RFI6519

Contacts between Defra and GM industry, including the Agricultural Biotechnologies Council, EuropaBio and their member companies, regarding the EU Commission and Greek Presidency's GM cultivation proposals since 1st September 2010.

E MAIL FROM THE AGRICULTURAL BIOTECHNOLOGY COUNCIL TO DEFRA 27/2/14

Morning [redacted],

Cc [redacted] and [redacted]

Please find attached a corrected version of the EuropaBio nationalisation position, which replaces the one I sent through yesterday.

Apologies for the confusion, apparently there was a correction which had not been made, so please disregard the previous version.

Best regards,

[redacted]

ABC information

EuropaBio nationalisation position – attached at Annex A

E MAIL FROM THE AGRICULTURAL BIOTECHNOLOGY COUNCIL TO DEFRA 26/2/14

Subject: EuropaBio nationalisation position ahead of Environment Council meeting (Monday 3rd)

Afternoon [redacted],

Cc [redacted] & [redacted]

Ahead of Monday's debate in the Environment Council, please find attached the industry position on nationalisation proposals, courtesy of EuropaBio (apologies if you have already received this directly from them). In particular, I would draw your attention to point 6, which underscores the pressing need for the meeting to include discussion on a solution to the adventitious presence of GM in conventional seeds.

If you would like to discuss the issues further with [redacted], or directly with EuropaBio, please just let me know and I will be happy to set up a call.

Best,

[redacted].

Agricultural Biotechnology Council

Europabio strategy paper September 2012 "New Strategy on GM issues". Sent previously as part of the reply to RFI6298 – please see

https://www.gov.uk/government/publications/communications-and-meetings-with-europabio

---

EMAIL FROM MONSANTO TO DEFRA 8/2/12

Subject: RE: GM Cultivation

[redacted]

Thank you for taking the time to meet on Monday. I have had a chance to discuss the issues further with colleagues.

Monsanto is very concerned at the atmosphere of "a deal at any price" that appears to be overtaking discussions. As discussed, our first priority is that EFSA should be

supported to develop its opinions based on the best available science and unencumbered by political interference or pressure.

We strongly oppose the proposals in their current form that create a new pathway for member states to opt out of cultivation based on quasi scientific or socioeconomic criteria. This duplicates the existing safeguard mechanism at a much lower threshold of evidence and opens the way to undermine trust and confidence in EFSA.

We remain open to a path forward that allows counties and or regions within them to opt out based on government fiat, with no reason given, at the pre voting stage, with opportunity to change country status at subsequent license renewals. This would provide one completely new mechanism for countries to opt out, achieved without legislative change, in addition to the existing safeguard clause.

We are concerned that the Danish focus on a deal risks creating a legislative debate that moves further away from science. The pressing issues are the backlog of dossiers and the wider implications and precedent of a non-science based assessment process. We urge the Presidency to address these matters.

Thank you again for the opportunity to comment.

Regards

[redacted]

EMAIL FROM DEFRA TO MONSANTO 2/2/12

Subject: GM Cultivation

http://www.reuters.com/article/2012/02/02/eu-gmo-cultivation-idUSL5E8D255X20120202

Relevant background to the issue we'd like to discuss with you.

[redacted]

EuropaBio principles for policymakers March 2011 – see attached Annex B

Paper sent by EuropaBio to Defra on nationalisation proposal September 2010 (identity of source not was not retained in our records) - see attached Annex C

Letters from industry in response to the August 2010 consultation were all supplied in the response to your enquiry ref. RFI6437 – please see

https://www.gov.uk/government/publications/responses-to-2010-defra-consultation-on-cultivation-of-gm-crops

---

EuropaBio position on proposal to nationalise decisions on GMO cultivation in the EU

27 February 2014

1. The plant biotech industry recognises past efforts to achieve progress on cultivation of GM crops in the EU and stands by its position. Under the existing legislation, geographical determination by the applicant is possible and legal and does not require any package that would include post approval opt-outs. The EuropaBio Agricultural Biotechnology member companies are prepared to focus on those markets where governments and farmers have shown they want access to the technology, and where it makes agronomic and commercial sense to market specific products. Most GM products are agronomically relevant only for some Member States, and some Member States are not commercially relevant as cultivation markets. Any proposal that leads to planting of GM in Europe makes it more **urgent to address the possible adventitious presence of GM seeds in non-GM seeds**.

2. The EuropaBio Agricultural Biotechnology member companies reiterate that they are **open to dialogue with individual Member States, on a product-specific basis**, if so desired. The Commission has indicated that geographic determination by the applicant is already possible and legal. It can be achieved under the existing legal framework, and any such agreed determination could be included in product approval decisions, by way of limitations where the product will be cultivated. The EuropaBio Agricultural Biotechnology member companies propose this approach only in the framework of the existing legislation, but not as part of any package with post-approval opt-outs. The advantages of this approach are: 1) it keeps in place the existing single EU approval system, 2) it can be achieved almost immediately, 3) it requires no legislative change, 4) it reduces Member State legal vulnerabilities.

3. The **EU legal framework for GM products has never been correctly implemented**. Most products for cultivation have not been put to the vote as required by law, and some Member States prevent others from cultivating safe GM crops. Efforts should focus on implementing EU law by putting GM products with a positive safety assessment to the vote, a legal requirement strongly confirmed in recent case law.

4. Industry accepts the principle put forward by President Barroso: "*A Community authorisation system based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory*", provided that its implementation is compatible with European law, good governance, predictability and workability, and science-based decision-making. Past proposals were only partly compatible because they allowed **post approval opt-outs that undermine the credibility of the science-based system and the reputation of the products.**

5. **Post-approval opt-out grounds are legally problematic**. Decision-makers have been unable to agree on opt-out grounds because such grounds are neither considered proportionate and non-discriminatory, nor based on "*substantive, persuasive or unequivocal evidence*" as required by law, nor able to withstand scrutiny in Courts and the WTO. The ECJ has already ruled twice that non-scientific grounds to limit GMO cultivation are not lawful.[i] Allowing opt-outs from approved products on the basis of non-scientific justifications sets a negative regulatory precedent for all technologies and sends a negative message about investment and innovation.

6. Irrespective of whether there is GM cultivation in the EU or not, **it is critical that a solution to the adventitious presence of GM in conventional seeds is put in place**. EuropaBio fully supports the position of ESA, the European Seed Association, on the issue[ii]. There is rapidly increasing global GM planting, and thus more GM seed presence, and growing trade in seeds. This is important for the wider seed industry (non-GM and GM producers). Member State Minsters requested a solution in 2006 and 2008. Political leadership is needed to set practicable technical testing protocols for detection of GM presence in conventional batches, and to set thresholds for adventitious presence of approved GM seed in conventional seed. In so doing, the diverging national approaches can be eliminated and the Single Market restored. Any measures associated with adventitious presence of GM in seed must apply uniformly across the territory of all 28 Member States, regardless of any negotiated/voluntary geographic limitations of a product approval, or of any Member State action, such as an opt-out.

---

[i] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:311:0008:0009:EN:PDF; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:220:0010:0011:EN:PDF

[ii] http://www.euroseeds.org/publications/position-papers/plant-biotechnology/esa_10.1100.3

The European Association for Bioindustries

7 PRINCIPLES FOR POLICYMAKERS
Regarding the proposed 'nationalisation' of GMO cultivation bans

March 2011

EuropaBio represents biotechnology companies, including the developers and providers of genetically modified (GM) seeds. EuropaBio encourages policymakers to consider the following principles with regard to the proposed regulation on the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (COM (2010) 375 final).

1. **Provide freedom of choice**
   Member States who want to offer their farmers access to modern agricultural technology should be free to do so. Reticence in one Member State should not restrict advancement in another. Not only should the freedom of choice of Member State governments be considered, but also particularly that of farmers. Progress on both aspects can only be made when Member States recognise that many farmers want access to this innovative technology to increase their productivity in a sustainable way. EU farmers currently have access to only two GM crops for cultivation, whereas their competitors in the Americas can choose among 30 or more GM crops and new traits. EU farmers are entitled to a level playing field.

2. **Ensure predictable and reliable conditions for EU farmers**
   Legal changes have to be announced early enough to all stakeholders to be able to adapt to the new rules, and they should not be applied retroactively. Neither of these two aspects of the proportionality principle is properly addressed by the current proposal. Any national ban for the cultivation of a specific GM product must be announced to all operators concerned well in advance of the start of the growing season. Member States should not only be required to notify the ban, but other Member States and economic actors should also be given the possibility to comment, as foreseen under EU internal market rules (Directive 98/34). Any ban must not cause undue retroactive consequences for affected groups as a result of their adhering to the current legislative framework. Especially, farmers who cultivate GM products legally today must not be made liable retroactively for any aspect resulting from the legal change.

3. **Co-existence should not be mandatory**
   Whether to impose mandatory co-existence rules is under debate. Currently EU voluntary co-existence guidance exists and this is an important tool to allow different farming systems to operate in parallel, but this guidance should not be made mandatory. Co-existence is a national responsibility and the Commission has provided clear guidance to reflect variation in national agricultural systems resulting from contrasting conditions within EU Member States. Each Member State must have the right to determine the appropriate nature of national coexistence measures. Voluntary approaches have proved highly effective in the EU Member States where GMOs are currently grown.

4. **Decisions should be product-specific, not blanket bans**
   The proposed system must ensure that those Member States who want to cultivate GMOs are free to do so. Any measures to restrict GM cultivation on all or part of the national territory must be product-specific and based on a case-by-case approach, because the EFSA risk assessment is also case-by-case. It is not logical to ban groups of products or all GM products indiscriminately.. Council conclusions under the French Presidency also advocated a case-by-case basis. Moreover blanket bans are also legally vulnerable.

5. **The grounds for opting-out are problematic**
   Currently, Member States can invoke a safeguard clause to ban the cultivation of a specific GM crop based on so-called "new scientific evidence". According to the draft Regulation, reasons for "opting-out" should be based on grounds *other* than those related to safety concerns. Most of the suggested grounds for opting-out are unlikely to withstand scrutiny by the European Court of Justice, because they are redundant, arbitrary, or both. Hence they are not a basis for substantive, persuasive or unequivocal evidence which would be required to justify a ban. To take one example, the proposed basis of "public order" does not stand-up to scrutiny. Following the same logic, governments could justify banning the use of large cars, not on objective measurable grounds like high emissions or higher mortality rates, but on the grounds that opponents of such cars may, at some future time, cause public unrest and damage these cars.

6. **Provide GMO thresholds for adventitious presence in seeds**
   To address the realities of the EU seed market, the Commission has been called upon repeatedly by the Council in the past 10 years to propose thresholds for the adventitious presence of GMOs in conventional seeds. The current zero-tolerance approach poses farmers and seed companies significant problems and uncertainty. Where GM cultivation is allowed in some areas and not in others, a pragmatic and workable threshold for adventitious presence in seeds is needed to ensure the happy coexistence between GM, organic and conventional farming.

7. **The current legal basis of the proposal is sufficient**
   Directive 2001/18/EC is based on EC Treaty article 114. Article 114 relates to the functioning of the internal market to promote harmonisation. Switching to Article 192 (environment policy article) as discussed in the European Parliament would reduce harmonisation; something this proposal has already been criticised on. While subsidiarity is at the core of the proposal, all Member States should still be required to base their decisions on common rules.

EuropaBio
Avenue de l'Armée 6
1040 Brussels, Belgium
Tel: (+32.2) 735.03.13
Fax: (+32.2) 735.49.60
E-mail: communications@europabio.org
www.europabio.org

Background note

Political Background

On 13 July 2010, the Commission proposed to devolve the responsibility and decision-making on whether or not to cultivate EU-approved GM crops to Member States. As a result, the cultivation of a GM crop, fully assessed and approved as safe at EU level, could be legally prohibited on all or part of a Member State's territory. The political logic behind this proposal appears attractive at first sight: Member States are divided over the issue, so why not let them approve GMOs for cultivation at their own speed? It is unclear if being able to opt out more easily from cultivation on a national level would change critical Member States' voting behaviour on product approvals.

Legal background

The legal services of both Council[1] and European Parliament[2] have issued critical legal opinions raising concerns about the proposal. There appears no obvious legal solution to this political problem. These opinions show the problems of upholding bans of GM products, approved as safe, following thorough assessment under the world's most stringent approval process, within science-based legislation and under EU internal market and WTO rules. Many Member States and MEPs are considering an outright rejection of the proposal.

Procedural Uncertainties

The Commission has drafted a list of possible grounds to support national opt-outs. It is unclear if and how this list can be integrated into EU legislation and if and how the Parliament will be consulted. Also, many Member States with contrasting views on GM cultivation have raised serious doubts about the legality of the proposal and the list. Much concern is expressed that this proposal threatens science-based decision-making. The proposal reduces EU innovation, investment and jobs in biotechnology. This would counter the objectives of the EU 2020 strategy which seeks to develop this sector. The approach could set bad precedents for other innovative sectors (e.g. nanotechnology, healthcare biotech, etc.) and risks to distort competition between farmers.

A political stalemate…

Under the existing regulatory framework, getting GM products approved at EU level is more difficult, more costly and slower than elsewhere in the world. By voting systematically against approvals at EU level, one group of Member States denies another group of Member States access to modern biotechnology crops, despite the fact that the products in question have been assessed scientifically to be safe for health and the environment.

… which needs to end to enable progress

This stalemate undermines the agreed prerogative that the decision making process should be science-based and it holds back technology-friendly farmers and Member States. The reasons for today's 15.4 million farmers and 29 governments to adopt/ allow cultivation of GMOs on 148 million hectares[3] are in line with many agreed EU policy objectives. GM crops can help farmers and the environment at the same time, by helping to achieve:

- Increased yields – by 6% to 30% on the same amount of land,
- greenhouse gas savings due to less tillage – savings equivalent to taking 6.9 million cars off the road,
- more sustainable water use and less erosion,
- food security – feeding a growing world population from a limited agricultural surface,
- a competitive European agriculture.

GM crop cultivation in the EU and worldwide

Partly as a result of a dysfunctional authorisation procedure, to date, only two GM crop types ('events') have been authorised for cultivation in the EU. These are an insect-resistant maize and, since 2010, a potato for industrial use. In 2010, cultivation in the EU was limited to 91,643 hectares in 8 Member States. At the same time, the number of GM products available worldwide is growing rapidly. Farmers in the US, Brazil and Argentina are allowed to grow 30+ different GM crops. The Commission's Joint Research Centre reported that the number of

[1] http://www.endseurope.com/docs/101125d.doc
[2] http://www.endseurope.com/docs/101125c.pdf
[3] Statistics from ISAAA 2010 report : http://www.europabio.org/PressReleases/green/ISAAA_release_22February.pdf

commercial GM crops was set to increase to 120 or more products in 2015[4]. In 2010, 15.4 million farmers planted over 148 million hectares of biotech crops in 29 countries, up by 10 % from 2009.

An ambitious authorisation procedure …

The EU authorisation procedure for GM products is widely recognised to be the strictest in the world. Applicants have to compile a large number of studies, to be scrutinised by the European Food Safety Authority (EFSA). EFSA then issues a science-based recommendation as to whether to authorise the product. The actual authorisation decision is taken in a comitology procedure. So far, EFSA has confirmed for all GM crops that these are 'as safe as' conventional crops. This is why until now EFSA has never recommended rejecting an application. Applicant companies spend several million € per product (according to Dutch COGEM report: 7 million on average) on this procedure. Already in 2001, the Commission concluded on GMOs that "the use of more precise technology and the greater regulatory scrutiny probably makes them even safer than conventional plants and foods"[5]. This was again confirmed in a recent compendium "A decade of EU-funded GMO research"[6]. The work of 130 EU-funded research projects, covering a period of more than 25 years of research, involving more than 500 independent research groups and with a budget of more than 300 million € concludes that biotechnology is not inherently more risky than conventional plant breeding.

… rendered dysfunctional by political fragmentation

Despite this, GM product approvals in the EU take substantially longer than anywhere else, and the backlog of approval dossiers is increasing. For cultivation, it took the latest approved GM crop more than 13 years to be authorised, and currently only 2 GM crops can be grown commercially in the EU. This denies farmers access to the same innovative tools their counterparts of the rest of the world are using. For imports there are currently 48 GM products in different stages of the approval system (February 2011) and this number keeps increasing[7]. This is leading increasingly to trade problems and negatively impacts access to feed sources, causing higher prices.

Co-Existence measures

Co-existence means using different cropping systems in parallel: conventional, GMO and/ or organic. Co-existence measures must allow for the existence of all these production methods without discrimination. According to the Commission, experience gained over the last years shows that Member States need more flexibility to take into consideration their particular local, regional and national conditions. This is why the Commission published a new Recommendation on co-existence in July 2010. Spain and the Netherlands are examples of countries where stakeholders successfully worked out voluntary co-existence measures.

Additional Information

- General Information about Agricultural Biotech
  - EuropaBio website http://www.europabio.org/green_biotech/GBE_about.htm
- GM crops worldwide and in Europe
  - 2010 ISAAA report http://www.europabio.org/PressReleases/green/ISAAA_release_22February.pdf
  - EuropaBio press release http://www.europabio.org/PressReleases/green/GM_in_Europe_Q&A.pdf
- Pressures on the global food system
  - UK Foresight Report http://www.bis.gov.uk/foresight/our-work/projects/current-projects/global-food-and-farming-futures
- Factsheets on green biotechnology
  - Benefits of GMOs http://www.europabio.org/positions/GBE/2010-GMO-Benefits-factsheet.pdf
  - Climate change http://www.europabio.org/positions/GBE/PP_090619_Climate_Change.pdf
  - Water-wise solutions http://www.europabio.org/positions/GBE/PP_101209_water.pdf
  - Socio-economic impacts http://www.europabio.org/positions/GBE/PP_080110-Socio-economic-impacts-of-GM-Crops-GMO.pdf
  - Co-existence http://www.europabio.org/positions/GBE/PP_100129_coexistence.pdf
  - Farmers' choice http://www.europabio.org/positions/GBE/PP_100129_Farmerschoice.pdf
  - Safety of biotech crops http://www.europabio.org/documents/ensuring%20the%20safety%20of%20biotech%20crops.pdf

[4] JRC Report The global pipeline of new GM crops (2009): http://ftp.jrc.es/EURdoc/report_GMOpipeline_online_preprint.pdf
[5] EU Commission: EU sponsored research on safety of genetically modified organisms, 2001
[6] EU Comission Research Compendium (2010) : http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf
[7] Data compiled by EuropaBio

EC NATIONALISATION PROPOSAL

Background

On July 13, 2010, the European Commissioner for Health and Consumer Protection John Dalli set out the EC's new proposals related to the nationalisation of the decision to cultivate GM crops. In March he had committed to give more freedom to Member States (MS) on the cultivation of GMOs.
The proposals announced on July 13 have two components:

New **Commission Recommendation on Co-existence**. Under the non-binding Recommendation the MS are granted more flexibility to organize coexistence between GM/conventional/organic. The Recommendation took effect on 22 July 2010. It allows for MS to potentially lower the agreed 0.9% GM labelling threshold and allows for GM-free zones.

Analysis: The Recommendation undermines the legally established labelling threshold and permits the establishment of variable alternative thresholds in different MS. It may trigger legal disputes involving authorities and operators (including farmers, buyers and producers) and further promote the development of a two-tier market, in which imported GM crops circulate freely while cultivation of the same crops is restricted within the EU. It will place Europe's farmers, food industry and consumers at a competitive disadvantage, and it could negatively impact the conventional seed market by effectively imposing de facto lower threshold levels for GM presence in conventional seed. It may result in damaging cost implications for seed supply to the EU and enable abuse of coexistence measures. The Recommendation, which says it 'may be necessary to exclude GMO from large areas' if a lower co-existence threshold is imposed, runs contrary to the EU internal market principles, by allowing a proliferation of different national or regional restrictions and conditions. Ultimately, it will be more difficult for Member States to allow farmers to choose to grow GM products. The UK and France have already complained that the recommendation did not pass through a proper consultation with MS and stakeholders.

Draft Regulation to Directive 2001/18/EC. This is a proposal to amend the directive that governs GM cultivation by allowing MS to restrict or prohibit the cultivation of GMOs on their territory. The legislative change must be adopted through the Ordinary Procedure (Co-decision Procedure) which involves achieving agreement between the EU Council (MS Governments), the European Commission and Parliament. The proposal is in line with the direction set out by president Barroso to combine an EU authorization system, based on science, with freedom for MS to decide whether or not they wish to cultivate GM crops on their territory.

Analysis: According to the Commission, the political price for normalization of GMO approvals is nationalization of cultivation decisions. It will allow the EC to claim that the authorization system is science-based, while not forcing any MS to cultivate against its will. Nationalization is considered by the EC as a pragmatic approach; the reality being that the Commission has not been – and will not be – able to lift national bans. The proposed change to Directive 2001/18 involves inserting a single new article (Article 26b) in the Directive. The article says that countries can "restrict or prohibit the cultivation of all or particular authorised GMOs for reasons other than possible adverse health and environment effects (using these reasons is already allowed, if evidence is provided).The proposed amendment enshrines the politicisation of decision-making into European law. MS governments would be able to use socio-economic factors as reasons to ban cultivation. External legal analysis (available upon request) states that it is contrary to EU internal market law as it promotes different and conflicting rules per country; that it is not in line with international legal and trade obligations (TBT under WTO). The measure may allow some countries to move ahead with cultivation (with the two events approved to date). There are no indications that EU cultivation approvals will be accelerated, to the contrary this process and the political discussions will most likely slow the process.

A **separate Commission Communication** explains the proposals.

REACTIONS TO THE PROPOSAL

MEMBER STATES

The proposal has received a lot of criticism. German, French, Polish, Spanish and other countries' Government Ministers relayed their objections. For example, Chancellor Merkel said, "…*the EU Commission has undermined the foundations of the single market*." The French Agriculture Minister Bruno Le Maire declared that "*Any re-nationalisation of agricultural issues is a step in the wrong direction. Everything that increases solidarity*, *working together, imagination, innovation and daring is a move in the right direction."* The German Lander Council has by a small majority rejected the concept of nationalization.

At the first meeting among MS where the proposal was discussed: three core arguments from MSs against the proposal were put forward: 1) That it is contrary to internal market rules and principles, 2) That it is incompatible with WTO (TBT) rules, making legal action against MS governments possible. 3) That a clear list of reasons to opt-out must be made by the EC. The EC rejected this request three times during the meeting (and later at public events).

The MSs criticised the proposal for different reasons, some of which related to GM, but others more related to the negative precedents the proposal sets. These precedents include the perception that it is devaluing science by politicising it, that it is fragmenting the internal market or that the EC is "passing the buck" on a politically hot issue.

There are concerns regarding the impact of the proposal on the process and speed of approvals for import events. Two specific concerns: 1) some countries, for purely political reasons, may see their vote on import approvals as a way to stop, slow or influence the cultivation proposal, 2) some countries have asked whether reasons used to opt-out of cultivation will also be applicable to import dossiers. In particular, at the first meeting on 27 July where MS discussed the proposals the EC representative made the following comment, which the EC recorded in minutes: ***"****It is not the intention of the Commission to make proposals in the food and feed area, <u>even though some of the justifications put forward by MS to support a prohibition of cultivation could be transposed to it</u> (ethics for instance*)". This for the first time openly suggests that ethical considerations could be used as regards imports. It is difficult to judge the value of the statement in the minutes but it is an interesting insight into EC thinking. It appears in contradiction to the official position set out in EC.

EUROPEAN PARLIAMENT

On 13th July, Commissioner John Dalli officially announced the proposal in front of the ENVI Committee; the reactions amongst MEPs were mixed. Dagmar Roth-Behrendt (S&D, DE) welcomed the proposal as "in line with reality", since several Member States already restrict cultivation through a safeguard clause in existing EU rules. Marisa Matias (GUE/NGL, PT) was among those fearing that decisions made on this basis may not stand up to a legal challenge, for example by the WTO. Corinne Lepage (ALDE, FR) and others were disappointed that health and environment grounds could not be cited, the Commissioner for his part stressed his view that these criteria should only apply in the EU-level authorisation procedure. Satu Hassi (Greens/EFA, FI) said, "we know the proposal is intended to open up authorisations for a long list of other GM crops". Commissioner Dalli denied an agenda to speed up further approvals and and guaranteed that there would be "no dilution" of the EU process.

Françoise Grossetête (EPP, FR) warned that entrenching differences in Member State policies could lead to "distortions in the market", while Pilar Ayuso (EPP, ES) added that the EU could not pretend to be a "bubble" against GMOs at the cost of farmers, especially considering its large-scale importation of GM feed.. The European Food Safety Authority (EFSA) came under some criticism, even if Renate Sommer (EPP, DE) suggested Member States tend to use criticism of the agency as a "smokescreen" and Environment Committee Chair Jo Leinen (S&D, DE) stressed that the independence of the agency's judgement should not be in question. Commissioner Dalli promised to return to the committee later in the year to discuss improvements that could be made to the overall process.

The latest information confirms that many MEPs in ENVI would like to avoid a 'GMO yes or no type of discussion', which seems to be a difficult goal to achieve considering that Corinne Lepage (ALDE, FR) has been appointed rapporteur in ENVI, while for AGRI it will be George Lyon (ALDE UK). Mrs lepage is a french MEP with a long history of anti-GM activity. ITRE and JURE (the other two committees delivering an opinion) have not yet nominated their rapporteurs.

OTHER STAKEHOLDERS
Private stakeholders with different views on GMOs have sharply criticised the EC proposals.

Green groups oppose it stating the proposal was *"...deeply flawed, legally and politically."* **Friends of the Earth** was critical affirming that '*the European Commission is seemingly offering countries the right to implement national bans, in reality the proposal aims to do the opposite, opening Europe's fields to GM crops. We urge countries to reject this deal".* The criticism was echoed by **Greenpeace,** which said that "*in an attempt to muddle through with his pro-GM agenda, Dalli is offering countries national bans if they turn a blind eye to the health and safety concerns they have about new crops during the EU authorisation process''.*

Criticisms also came from some of the major EU trading partners. Ambassador Kirk, the **US Trade Representative** confirms *''What we want is an open transparent process that conforms with internationally accepted scientific standards and you're not going to be able to do that if you have members states all coming up with their own rules."*

COPA wrote of "…*legal and commercial risks for farmers"*. **European Seed Association** (ESA) said the "proposal gives up the main legal and policy principles established by the existing GM related legislation". **EuropaBio** affirms that the proposal is ''*damaging for the future choice of farmers and consumers"* and calls for the correct implementation of Directive 2001/18/EC. 10 associations representing the **European Food and Feed chain** put forward a common position to EU stakeholders to underline the: a) independent risk assessment by EFSA must remain the basis of the EU GM authorisation system, b) EU food and feed chain operators need more legal certainty with regard to the implementation of the EU GM legislation, c) the new approach on GM cultivation sets a dangerous legal precedent jeopardizing the Internal Market for authorised products.

(See annexes for full statements)

NEXT INSTITUTIONAL STEPS

Month	Starts	Ends	Event Description	Event Description
September	27	27	Agriculture Council	EC explains proposals
September	27	29	EP ENVI Committee	
September	28	29	AGRI Committee	
October	4	5	ENVI Committee	
October	11	11	AGRI Committee	
October	14	14	ENVI Council	EC explains proposals

ANNEX: STATEMENTS FROM ORGANISATIONS

EU FOOD AND FEED CHAIN (FFC) CALLING FOR ADOPTION OF EFFECTIVE LEGAL MEASURES TO PRESERVE THE INTERNAL MARKET AND VITAL FEED AND FOOD SUPPLIES LINKED TO NEW EU GM CULTIVATION INITIATIVE

The EU Food and Feed Chain partners take note of the efforts of the European Commission to achieve a more rational, constructive and balanced debate among all interested parties on GMOs and to follow science-based decision-making, while ensuring freedom of choice for farmers and consumers, legal certainty for operators and the competitiveness of the EU feed and food chain. However the EU FFC partners are deeply concerned by the new proposal regarding GM cultivation launched by the European Commission. We fear that the new initiative will not be sufficient and effective to solve the existing problems related to the implementation of the EU GM legislation for farmers and business operators. The new Commission initiative fails to address the most urgent need of all EU food and feed chain operators for a clear, practical "technical solution" regarding trace levels of GM events not yet authorised in Europe, as first requested by the College of Commissioners in May 2008. The EU must tackle this crucial issue as a key working priority by recognising the reality of the sharp rise of the number GM crop events grown in key exporting countries (cf. JRC report on the global GM pipeline, 2009). The lack of acceptance of a practical low-level presence along the entire food and feed chain is jeopardizing vital seed, food and feed supplies to the EU and the competitiveness of EU food and feed business operators.

EU FFC partners would therefore like to remind decision-makers at EU and national level of the following general principles that must guide discussions on the new legislative initiative in this sensitive area:

- The independent risk assessment by EFSA must remain the basis of the EU GM authorisation system. Any attempt to dilute the scientific basis of the current robust risk assessment methodology would ultimately lead to a loss of credibility of the EU's food and feed safety system putting at stake the hard-won trust and confidence of European consumers and operators of the EU food and feed chain.
- EU food and feed chain operators need more legal certainty with regard to the implementation of the EU GM legislation. The proposed re-nationalisation of the decision to ban the cultivation of EFSA risk-assessed GM crops will seriously undermine the "acquis communautaire" in the area of agriculture and food and feed safety. EU farmers, food and feed chain operators may face arbitrary, non-scientific decisions of national authorities related to the cultivation and co-existence of GM crops with conventional crops. This will lead to even more legal and commercial risks[1] against which operators can take no coverage.
- The new approach on GM cultivation sets a dangerous legal precedent jeopardizing the Internal Market for authorised products. In the absence of effective safeguard measures, EU farmers, food and feed chain operators fear the risk of exposure to uncoordinated actions by Member States which could lead to blocking products containing GM events "banned" on their territory.

AAF (Association des Amidonniers et Féculiers)
a.v.e.c (Association of Poultry Processors and Poultry Trade in the EU
CIAA (Confederation of the food and drink industries of the EU)
COCERAL (Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures)
COPA-COGECA (European Farmers and Agri co-operatives)
ESA (European Seed Association)
EUROPABIO (European Association for Bioindustries)
FEDIOL (The EU Oil and Proteinmeal Industry)
FEFAC (European Feed Manufacturers Association)
UECBV (European Livestock and Meat Trading Union)

COPA-COGECA VOICES CONCERNS ABOUT NEW EUCOMMISSION PROPOSAL TO INTRODUCE NATIONAL AUTHORISATION ON GM CULTIVATION

Copa-Cogeca voiced concerns today about the new EU Commission proposal which allows member states to ban the cultivation of an authorised genetically modified crop on their territory. The proposal foresees a two step approach, enabling member states to prohibit the cultivation of authorised GM crops on all or part of their territory, for any reason except food security or environmental protection. Speaking in Brussels, Copa-Cogeca Secretary-General Pekka Pesonen said "We are concerned that the new approach on GM cultivation sets a dangerous legal precedent, jeopardising the internal market for approved products and increasing distortions of competition amongst EU farmers by diverging label thresholds. Furthermore, farmers may face arbitrary, non-scientific decisions by their competent national authorities relating to the cultivation and co-existence of GM crops with conventional and organic ones. This will result in new legal and commercial risks, which farmers cannot cover themselves for". He continued "Copa-Cogeca realises that the Commission is trying to have a more rational, constructive and balanced debate amongst interested parties on GM crops and to follow science based decision-making, whilst ensuring freedom of choices for farmers and consumers, as well as ensuring the competitiveness of the EU feed ad food chain. But we have major concerns about this new initiative. We also urge the Commission to make sure that the independent EU Food Safety Authority (EFSA) risk assessment process remains the basis of the GM authorisationsystem". Copa-Cogeca is meanwhile still calling for a threshold to be set as the low level presence (LLP) of unapproved GM material in imports is causing serious trade disruption and economic problems for the EU feed and livestock production sectors. Given the bulk handling of grains in international trade, compliance with a zero tolerance policy for LLP of unauthorised material is impossible. A practical solution must be found; otherwise it could cost EU farmers hundred of millions of euros. In the longer term, Copa-Cogeca want to develop its own protein supply further, to reduce its dependence on imported soybean.

[1] Diverging labelling thresholds for "GM-free" product and seed.

ESA on the European Commission's proposals for a new policy approach to the authorization of GMOs for EU cultivation and coexistence of GM and non-GM crop production

ESA European Seed Association has taken note of the announcement of Commission President Barroso in his policy guidelines for the new European Commission to put forward proposals that would provide Member States with greater flexibility in their decision making on the actual cultivation of GM crops while the assessment of safety of GMOs for release into the environment and for their use in food and feed would continue to be decided on European level. We are aware that the responsible service of the Commission, DG SANCO, is currently conducting a consultation with other relevant services on a possible political and legislative approach to this effect. While we understand that this consultation is still ongoing, we herewith want to provide a number of principle comments that are based on our understanding of the main elements of the proposals under consideration.

I. Revision of the guidelines for coexistence

Following the adoption of the GM food and feed and GM traceability and labelling Regulations and specifically the setting of the new GM labelling threshold of 0.9%, the 2003 Commission guidelines on coexistence established some principles how farmers should be enabled to grow GM and non-GM crops side by- side while respecting this labelling threshold. The very base of the coexistence guidelines is thus to enable choice and compliance of different farming models with a specific regulatory requirement – that of a labelling threshold for GM presence in non-GM crops. In its Communication and later discussions, the Commission quite rightly underlined that coexistence is not a safety issue, rather a mechanism to fairly distribute the burden and possible related costs between groups with different economic interests, considering differing practical farming environments. Hence, it was considered most appropriate to leave detailed practical planning of how best to achieve this coexistence, i.e. the compliance with the 0.9% labelling threshold, to Member States to consider their respective individual landscape and farming structures. However, these measures were subject to the Commission's scrutiny and acceptance as they were not supposed to go beyond what was considered necessary to comply with the legal obligation.

The new proposal ("Guidelines for the development of national cultivation measures") gives up the main legal and policy principles established by the existing GM related legislation.

- **No more scrutiny of proportionality and scientific basis of national coexistence measures**. The Commission gives a 'carte blanche' to Member States and potentially to any regional entity to set their own regulatory framework for GM cultivation and coexistence. With that, it abandons its proper role of ensuring the adoption of science-based and proportionate measures that provide legal certainty and are compatible with the principles of a common European single market. It effectively accepts that in the future, any requirement that supposedly may help to further minimize or even avoid any presence of GMOs in non-GM products may be established by any public entity. This approach makes European plant breeders, seed producers and farmers subject to a patchwork of different regulatory obligations. This is incompatible with the Internal Market and fair competition under common rule of law. It is also an unacceptable policy approach for the institution that is supposed to be the "guardian of the Treaty".
- **Acceptance of (labelling) thresholds lower than 0.9%.** The Commission intends to allow Member States (or regions or other entities) to set their own individual labelling requirements, provided these are lower than the EU labelling requirement established by a Council and European Parliament decision. As stated above, this will lead to a fragmentation of the Internal Market and greater legal uncertainty regarding the conditions under which material must or must not be traced and labelled and may or may not be moved from one legal entity to the other. It will establish an environment of mistrust controlling and dividing European farming communities. It must also be underlined that these obligations will further distort fair competition between European and non-EU production. While imported material with GM contents up to 0.9% will not fall under the traceability and labelling obligations (and at least benefit from legal certainty), home grown GM produce would likely fall under the potentially stricter criteria and thus be seriously disadvantaged. It is incomprehensible that a Commission proposal would suggest to disregard an EU-wide standard, established by co-decision of the Council and the European Parliament, and to contradict it by regional or local measures to which no EU scrutiny is applied.

II. Revision of Directive 2001/18/EC

The current Directive 2001/18/EC contains a so-called 'safeguard clause' which allows Member States to suspend or restrict the cultivation of GM plants on grounds of environmental or consumer safety. Such a decision must be: based on specific scientific evidence; subject to a review by the European Food Safety Authority; and may be revoked in case the claim cannot be substantiated. In the past, the Commission defended this policy of science based decision making and regulatory decisions; a number of unfounded, unspecific and unscientific bans of GM crops could consequently not be upheld. The Commission thus fulfilled its obligation to assure a proper implementation and interpretation of EU law. The Commission's new proposal abandons the principle of a European product authorisation. It accepts that European breeders, seed producers and farmers will have different access to technology and resulting products, despite the fact that the product has been evaluated and found to be safe following assessment against stringent EU rules and that its harvested material may circulate and be used freely according to the GM food and feed Regulation.

- **Abandoning science and Community principles**. In the past, national measures restricting the use of an approved product were subject to Commission scrutiny and acceptance, not simply notification. Only where these measures were based on product-specific scientific findings showing that the individual product would pose a threat to environmental safety or public health, could such national bans be accepted. Unspecific measures have always been rejected by the Commission as political measures favouring or discouraging a specific type of agriculture or economic interest. The new approach singles out GMOs as a specific category of products to which the founding policy principles and established legal framework of the European Union, such as non-discrimination and the Internal Market, do not apply.
- **A patchwork of rules instead of Community law**. While the new provision could allow Member States to ban the planting of GMOs, their free movement, processing and use in food and feed products shall still be allowed. In practice, this would mean that a GMO would be 100% legal for planting in one country and 100% illegal in another. As the harvested product may be freely transported and moved across the EU, it is unavoidable that traces will be found also in those Member States that will ban the product for planting. With the expected highly differentiated approaches of Member States and/or regions to Coexistence (see above) this will lead to a proliferation of applicable rules and consequences for operators. This will even further reduce legal certainty for seed companies and farmers.

- **The absence of enabling measures**. The Commission's draft proposal contains no provisions designed to manage a situation where authorisations for planting will differ among countries or regions, while the products as such may move freely in the internal market. It is imperative that the Commission sets thresholds for the unavoidable presence of GMOs in non-GM seed as one of the principle requirements for the implementation of its new policy approach. Without such thresholds, the proposal does not solve existing problems, rather creates new ones for seed companies, farmers and the whole agri-food chain in Europe.

Conclusion
ESA supports the Commission in its aim to break the political deadlock in the authorisation of new GMOs for planting in the European Union. At the same time, we underline that the common market for seed must not be jeopardised and that without practical thresholds for the adventitious presence of GMOs in seed, the proposed measures and approach are unworkable, further increase legal uncertainty for breeders and farmers and will divide the farming community in Europe.

EUROPABIO STATEMENT

The Commission's Proposals to Nationalise the Approval of GM crops for EU Cultivation

EuropaBio has taken note of the Commission's proposed measures, announced on Tuesday 13 July, to devolve the responsibility and decision making on whether or not to cultivate GM crops, to Member States. Industry is deeply concerned that these measures will disable rather than enable those that wish to grow safe, beneficial and rigorously scientifically tested GM crops within the EU. As a result, we feel that in its current form, the proposal will be deeply damaging for the future choice of farmers and consumers as well as for responsible European innovation, conservation of our natural resources and for the environment as a whole. The proposal advocates non-science, ideologically-based decision making and proposes that this is backed up by measures that could be disproportionate and discriminatory. We believe this will ultimately deny farmers the right to choose to grow the products and use the technologies that work best for them and their environments.

In its current form, the proposal:

1. Threatens to undermine the legally established 0.9% labelling threshold by permitting the use of a range of alternate thresholds. This may trigger legal disputes involving authorities and operators (including farmers, buyers, producers).

2. Enables abuse of coexistence measures for the sake of denying existence of certain products or technologies.

3. Runs contrary to the EU internal market principles, by allowing a proliferation of different national or regional restrictions and conditions.

4. Undermines the scientific basis and the credibility of EFSA's assessments.

5. Makes it more difficult for Member States to allow farmers to choose which products to grow by creating legal uncertainty

6. Creates a precedent that would imply that other sectors, and other nations, could use non-scientific reasons to reject the approval of products despite a positive safety assessment by the EU scientific authorities (EFSA)

In order for Europe to move forward, industry calls for a clear legal framework in which innovative, beneficial, approved and safe products can be made available to those that wish to grow or buy them. EuropaBio will continue to study the proposals in depth, will respond to the Commission in due course and will share its views with relevant stakeholders.