Advanced genetic techniques for crop improvement : regulation, risk and precaution : Government response to the Committee's fifth report of session 2014-15 : third special report of session 2015-16 / House of Commons, Science and Technology Committee.

House of Commons

Science and Technology Committee

Advanced genetic techniques for crop improvement: regulation, risk and precaution: Government Response to the Committee's Fifth Report of Session 2014–15

Third Special Report of Session 2015–16

Ordered by the House of Commons
to be printed 13 October 2015

HC 519
Published on 21 October 2015
by authority of the House of Commons
London: The Stationery Office Limited
£5.00

Science and Technology Committee

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Third Special Report

On 26 February 2015 the Science and Technology Committee published its Fifth Report of Session 2014–15, *Advanced genetic techniques for crop improvement: regulation, risk and precaution* [HC 328]. On 17 September 2015 we received the Government's response to the Report. We also received correspondence dated 9 July 2015 from the European Commission. They are appended below.

Appendix 1: Government response

Introduction

1. The Government welcomes the Committee's report as a valuable contribution to the debate in this area. It offers a considered and challenging perspective on how advanced genetic plant breeding techniques should be addressed in policy and regulatory terms. This is timely for various reasons, not least the need to have a clear strategy for ensuring a sustainable food supply in the future, and recognising the role that advanced crop breeding could play in this.

2. Innovation is vital in agriculture and the Government is seeking to encourage this in various ways. High-level initiatives include the Agri-Tech Strategy and the Global Food Security Programme. Specifically in relation to crop innovation, the UK has a world-class plant science base which makes us well-positioned to develop and benefit from advances in breeding methods. We want to encourage use of the full range of techniques that can deliver improved crop performance, by having the right frameworks in place to underpin R&D and follow-through to commercial exploitation. It follows that the Government would also like any unjustified obstacles to the use of advanced breeding techniques to be overcome. In this respect there is, as highlighted by the Committee, a particular issue with the operation of the EU controls on GM organisms. The Government's general objective is to reduce the burden of regulation, and to ensure that any necessary controls are pragmatic and proportionate. To support innovation products made from safe technologies must have a clear and certain means of gaining access to the market.

Response to the specific recommendations directed at the Government:

We recommend that the Government initiate a reframing of the public conversation by similarly moving away from the overly simple notion of 'GM' in its own policies and communications.

3. The Government accepts the Committee's recommendation that the debate on GM needs to be reframed. We will actively play our part to encourage this with the aim of moving the debate on from a polarised discussion on GM. However, we would caution against the idea that the Government on its own can ensure the discussion is always framed in the most appropriate way.

4. Moreover, as the Committee itself has noted the term GM has become commonplace, and some stakeholders may be confused or even suspicious if it were to seem that the Government was deliberately using a different terminology. The Government has consistently used the term GM to mean those technologies and products which are subject to regulatory control under the relevant EU legislation. We will need to continue using 'GM' when it arises in, or is relevant to, this specific context.

5. On the emerging debate around what are being called 'new breeding techniques' (NBTs), meaning the range of advanced genetic techniques whose status relative to the EU legislation on GM needs to be clarified, we are making our position clear. It is our view that any necessary regulation of these techniques should be pragmatic and proportionate to the overall objective to be achieved. We are working closely with the Commission and other Member States to this end. The Government did not invent the NBT terminology and it has already become standard within official EU circles, so we will need to use it when the occasion demands, but when addressing a lay audience we should explain it carefully to ensure that the overall context is properly understood.

We recommend that both the Government and the Food Standards Agency review their public communications on genetic modification and related topics to ensure that these are framed in a way that encourages constructive public debate. Advice on this process should be sought from the Sciencewise expert resource centre and identified changes should be made by the end of 2015.

6. The public communications from both Defra and the FSA on GM and related issues are guided by our approach to GM policy. The focus is therefore on our regulatory role and our manifesto commitment that decision-making on GM should be science-based. The Government is also a keen proponent of innovation in agriculture, so our public communications seek to highlight the opportunities of a range of innovative technologies, including GM crops.

7. The Government has noted the Committee's comment that wider debate is impeded by an insistence that decisions are taken solely on scientific advice. The Government believes that science-based decision-making is the right approach on GM, hence our manifesto commitment. For this reason we support the principles behind the EU GM legislation that requires national decisions on GM crop trials or EU-level decisions on the marketing of GM products to be based on whether or not a science-based assessment indicates a risk to human health or the environment.

8. It is recognised of course that some people have wider concerns about the potential impact of GM crops, and the EU regime now gives Member States the option of banning the cultivation of EU-approved crops for reasons unrelated to safety, but the Government does not think it would be appropriate to require an assessment of non-safety factors as part of the formal decision-making process (see also the response at paragraphs 33-35 below which deals with the same theme). We supported this new regime as it should improve the current EU authorisation system for GM cultivation.

We recommend that the Government's annual Science, Engineering and Technology statistics be enhanced to provide greater aggregate detail on the areas of research in which public funds have been invested. We also recommend that each UK Research Council

includes an aggregated breakdown—for example, at the level of each strategic 'theme'—in its annual report and provides additional information on past funding decisions in areas where there are common misconceptions, such as plant science.

9. The Government does not have any current plans to provide further aggregate detail in SET statistics. Research Councils UK (RCUK) provides a free web facility 'Gateway to Research' (http://gtr.rcuk.ac.uk/) which allows users to search for details of all research funded by research councils from 2006. This allows for breakdown by topic and includes each funding award. This facility provides transparency, however the Government will consider with RCUK whether any additional information needs to be included in research council annual reports.

We recommend that the Government conduct a review of the intellectual property landscape, specifically in relation to agricultural technologies, and its potential impact on the commercialisation of both conventionally bred and genetically improved crops. We would expect this to be delivered to our successor Committee by the end of 2015.

10. The Government recognises that a review of the intellectual property landscape relating to agri-tech might be valuable, in line with the Committee's observation that it is a complex issue which raises strong emotions. However, we also note the Committee's statement that "*We have not been convinced by the argument that the application of intellectual property rights to genetically advanced crops has hindered other innovation trajectories and we have seen little evidence to support claims that patents pose a significant barrier to independent research*".

11. Patent law in this area is governed by EU legislation and the European Commission has committed to reporting on the impact of this legislation shortly. This will include reviewing the impacts in the area of plant breeding. Therefore, we have decided to wait until that report is available before deciding whether to take forward a national review. We will revisit this recommendation at that point.

In its response to this report, the Government should set out how the Nuffield Council's work on emerging biotechnologies has informed its research policy. We are particularly interested in how it has responded, or intends to respond, to the Council's call for structural reorganisation.

12. The Government fully recognises the importance of ethics as emerging technologies develop. BBSRC's Bioscience for Society Strategy Panel considered the Nuffield Council's report on emerging biotechnologies in January 2013, taking account in particular of the need for "*a diversity of values to influence research policy, beyond advice from science and industry... so that social and not just economic benefits are realised*".

13. Regarding the Council's call for the structural reorganisation of the Government Office for Science, the Government believes there are strong benefits to GO-Science being located in the Department for Business, Innovation and Skills, particularly the proximity to the science, universities, innovation, and industrial sector teams. This does not preclude GO-Science from taking a leadership role on cross-government issues, for example on its data science agenda and from taking a cross-disciplinary approach spanning the natural and physical sciences, engineering, technology and the social sciences.

We recommend that the Government publicly acknowledge that genetically modified crops pose no greater inherent risk than their conventional counterparts. A statement recognising this fact should be included in the Government's response to this report and relevant areas of GOV.UK should be updated to reflect this.

14. The Government's communications on GM crops and foods are often conditioned by its role as custodian of the EU regulatory regime, where the key requirement may be to provide reassurance about the existing safety controls. Hence, Defra and the FSA commonly state that they support the need for science-based, case-by-case risk assessments of proposed GM products, and that the EU assessment process is robust enough to ensure that authorised products will be as safe as their non-GM counterparts. This is consistent with the advice the Government received from the Council for Science and Technology in 2013, that:

- *"We should have confidence in the consensus on the scientific evidence which concludes that, when properly controlled, GM products are as safe as their conventional counterparts".*

15. The Committee has usefully highlighted a more fundamental point; that regardless of the regulatory position there is no sound basis for considering GM crops to be inherently riskier than conventionally-bred crops. This is borne out by the following statement made by the European Academies Science Advisory Council in 2013:

- *"There is no validated evidence that GM has greater adverse impact on health and the environment that any other technology used in plant breeding".*

The Government accepts this point and, where appropriate, already reflects it in its communications.

We recommend that the Government formally adopt a move to trait-based novel plant regulation as a long-term policy goal and begin to develop its preferred framework for such a system so that this can inform EU discussions. The Government should provide our successor committee with an update on this work by the end of 2015.

We recommend that the Government publicly state its long-term commitment to major reform of the EU legislative framework for genetically modified organisms and other novel crops.

16. The Committee has put forward a strong argument for fundamentally recasting the EU regime applicable to GM crops. It has also set out clearly why the operation of the regime to date is a matter of real concern. The key question is how best to reach a situation where innovation through GM and other advanced genetic breeding techniques is possible without unjustified regulatory barriers?

17. Our aim is to ensure that we have a GM regulatory system that allows farmers in England to have access to this technology. To this end we are working with the Commission and like-minded Member States to try to improve the current EU regulations. However we are limited in what we can realistically achieve given the nature of the politics around GM at European level. We're focusing our efforts at the moment on pushing the Commission to operate the GM authorisation in a timely manner and to reduce burdens

on applicants, and working with the Commission on the best way to regulate new breeding techniques.

18. For the foreseeable future it is improbable that EU agreement could be reached for a thorough-going reform that delivers a positive outcome. Indeed, there is a strong risk that pushing for such reform might lead to the EU regime becoming in practice worse than it is now. The challenge of making progress at EU level was illustrated by the negotiations on the proposal which became the new Directive on GM cultivation decisions[1]. It took over four years to discuss and adopt this measure, which has only two main operative articles. Although it enables a fresh start to be made in operating the EU authorisation process for GM crops, the outcome is less ideal than the one the Government had striven for, and the negotiations confirmed in particular the strong antipathy of the European Parliament to changes that might better facilitate the use of this technology.

19. Judged from our current vantage point extending the scope of the current EU regulations is likely to have a negative impact. For example, if the EU were to adopt trait-based regulation it could mean that all novel crops would be subject to a problematic risk assessment and decision-making process, akin to that experienced to date under the GM-focused regime. Similar considerations arise with the idea of taking benefits into account alongside risks. Ordinarily this would seem to be a sensible approach. However, in the EU context it could result in a disproportionate requirement to assess the potential socio-economic impacts of novel crops. This would add a further layer of complexity, burden and subjectivity to the regulatory process, with practical difficulties also likely to arise from a lack of evidence to support *ex ante* assessments. Rather than enabling responsible innovation, it could become a further barrier to this.

20. In the short to medium term, the GM cultivation Directive should enable some progress to be made at EU level. By providing new options for Member States to avoid the planting of EU-approved GM crops in their own territory, unrelated to the outcome of the risk assessment process, it should in principle make it easier to secure EU authorisation. There are eight types of GM crop in the pipeline for EU cultivation approval, and we now need to see how these applications are treated in the light of the new Directive.

21. The Government will continue to press for the EU regime to function properly as it is, without unjustified delays and burdens on applicants. Our objective remains to have a system which allows safe products fair access to the market, and we are working to influence the Commission and other Member States towards that end.

We recommend that the Government give greater consideration to the value that participatory processes might contribute to its own treatment of risk and uncertainty in policy development. We particularly refer the Government to the Risk Governance Framework and Safe Foods Initiative and ask it to set out how the perspectives offered by these documents will inform its future approach to risk governance policy.

22. The Government is committed to open policy making as set out in the Civil Service Reform plan. To support this and facilitate public involvement in the development of policy around emerging technologies and innovative or cutting edge science, the

[1]Directive (EU) 2015/412 which entered into force in April 2015 (accessible at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0412&from=EN).

Government supports a public engagement programme that since 2004 has included Sciencewise. Sciencewise is a national resource that supports public bodies to commission and use public dialogue to inform their science and technology policies. Through the Sciencewise programme a number of deliberative dialogues have explored public views on agri-science issues including food production and food security.

23. Defra has considered the regulatory frameworks proposed by the International Risk Governance Council and the Safe Foods project from the perspective of the EU's regulation of GM crops. From a theoretical standpoint the ideas put forward are interesting, but it is not clear how they could be made to work in a way that was pragmatic and would improve the existing situation. They would require a major revision of the EU regime and, for the reasons set out above, this is not seen as realistic objective for the foreseeable future.

The Government should prepare a short document, informed by wider consultation, detailing its understanding of the [precautionary] principle and the circumstances in which it intends to use the precautionary principle as a guide to policy making. This should be made publicly available by the end of 2015.

24. There is no single definition of the precautionary principle. It is expressed in a number of different ways with, for instance, the wording of the 1992 Rio Declaration often being cited. Within the EU context, the fundamentals and the approach to the application of the precautionary principle are described in the relevant Communication issued by the European Commission in 2000[2]. Amongst other elements, it notes that application of the principle should: be based on the fullest possible scientific evaluation (including determining the degree of scientific uncertainty at each stage); be preceded by a risk evaluation and an evaluation of the potential consequences of inaction; involve the greatest possible transparency; and take into account principles of risk management.

25. The Government supports the explanation of the precautionary principle as set out by the Commission, and does not believe that further clarification on this matter is necessary. The Commission's Communication provides for an appropriate understanding of the issues of risk, uncertainty and precaution, and as such will help to ensure sound decision-making if applied responsibly.

We recommend that the Government work with the National Academies, in collaboration with Sciencewise, to develop a new online information 'hub' covering emerging topics in science and technology. This should include sections on both climate science and new plant breeding technologies. Each topic area should provide a basic overview of the current evidence base, acknowledging uncertainties where they exist, and should make reference to both scientific and non-scientific considerations.

26. Government already works closely with a variety of stakeholders including the National Academies, Sciencewise and others to improve public understanding of emerging topics in science and technology through a range of activities including on-line channels. At this time we do not believe that there would be significant additional value in creating an online hub, bearing in mind also that it would require extra resources at a time when public expenditure is necessarily under tight control.

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[2] http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

27. DECC has made improvements to how information on both climate science and government activities to tackle climate change is communicated through the GOV.UK website. DECC plans to meet with relevant experts to consider how best to improve the communication of climate science, and will explore how we can take forward our work with key organisations.

28. In relation to new plant breeding technologies, including GM, the Government has consistently sought to inform the public debate by referring to authoritative, independent scientific advice, such as that provided by the Council for Science and Technology, the European Academies Science Advisory Council and the Advisory Committee on Releases to the Environment. As recommended separately by the Committee, Defra and the FSA will review their communications in this area to ensure they are framed in the right overall context.

We recommend that the Government renew its support for Sciencewise and commit to stable or uplifted funding over the next five years.

29. The Sciencewise deliberative dialogue programme is part of a wider government public engagement programme and future funding for the programme will be considered as part of the Spending Review. It would be inappropriate to prejudge the Spending Review outcome.

We recommend that the Government use the current project[3] as a springboard to a more substantial public dialogue on the future of the UK food system. This should be on a similar scale to the 2003 'GM Nation' debate, but should draw upon the lessons learned from that exercise and should utilise the information hub recommended in paragraph 138 as an additional centre of dialogue. The information gained from this process should inform the direction of future policy in these areas. We ask that the Government set out in its response to this report a high level plan for this exercise, together with a proposed timeframe and initial budget.

30. The Government recognises the need for dialogue on the challenges and opportunities facing the UK farming and food sector, and that this must include a consideration of what science and technology can contribute. The Government also accepts that it has a role in helping to further such dialogue, although Government-led initiatives may not be the only or most valuable way forward, and it is important to recognise that all stakeholders have to play their part to enable a successful dialogue in whatever form it is undertaken. This is perhaps especially the case when discussion focuses on the use of new technologies. The GM example has shown the difficulty of achieving an informed and balanced debate of the risks, benefits and values involved, and the risk that polarised attitudes among key stakeholders can prevent a meaningful discourse.

31. In practice, various initiatives are already in hand or being considered that will provide opportunities for dialogue on the future of the UK food system. They include:

- Food and Farming Strategy: since the Committee issued its report Defra has initiated work to establish a long-term strategy for UK food and farming. Several

[3] This refers to the public dialogue project on food system challenges sponsored by Which? and the Government Office for Science. The substantive work on this project has been completed and it is due to be reported on shortly.

engagement events are planned that will enable stakeholders to contribute their thinking on the shape and direction of the strategy.

- Global Food Security Programme (GFSP[4]): having previously undertaken work to better understand public views on food security issues, the GFSP is planning to establish, with the support of Sciencewise, a large-scale citizen's panel to engage on its future activities.

- Food Standards Agency (FSA): as part of its strategic plan, the FSA will be taking forward a public dialogue on 'Our Food Future', to explore the future of the global and UK food system to 2025. This will include structured consumer engagement, an interdisciplinary conference in February 2016 and a public engagement project with partners such as the Wellcome Trust and Which?. It will aim in particular to explore the effect of global changes to the food system on the UK consumer, and how the food 'ecosystem' might look for a stable transition, identifying any associated issues, risks and opportunities for consumers.

32. Taken overall, the Government believes that alongside any complementary activities[5], the above will provide for a significant amount of productive dialogue of the type recommended by the Committee.

We recommend that the remit of the Advisory Committee on Releases to the Environment be expanded to include cultivation of all novel plants, including those not legally defined as genetically modified organisms. The name of the committee should be amended to reflect this expanded remit.

33. This recommendation is linked to that considered above, calling on the Government to aim for a trait-based novel plant regime at EU level. For the reasons stated, the Government does not see this is a realistic objective at the present time.

34. ACRE's key role is to provide independent scientific advice to Ministers on applications to release GMOs into the environment, so that the Government and Devolved Administrations can fulfil their duty to implement the EU requirements in this area. ACRE performs this role as a statutory non-departmental public body, formally established for this purpose under Part VI of the Environmental Protection Act 1990. Extending ACRE's remit to include the risk assessment of plans to cultivate any novel plants, GM or non-GM, would be likely to require new primary legislation to be adopted, to impose a requirement on those intending to release novel plants to submit relevant information, and to enable Ministers to take appropriate risk management decisions if necessary.

35. It would be a major development to bring forward such legislation and Ministers would need to be firmly convinced of its necessity, not least given the Government's overall agenda on better regulation. The Government appreciates the strength of the argument

[4] The UK's main public funders of food-related research and training are working together through the GFSP to meet the challenge of providing the world's growing population with a sustainable, secure supply of safe, nutritious and affordable high-quality food using less land, with lower inputs, and in the context of global climate change, other environmental changes and declining resources.

[5] For example the Wellcome Trust's public engagement initiative on food and drink (http://www.wellcome.ac.uk/Funding/Public-engagement/Funded-projects/Major-initiatives/Food-and-drink/index.htm).

that a trait-based system for novel plants would be more logical than the existing GM-specific regulation. However it does not believe that it would be appropriate to pursue this course domestically in the absence of any real prospect of a corresponding change in the EU regime. It would subject our plant research base and crop production sector to controls that do not apply in other Member States, and in a context where we could not prevent trade from other countries in products made from novel non-GM crops.

We recommend that ACRE should, in its recommended expanded role, establish a permanent 'Citizens Council' based on the model developed by the National Institute for Health and Care Excellence. This new Council should be responsible for considering and providing advice on the potential social and ethical impacts of developments within ACRE's remit. Sciencewise could ensure best practice in the framing and facilitation of debate as well as coordinating the work of all such citizen councils.

36. As confirmed in response to the preceding recommendation, it is envisaged that ACRE's role will remain focused on providing scientific advice on GM crops rather than all novel plants. In that context, the Government does not propose to establish a new body to advise on social and ethical impacts, either operating through or in addition to the present ACRE structure. Whilst recognising that GM cultivation can raise wider issues beyond human and environmental safety, the Government believes that a distinction needs to be made between having a general debate that reflects those considerations on the one hand, and on the other establishing a formal mechanism to take such issues into account in regulatory decisions.

37. As noted, there will be various opportunities for dialogue on the future of the UK food system, and this can be expected to involve consideration of the social and ethical dimension of GM and similar novel crop technologies. As it is, GM crops have already been extensively debated in the UK, so that the broad issues around this technology have become well known. For its part, the Government does not believe that there are strong reasons to justify special regulatory treatment for GM or other novel crops in relation to non-safety impacts. The Government would observe in this respect that:

- the correspondence and representations that Defra has received on GM crops has not highlighted significant non-safety issues that Ministers have felt should influence regulatory decisions;
- the EU Directive on GMO releases provides for the Commission or Member States to refer ethical questions to a specialist EU committee. To the best of our knowledge this facility has never been used, which also suggests that this is not thought to be a pressing area of concern; and
- EU rules require approved GM food or feed products (or ingredients within composite products) to be labelled. Therefore if people object to GM products on the basis of their own social or ethical values they can choose not to buy them.

Appendix 2: Correspondence from Frans Timmermans, First Vice-President, and Vytenis Andriukaitis, Member of the Commission, European Commission

The Commission would like to thank the House of Commons for its Opinion on "Advanced genetic techniques for crop improvement: regulation, risk and precaution".

On the question of whether the EU regulatory process fits its purpose, the Commission would like to draw the House of Commons' attention to two independent reports evaluating the European Union's legislation on Genetically Modified Organisms (GMOs) in 2010[6] and 2011[7]. They found a broad support from the stakeholders for the legislation's objectives and pointed out that only some adjustments were necessary to meet the objectives of the legislation and to ensure its proper implementation.

The Commission has addressed the evaluation's recommendations, amongst others by amending Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001[8], the work on co-existence and the study on "GMO-free labelling". The Commission considers that the current system, based on an EU-wide authorisation upon a favourable scientific opinion, addresses the safety objectives of the EU legislation. The Commission does not foresee a change in this basic principle.

The Commission endeavours to observe the 3-month deadline for food and feed authorisations, bearing in mind that it must engage in a series of steps and procedures before submitting a draft Decision to the Member States. New scientific information or concerns of Member States can lengthen this period.

Concerning the conclusion that the current EU system on GMOs fails to observe the principle of subsidiarity, the Commission would like to point out to the recently adopted amendment of Directive 2001/18/EC (Directive (EU) 2015/412), allowing Member States to restrict or ban cultivation on their territory. This amendment retains a strong EU risk assessment and authorisation system for GMOs, while at the same time giving Member States extended prerogatives to decide on GMO cultivation. This is a positive step towards the alignment of the legislation with citizens' expectations, while respecting the rights of all parties.

6 Evaluation of the EU legislative framework in the field of GM food and feed, Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain Final Report, July 2010 http://ec.europa.eu/food/plant/docs/plant_gmo_report_studies_evaluation_gm_report_en.pdf

7 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 EPEC for DG SANCO, European Commission, Main Report March 2011, European Policy

http://ec.europa.eu/food/plant/docs/plant_gmo_report_studies_gmo_cultivation_report_en.pdf

8 Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory Text with EEA relevance, Official Journal of the EU L 68, 13 March 2015, pp. 1–8.

In addition, based on the Political Guidelines on which it was appointed, the Commission has recently concluded the review of the authorisation process for GM food and feed in the EU and proposed changes to the legislation[9] allowing Member States to opt out from the use of a GM food or feed, in coherence with the model of Directive (EU) 2015/412. This proposal is another important step in bringing more subsidiarity in the EU system on GMOs.

As to the evaluation of costs and benefits, the Commission would like to point out that although not being considered in the EU decision-making process on individual GMO events, socio-economic impacts of GMOs are analysed, as also explained during the evidence session. Indeed Directive 2001/18/EC requires information to be gathered on socio-economic impacts of GMO cultivation, and such impacts might be part of the elements invoked by Member States to justify opting out from GMO cultivation under Regulation (EU) 2015/412. In 2013 the Commission set up a European GMO Socio-Economic Bureau, where experts from Member States are defining common science-based indicators to objectively measure the impacts of cultivation and use of GMOs in the EU. The Bureau is finalising a first general methodological document and subsequent reference documents will set indicators for socio-economic impacts per crop/trait at country/EU level.

On the question of the new plant breeding techniques, the Commission is currently working on a legal analysis to clarify which of these techniques fall under the definition of GMO in the Directive. The Commission expects to be in a position to present the results of its assessment by the end of 2015.

Regarding the precautionary principle, the Commission would like to stress that the precautionary principle is a cornerstone of EU legislation in general, and of the EU GMO legislation in particular. The risk assessment/risk management approach translates this principle into practice, in particular via the pre-market authorisation system based on risk assessment and risk management including monitoring of the effects of the released GMOs and possible risk mitigation measures or the possibility to amend or terminate the consent of a GMO based on the findings. Systematic review of new scientific data and monitoring obligations for authorised GMOs ensure that appropriate safety measures are taken if new risks arise. As explained during the hearing, the Commission has never used the precautionary principle to ban a GMO.

As regards Other Legitimate Factors (OLF), Regulation (EC) No 1829/2003 allows the Commission to take them into account in addition to the risks assessment carried out by EFSA. However, it has never been possible to identify an OLF justifying an EU-wide ban on products considered safe by EFSA.

The Commission hopes that these clarifications address the issues raised by the House of Commons and looks forward to continuing our political dialogue in the future.

9 COM(2015)176 and 177 final.

Printed in the United Kingdom by The Stationery Office Limited
10/2015 51804 19585

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PEFC/16-33-622

ISBN 978-0-215-08638-9

9 780215 086389