To: President José Manuel Durão Barroso, Commissioner Tonio Borg

Cc: Commissioners Karel De Gucht, Dacian Cioloş, Vice President Antonio Tajani, Janez Potočnik, Máire Geoghegan-Quinn;
EU Chief Scientific Advisor Anne Glover

By E-Mail only

Subject: Proposed improvements to implementation of policies related to agricultural biotechnology

2 September 2013

Dear President Barroso, dear Commissioner Borg,

As you know, EuropaBio represents more than 2,000 companies active in the biotechnology sector across Europe, including in the pharmaceutical, industrial technology, food and agricultural sectors. Jointly these companies contribute billions to the EU economy, and they are a major motor of job creation given the large SME base.

We write to you to register our concern about the implementation of EU policy related to biotechnology in agriculture. We believe the implementation of EU policy is increasingly at odds with the Union's current top goals of growth, job creation, innovation, investment and good governance. During the present economic crisis, the regulatory uncertainty experienced by our companies and the resulting threat to investments in the EU are particularly regrettable. After describing the main issues, we make suggestions for a series of improvements that would in our view improve this situation tremendously without requiring changes to existing legislation. We would ask for your leadership in implementing said required improvements.

Unexploited economic potential

Genetically Modified (GM) crops are being grown on 12% of the world's cropland. Our clothes and Euro notes are mostly made from GM cotton, the diet of most EU farm animals includes GM soy, GM technology is widely used in food production, and GM plant-based ingredients are more and more likely to be present in food above the current labeling threshold of 0.9%. Biotechnology could contribute up to 2.7% of GDP in OECD countries by 2030, and even more in developing countries according to the most recent OECD figures[i]. The EU has repeatedly recognized that biotechnology plays an important role in economic growth, and the European bioeconomy is set to play an integral role in the "Horizon 2020" strategy. In June 2013, OECD and FAO warned of potential world food price increases of 15 to 40%[ii], with important ramifications for consumers. However, as a result of the malfunctioning system for GM import authorisations in Europe, our sector as well as other related sectors such as the grain traders, the food and feed industries, and farmers, are confronted with increasing barriers to trade and costly and unnecessary trade disruptions[iii]. Regarding planting

of GM crops, EU farmers are denied the choice of growing biotech crops, causing estimated annual forgone revenues to EU farmers in the order of €443 to 929 million every year.[iv]

Problems with improper implementation of the regulatory system

The EU has a solid legal framework regarding agricultural biotechnology, but in practice, the process for authorizing GM products is dysfunctional, and the lack of implementation and enforcement of EU legislation by the Commission and some Member States is obvious and systemic. 25 Member State science academies united in the European Academies Science Advisory Council (EASAC) released a report[v] in June 2013, that expressed concerns about the *".. Time-consuming and expensive regulatory framework in the EU, compounded by politicisation of decision-making by Member States and other policy inconsistencies…".* The Commission is aware that the authorization system for import of products could be implemented more efficiently and admitted that it regularly fails to comply with the timelines as set out in the legislation.[vi] The backlog of GM dossiers pending authorization continues to grow. It currently stands at 74 products, with our industry intending to double its submissions in 2013 and 2014.

Counter-productive risk management measures

The reasons advanced to explain the political situation regarding GM in the EU are often related to suspected risks and negative public perception, despite the solid scientific consensus, as evidenced in the more than 2,500 individual science-based GM product authorizations granted by governments around the world, and by various reports and studies published by the EU and others. It is challenging to reassure citizens about safety when some governments persistently vote against the scientific consensus expressed within EFSA positive opinions. We recognize that the Commission intends to defend the science-based system, but it is regrettable that some of the Commission's initiatives have contributed to undermining the best scientific advice and evidence. This happens when the Commission fails to process dossiers with positive risk assessment within the timelines foreseen[vii], and when it fails to challenge Member States that illegally ban imports or cultivation of EU-approved products. It also happens when the Commission lends credibility to universally rejected studies (such as the recent Séralini study on rats, which was rejected by EFSA and Member State authorities), by way of reproducing the same studies funded with taxpayers' money.

We are particularly concerned about the increasing political interference with the risk assessment stage of the process, as demonstrated with the recently adopted Implementing Regulation No. 503/2013. The introduction of non-scientific, politically driven criteria, via this implementing regulation, into the risk assessment against the advice of the risk assessor itself and of many other stakeholders including Member States, science and animal rights groups, and WTO trading partners, goes against the EU's science-based system[viii]. It only leads to a disproportionate increase in regulatory bureaucracy regardless of the potential risks to be examined. Despite the fact that no potential hazards from genetic modification have been identified in any of the products widely marketed for more than 15 years, GMOs are assessed and treated more restrictively in the EU than most known hazardous substances. The work of risk assessors must not be based on public perception of risk, but needs to remain objective and scientifically sound.

We trust that the Commission will actively promote the objectives it used to argue on the occasion of the inclusion of non-scientific requirements into risk assessment, namely, that it will help increase public acceptance, help achieve better support - including from Member States when voting, avoid process delays and increase legal certainty. We would appreciate receiving insight into how the Commission intends to achieve these objectives and to measure progress.

Recommendations for improvement

EuropaBio would like to put forward the following recommendations for improvement:

1. Achieve efficiency gains in the authorisation system by putting products with an EFSA positive opinion to the vote in accordance with the timelines set out in EU legislation, and by

implementing a management plan to clear the growing backlog of pending products for approval.

2. Protect international commodity trade by introducing a harmonised sampling and testing protocol for food ("technical solution") to achieve some legal certainty for economic actors and authorities when implementing the current zero tolerance principle. The EU should also actively participate in on-going international efforts to address the challenge of low level presence (FAO, OECD, intergovernmental series of conferences).

3. Protect the internal market by enacting a technical solution for seed, and a labeling threshold for the adventitious presence of GM seeds in non GM seed lots, as repeatedly and unanimously requested by the Member States since 2006. Divergent national approaches are distorting the internal market for seeds considerably, and there is an important lack of legal certainty.

4. Ensure that decisions are taken on the basis of science-based risk assessment and not based on public perceptions of risk. To advance better regulation efforts and reduce administrative burden, it is suggested to create a dedicated role within the Commission to ensure that product authorisation processes remain science-based, to promote process efficiency and to foster proper risk management that is based on purely scientific risk assessment. Regulatory processes should be based on good administrative practice, encouraging good communication with applicants, and avoiding retroactive application of new requirements.

5. Communicate clearly that EU-authorized products are as safe as conventional crops.

A negative EU precedent affecting other regulated sectors

The systemic institutional failure described in this letter, may be specific to the field of agricultural biotechnology. However, it is increasingly felt among many regulated industries, that undue political interference is more and more prevalent in EU approval processes. Product safety policies based on non-objective criteria threaten reliability, investments and international trade not to mention reduce consumer confidence in the regulatory system, in the products and ultimately in the regulators themselves.

We will address similar letters to Member State governments. We remain at your disposal for any further information and thank you in advance for your kind attention.

Best wishes,

Nathalie Moll,
Secretary-General EuropaBio

[i] http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/42837897.pdf
[ii] OECD-FAO Agricultural Outlook 2013-2022: http://www.oecd.org/site/oecd-faoagriculturaloutlook/
[iii] An EC-published report estimated the potential cost at €9.6 billion *http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/summary_en.pdf*
[iv] http://www.ncbi.nlm.nih.gov/pubmed/21272674
[v] "*Planting the Future*", European Academies Science Advisory Council (EASAC), www.easac.eu
[vi] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-004184&language=EN
[vii] http://www.europabio.org/positions/49-years-undue-delays-eu-approval-gm-products
[viii] *"New EU legislation for risk assessment of GM food: no scientific justification for mandatory animal feeding trials",* Plant Biotechnology Journal, H. Kuiper et al. See also: EuropaBio letter to Mr Ladislav Miko and Ms Geslain-Lanéelle, dated 11 June 2013, subject: Commission Implementing Regulation

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