To the President of the European Commission,
the President of the European Council, and
the President of the European Parliament

16 October 2013

Dear Mr. Barosso, Mr. Van Rompuy and Mr. Schulz,

I write to you on behalf of the Public Research and Regulation Initiative (PRRI) and the European farmers' organisations below. PRRI is a world-wide organisation of public sector scientists active in modern biotechnology for the common good. The farmers' organisations below support the freedom of farmers to choose the crops, including approved genetically modified (GM) crops, they find best suited to address the increasing challenges in farming.

Today, on World Food Day, we write to express our deep concern about the effects that the EU GMO policies and regulations have on the potential of modern biotechnology to strengthen the sustainable production of food.

If the EU wants to make its farming more sustainable and be less dependent on import of agricultural products, then EU farmers will need to have access to crop varieties that are less dependent on pesticides, that produce more per hectare, that require less mechanical soil treatment, that can withstand the effects of climate change, etc.

Developing such crop varieties cannot be done by conventional breeding alone. Modern biotechnology can help considerably in reaching these goals, and in some cases it is the only solution available. This is reflected in Agenda 21 and in the Convention on Biological Diversity as well as in the hundreds of millions Euros that the EU has invested in modern biotechnology research over the years. Biotechnological innovation is key to achieving sustainable intensive agriculture.

In 1990, the EU established a regulatory system for GMOs in which the key was scientifically sound risk assessment as the basis for informed decision making. For several years that regulatory system worked as it was designed: decisions were made within the legal time frames and were based on sound science.

However, since the second half of the 90s, some member states and EU institutions have, in a reaction to public concern in various food areas, embarked on some very counterproductive policies with regard to GMOs. We address these policies below.

1. Continuously intensifying the regulatory system, against mounting scientific evidence on safety.

Extensive biosafety research inside and outside the EU, and the cultivation of GM crops on hundreds of millions of hectares in many different environments worldwide, confirm that the GM crops cultivated today are as safe as - and sometimes safer - for human health and the environment than their non modified counterparts. However, rather than fine tuning the regulations on the basis of this evidence, the EU moves in the opposite direction, by continuously intensifying the regulatory requirements.

A recent illustration of this trend is the transformation of EFSA guidance into an Implementing Regulation that makes data and tests mandatory, without scientific justification. To give a specific example: despite scientific evidence and EFSA opinions that 90-day feeding tests provide only in specific cases useful additional information, those tests are now made mandatory.

The consequence is unnecessary use of test animals, which is a violation of Directive 2010/63, and a substantial and unnecessary increase in costs and delay for applicants. Another example is the blanket phasing out of antibiotic resistance genes, which are a tool in the transformation process. As scientific evidence and EFSA opinions show, there is no scientific basis for such a blanket phasing out. In addition, it hurts research in the public research sector, in particular in developing countries.

The result of all this is that the regulatory framework has changed from a tool for informed decision-making into an unnecessary, insurmountable hurdle for public research institutions. In fact, over the last years the regulatory system has derailed so much that even big biotechnology companies are moving their activities to other parts of the world. In this context, we also refer to the June 2013 report produced by 25 Member State science academies united in the European Academies Science Advisory Council (EASAC) expressing 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 EASAC is right in its conclusion that one of the key causes of all this lies in the trend of decision making based on short term political motives, rather than on scientific evidence and a long term, holistic vision.

In addition, and perhaps as a consequence, we also note that the implementation of risk assessment is gradually moving away from the principle of 'scientifically sound' as stipulated in the Directive. Some member states, and sometimes EFSA too, keep asking for more and more scientific data and tests, without a scientifically sound scenario of risk, but just with reference to undefined 'uncertainties'. The fact that some authorities keep asking for more and more scientific data without scientific justification seems to based on what is commonly known as the 'genomic misconception', i.e. the idea that genetic transformation causes more unintended changes in the genomes than natural crossing. Solid scientific data shows that this is a misconception.

We therefore call upon the European Institutions and EU Member States 1) to return to scientific evidence as the basis for decision making, 2) to bring the risk assessment back to the domain of 'scientifically sound', and 3) to acknowledge that the accumulated scientific evidence allows for reducing technical and/or procedural requirements for certain categories of GMOs.

2. Delaying decision making, despite positive EFSA opinions.

Despite positive opinions issued by EFSA, there are many dossiers that the European Commission has not submitted for a vote by the member states as the rules require. Currently there are many dossiers that are seriously delayed, sometimes for many years.

This practice of the Commission of not submitting dossiers for a vote is first of all a violation of EU rules as a recent ruling of the European Court of Justice made clear. In addition, these decisions by the Commission not to submit for voting means that farmers in Europe are *a priori* deprived from the freedom to choose. Moreover, this practice of delaying fuels the incorrect assumption that there must be something wrong with those GM crop varieties.

We call upon the President of the European Commission to secure that the European Commission abides by the law, and that it forwards dossiers for voting once they have received an opinion from EFSA.

Signatories: Association Française des Biotechnologies Végétales (AFBV, France), AgroBiotechRom (Romania), Conservation Agriculture Association (APOSOLO, Portugal), Asociación Agraria Jóvenes Agricultores (ASAJA, Spain), ASOPROVAC (Spain), FuturAgra (Italy), InnoPlanta (Germany), Ligii Asociatiilor Producatorilor Agricoli din Romania (LAPAR, Romania), The UK Farming Unions NFU, UFU, NFUS and NFU Cymru, Société des Agruculteurs de France (SAF), Public Research and Regulation Initiative (PRRI)

3. Invoking bans, without scientific justification.

Since the late 90s, some member states have made repeated use of the 'safeguard clause' in the regulations that allows the provisional prohibiting a GMO if there is new scientific information that suggests risk. As the opinions of EFSA demonstrate, for none of these bans was there a valid scientific justification. The reasons for these bans were political. For example, in an interview former French Prime Minister Fillon confirmed that there had been a deal between President Sarkozy and ecologists in which GM technology was 'traded off' for nuclear energy.

To make the situation worse, the Council did not support the attempts by the European Commission to force the Member States that had inappropriately invoked the safeguard clause, to abide by the law. To add to the confusion, the Commission then presented a 'nationalisation' proposal that would effectively reward those member states that have been ignoring the existing regulatory system.

We call upon the Member States and the EU institutions to abide by the rules that they themselves have created.

4. Supporting dubious biosafety research.

Last year a French research group published an article suggesting that rats developed cancer due to the consumption of GM crop plants. The article has appropriately been referred to the rubbish bin by EFSA and many national authorities and agencies, concluding that the methodology of the study was fundamentally flawed, the data misinterpreted, and the conclusions unsubstantiated. Nevertheless, some MEPs keep parading that flawed research, and the European Commission has recently made considerable funds available for research that would in fact be a repeat of the above research. This is not only a waste of research budget and – again - misuse of laboratory animals, but it also fuels the misperception that the suggestions of the French article may be true.

Conclusion.

In summary, the consequences of the above policies are:

- Unlike their competitors outside the EU, farmers in the EU do not have access to GM crop varieties that could help to increase productivity while having less impact on the environment. Not having these options available equals significant loss of income for farmers and significant missed opportunities to, for example, reduce the use of pesticides.
- There is a continued brain drain of public sector scientist and slowing down of public research in areas that are essential for the future of sustainable farming and self-sufficiency in Europe. As a result of this, an important root of innovation in the EU is constantly being cut back, and it may die.
- Europe remains a major food and feed importer, thereby continues to push prices up on the global food and feed market, with consequences for people in developing countries who often spend half of their income on food.
- The credibility of the EU objective of an internal market with freedom of choice, as well as the credibility of the EU regulatory system are seriously affected.

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We therefore call upon the EU institutions and Member States to take a broader, more holistic, and longer term view on agricultural production of food, feed and biomass, and to adjust the GMO policies and regulations accordingly.

The undersigned organisations are available for any questions you may have, and we offer to meet with you to provide further background and detail about the points in this letter.

A copy of this letter will be sent to involved Commissioners, the Chief Scientific Advisor to the President of the European Commission, EFSA, other involved services of the Parliament, Council and Commission, as well as to Member States. This letter will also be placed on the websites of the co-signing organisations.

Very sincerely

Em. Prof. Marc baron Van Montagu,

World Food Prize Laureate 2013
Chairman of the Public Research and Regulation Initiative (PRRI)

On behalf of: Association Française des Biotechnologies Végétales (AFBV, France), AgroBiotechRom (Romania), Conservation Agriculture Association (APOSOLO, Portugal), Asociación Agraria Jóvenes Agricultores (ASAJA, Spain), ASOPROVAC (Spain), FuturAgra (Italy) , InnoPlanta (Germany), Ligii Asociatiilor Producatorilor Agricoli din Romania (LAPAR, Romania), The UK Farming Unions NFU, UFU, NFUS and NFU Cymru, Société des Agruculteurs de France (SAF), and the Public Research and Regulation Initiative (PRRI).

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