanisms at both EU and Member State levels, and to review both the criteria are used in making those decisions and their relative weight. The consultations revealed support among officials in various Member States for options that would provide Member States with more flexibility and freedom within the framework of a common science-based safety assessment.

In July 2010 the Commission released a package of proposals which provide such options. Its proposals offer Member States the right to opt out of cultivation of a centrally approved GMO and also greater freedom in the definition of national co-existence measures. The incorporation of an opt-out provision would be a significant departure from the current model. It offers a more flexible but also more complex system for cultivation approvals. The grounds on which an individual Member State might decide to exercise an opt-out are the subject of discussion through the co-decision process.

The decision-making framework could also be modified to give Member States greater freedom to use non-scientific factors in setting national rules and regulations that affect GMO cultivation. Co-existence measures could provide more flexibility than those introduced under the previous guidelines and more use made of opportunities provided by the existing legislation to define 'GMO-free' areas. Proposals of this kind are included in the July 2010 package.

Other options could also be considered. The scope of the information that can legitimately be used to inform the authorisation decision could be expanded through more explicit consideration of socio-economic factors. The geographic scope of an application could be qualified by the notifier either (i) at the outset or (ii) after a final scientific Opinion from EFSA that contains a favourable assessment in cases in cases where a Member State then declares reservations about the GMO. Geographically qualified applications could, in principle, mimic some of the effects of a system of Member State opt-outs.

Experience with practical risk management measures is limited given the lack of cultivation approvals within the last decade. The evidence suggests that the infrastructure which is needed to support the legislation's requirements for monitoring and surveillance will have to be strengthened, especially

if cultivation approvals did begin to emerge. Investment in these systems and protocols has the potential to create positive feedback loops into the risk assessment process by providing more robust evidence on impacts.

The communication of risk concerning the release of GMOs into the environment and the manner in which it has been implemented: The legislation's provisions on risk communication remain relevant. The degree to which they are being fulfilled varies; research suggests low levels of public engagement and limited impact of public feedback on decisions. There is considerable variation in practice among Member States and notifiers in the communication activities linked to field trials but a general trend towards more openness. There seems to be less public engagement with cultivation applications than field trial applications. The accessibility of information, which is often highly technical, is a recognised issue. There is a case for more effort to be made to upgrade and extend communication activities.

The procedures on national safeguard / emergency measures: The national safeguard measures and emergency measures are not functioning as intended and are not, at this time, efficient, time-limited or transparent. There is a general understanding amongst most Member States and other consultees that the use of national safeguard measures, while presented as having a scientific justification, is sometimes an expression of frustrations with the current risk assessment practice, of non-scientific objections to GMO cultivation and of political circumstances. Changes to the authorisation process that result in more efficient and transparent institutional decision-making could help to prevent the 'misuse' of national safeguard and emergency measures. Special effort should be made to resolve and explain the differences of EFSA/MS interpretation of the science being used to justify existing bans. Differences, especially in application, between the Regulation's emergency measure and the Directive's safeguard clause should be made clearer.

Consistency of rules on confidentiality and data protection in the Directive with those of the Regulation and Regulation (EC) No 1049/2001: The confidentiality provisions of the legislation remain relevant. The balance struck between transparency and protection of intellectual property has the support of most MS authorities and notifiers consulted. There are considerable differences between the confidentiality provisions of the Directive and Regulation 1829/2003. Aligning the Directive with the Regulation is something to consider for the future.

The effect that national measures on GMO cultivation have on the internal market, environmental and health protection: No information emerged from the research and consultations on specific national measures that had a direct impact on the system under evaluation. However, half of the Member State authorities surveyed said that they have national or sub-national legislation in place that must be observed when a GMO is placed on the market.

The inspections and controls of the presence of unauthorised GM material in seeds as carried out by the Member States: More work is needed to deal with the risk of adventitious presence of unauthorised GMOs in conventional seed lots. There is a need for new measures to deal with

the risk of adventitious presence of unauthorised GMOs in conventional seed lots and proper enforcement of these regulations in Member States.

The effect of zero – tolerance policy on unauthorised seeds in the EU, with specific reference to the impact of this policy on imports of seeds and on related seed prices: The seed industry, notifiers and many Member States believe that the zero tolerance policy on unauthorised GMO seeds has a negative effect on trade and the EU seed sector, and will become more difficult to sustain over time. Europe's seed imports are smaller than its food and feed imports. There is no evidence yet of significant economic impact but clearly a risk that trade disruptions could become more frequent and severe and affect more products as more GMOs are approved outside Europe. The problem is aggravated by the slow pace of EU authorisation processes. Inspection and controls were not harmonised in the EU (with the exception of Commission Decision 2005/317/EC). The scope and frequency of controls vary.

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GHK Consulting was the lead partner for EPEC in this assignment.