Rfi6298 – CONTA CTS WITH EUROPABIO

EMAIL FROM EUROPABIO TO GM TEAM 13/2/14

Subject: Polish minsitry supportive of seed solution

Poland seems to have joined the group of countries calling for TS for seeds – we will need to discuss how to capitalize on this.

The Polish chain group have received the attached official response form the Ministry of Agriculture, which states that they will support TS for seeds (if a proposal were made by the EC), and confirms necessity of implementing unified threshold in EU.

Main points of this response are:

1. Poland like some of Member States understand necessity of implementing TS in seed. Council of European Union in "Council Conclusions on Genetically Modified Organisms (GMOs)" 2912th Environment Council meeting Brussels on 4 December 2008 also reaffirmed necessity of such regulations and invited the Commission to adopt appropriate thresholds (point (iv) 12-14).
2. So far Commission did not take action on this matter.
3. This issue returns regularly in the discussions, but is limited to postulates only. Commission informed that the discussion will be held soon.
4. If Commission or one of the Member Sate will presents a proposal on this issue, Ministry of Agriculture will consult this matter with signed organizations.

Signature:

Małgorzata Surawska is Head of Department of Breeding and Plant Protection in Ministry of Agriculture. This department is also dealing with GMO.

Best regards

PS : according to the MS overview table on the « gentlemen's agreement, PL is applying 0,5%

MINISTERSTWO
ROLNICTWA I ROZWOJU WSI

Warszawa, 24 stycznia 2014 r.

Departament Hodowli i Ochrony Roślin

HORzg 079- 19 /14

Otrzymują wg rozdzielnika

Szanowni Państwo!

W nawiązaniu do wspólnej prośby Federacji Gospodarki Żywnościowej RP, Izby Zbożowo-Paszowej oraz Polskiej Izby Nasiennej dotyczącej propozycji wprowadzenia unijnego, dopuszczalnego poziomu dla niezamierzonej (przypadkowej) obecności nasion GMO w partii tradycyjnych nasion, informuję uprzejmie, że resort rolnictwa jest szczególnie zainteresowany tą sprawą.

Potrzeba wprowadzenia w UE jednolitych poziomów domieszek nasion GMO w partiach nasion tradycyjnych była od wielu lat wskazywana przez większość delegacji podczas różnego rodzaju spotkań w Brukseli. Formalnym wezwaniem Komisji Europejskiej do podjęcia działań były konkluzje Rady przyjęte 5 grudnia 2008 r., w których znalazł się zapis

„*(iv) europejskie wartości progowe etykietowania materiału siewnego*

12. RADA PRZYJMUJE z zainteresowaniem wiadomość o rychłym zakończeniu analizy skutków, jaką Komisja prowadzi w odniesieniu do ustanowienia progów dla materiału siewnego;

13. RADA PONOWNIE PODKREŚLA, że na szczeblu europejskim potrzebna jest co najmniej jedna wartość progowa – ustalona na podstawie odnośnych kryteriów, takich jak kryteria określone dla danego gatunku czy informacje naukowe – powyżej której należy na etykiecie informować o możliwej przypadkowej obecności dozwolonych GMO w konwencjonalnym materiale siewnym; PODKREŚLA, że wspomniane wartości progowe należy ustalić na możliwie niskim poziomie, który byłby realistyczny, proporcjonalny i funkcjonalny dla wszystkich podmiotów gospodarczych, oraz że wartości te muszą przyczynić się do zapewniania wyboru producentom i konsumentom produktów konwencjonalnych, organicznych oraz genetycznie zmodyfikowanych;

14. RADA ZWRACA SIĘ do Komisji, aby jak najszybciej przyjęła odpowiednie wartości progowe w trybie określonym w art. 5 decyzji 1999/468/WE, uwzględniając najnowsze naukowe obserwacje i informacje o rozprzestrzenieniu, przypadkowej obecności i mieszaniu się w trakcie hodowania, rozmnażania, sprzedaży, a także stosowania materiału siewnego."

Jak dotąd Komisja nie podjęła czynności w kierunku wypełnienia niniejszego zobowiązania.

Sprawa braku regulacji unijnych określających poziom domieszek GMO w nasionach tradycyjnych wraca regularnie w dyskusjach podczas szeregu spotkań, jednak ogranicza się wyłącznie do postulowania przez państwa członkowskie potrzeby dyskusji na ten temat, zaś ze strony Komisji sygnalizowane są jedynie informacje, że dyskusja nastąpi wkrótce. W sytuacji przedstawienia przez Komisję, albo jakiekolwiek inne państwo członkowskie konkretnej propozycji rozwiązań Departament zadba, aby została ona przekazana Państwa organizacjom do konsultacji.

Z poważaniem,

DYREKTOR DEPARTAMENTU

Małgorzata Surawska

Otrzymują:

1. Pani Maja Karpiel – Sekretarz Generalny Polskiej Izby Nasiennej, ul. Kochanowskiego 7/603, 60-845 Poznań
2. Pan Adam Tański – Prezes Izby Zbożowo-Paszowej, 00-131 Warszawa, ul. Grzybowska 2 lok. 49
3. Pan Rajmund Paczkowski – Prezes Federacji Gospodarki Żywnościowej RP, Kopernika 34 lok. 2, 00-336 Warszawa

Do wiadomości:

Ministerstwo Zdrowia - Departament Zdrowia Publicznego

EMAIL FROM ESTEL CONSULT LTD GM TEAM 11/2/14

Subject: EuropaBio workshop

Dear all,

Thank you very much again for agreeing to chair a session at the workshop. As chairs all you have to do is introduce the speakers, moderate the time and questions after each talk and during the Q&A sessions. The programme is very packed and some of the talks look a bit long, so if a speaker goes over time they will miss the chance of questions after their talk and these will have to come up during the Q&A at the end of the session. The only exception would be the EFSA talk where at least a couple of questions should be allowed. I attach a copy of the updated programme and a copy with most of the biographies. Please let us know if you have any questions. Otherwise we will see you on Tuesday.

Best regards

PLEASE SEE EUROPABIO WORKSHOP PROGRAMME ATTACHED – FEBRUARY 2014

EUROPA BIO WORKSHOP

SPEAKERS BIOGRAPHIES

Session 1:

Cecile Girard

Cécile Girard is a senior evaluator with the Plant and Biotechnology Risk Assessment Unit of The Canadian Food Inspection Agency. Cecile graduated from the Institut National Agronomique de Paris-Grignon in France and completed her PhD at the INRA de Versailles on the impact of GM canola on pest beetles and honeybees. Then she worked for three years at a post-doc fellow at Université Laval in Quebec, Canada on plants' response to pests and pathogens. She joined the Canadian Food Inspection Agency in 2003 and cumulates 10 years experience in evaluating the environmental safety of plants with novel traits.

Flavio Finardi

Associate Professor at Department of Food and Experimental Nutrition, at University of Sao Paulo, MSc and PhD in Food Science (University of Sao Paulo); he was Visitor Researcher at FDA - Washington, DC, Research Fellow at University of California, Davis, Associate Researcher in Plant Molecular Biology at University of California, San Diego, Research Fellow in Biotechnology at Universidad Politécnica, Madrid and Visitor Researcher at University of Nottingham, UK. Research interest: GMO and Food Safety. President of the Brazilian National Technical Commission of Biosafety - CTNBio (March, 2012-March,

2014).

Claudia Paoletti

Session 2:

Wayne Parrot:

Wayne Parrott received a degree in agronomy from the University of Kentucky, and MS and PhD degrees in Plant Breeding and Plant Genetics from the University of Wisconsin-Madison. He joined the faculty at the University of Georgia in 1988. Since then he has been conducting research on the development, use and safety of transgenic (i.e., GM) crop plants, using grant monies from USDA-NIFA, NSF, DOE and the United Soybean Board. He has published a guide for environmental risk assessment of GMOs, along with over 90 journal articles in refereed publications and 14 book chapters. He has served terms on the editorial boards of Plant Cell Reports, Plant Cell Tissue and Organ Culture, and Crop Science. He has served as elected chair of the biotechnology section of the Crop Science Society of America and of the plant section of the Society for In Vitro Biology, and is a fellow of both of these societies. He is actively engaged in training graduate students and postdoctoral fellows, and teaches graduate-level courses in genetics and undergraduate courses in agroecology and sustainable agriculture. He has traveled extensively throughout Latin America and other countries, and advised legislators and regulators in the various countries on the requisites for a functional regulatory system that ensures the safety of GM products. He volunteered for 6 years as a scientific advisor to ILSI-IFBiC.

Peter Shewry

Prof Shewry is currently Distinguished Research Fellow at Rothamsted Research and Professor of Plants and Health at the University of Reading.

He leads a research programme on the development, structures and composition of wheat grain focusing on improving the quality of wheat for human health, notably the content and composition of dietary fibre and phenolic acids, and for milling and breadmaking including grain architecture and the deposition, composition and properties of grain proteins and lipids.

He is the author of over numerous refereed papers in international journals, has edited or co-edited 17 books (including co-editing the 4th edition of Wheat: Chemistry and Technology) and has written many major reviews and book chapters. In 2000 he was awarded the Thomas Burr Osborne medal by the AACC and in 2002 was the joint recipient (with Donald Kasarda) of the Rank Prize for Nutrition.

Over a 40 year career he has collaborated with many international scientists, most recently on the EU FP7 HEALTHGRAIN project (Exploiting the bioactivity of European cereal grains for improved nutrition and health benefits). He is currently Reviews Editor for Journal of Cereal Science and a Trustee and Chair of the Nutrition Committee of the Rank Prize Funds

Philip Brune, Ph.D.

Syngenta Crop Protection, LLC

Dr. Philip Brune currently holds the position of Technical Expert for Compositional Analysis, Product Safety for Syngenta Crop Protection, LLC in Research Triangle Park, NC, USA. He has been in this position since 2009. Dr. Brune received a B.A. degree in Biology from Wittenberg University (Springfield, OH), and a M.S. degree in Plant Pathology from The Ohio State University. He then went on to obtain a Ph.D. degree in Plant Pathology from North Carolina State University. From 1995 to 1997, Dr. Brune held an assistant professorship in the Math and Science Department at St. Mary's College (Raleigh, NC). In 1997, he accepted a position with Syngenta Crop Protection, where he has held positions as a research scientist (conducting field research on disease control of most major field, fruit, and vegetable crops), in data management (data capture, analysis, and mining; experimental design), and as team lead for Compositional Analysis of genetically modified crops. Dr. Brune was Co-Chair of the International Life Sciences Institute (ILSI) Crop Composition Task Force, and was one of the organizers of the ILSI International Food Biotechnology Committee (IFBiC) Crop Composition Workshop held in Washington D.C. in September 2012.

Session 3:

Agnes Ricroch

Dr Agnès Ricroch is a national correspondent of the Academy of Agriculture of France. She is associate

professor in Evolutionary Genetics and Plant Breeding at AgroParisTech in Paris, France. She is adjunct professor at Pennsylvania State University, College of Agricultural Sciences, USA. She carries out her research at the Ecology, Systematics and Evolution laboratory (Orsay University, Cnrs, AgroParisTech). She holds a PhD in Genetic Resources and Plant Breeding and Accreditation to Supervise Research in Genetics (Orsay University). She was a Visiting Researcher fellow at Texas Tech University and Duke University, USA, and the John Innes Institute, UK. She was a visiting professor at melbourne University, Australia. She is editor of three books on plant biotechnologies. She is member of the Society of Writers of France.

Rod Herman

"Rod is currently a Science Advisor in the Biotechnology and Regulatory Sciences Group within Dow AgroSciences. He has worked in the area of GM safety assessment for 14 years, over which time he has published over 50 papers on the subject."

Session 4:

Louise Ball

Greg Ladics

Gregory Ladics received his BS in Toxicology from the Philadelphia College of Pharmacy and Science and his PhD in Pharmacology and Toxicology from Virginia Commonwealth University. He is a Research Fellow with the DuPont Co., Diplomate of the American Board of Toxicology and Fellow of the Academy of Toxicological Sciences. He serves on the International Life Sciences Institute's Technical Committee on Protein Allergenicity as Co-Chair and chairs the Crop Life International Expert Allergy Team. He is a member of the Editorial Boards of the Journal of Immunotoxicology and Toxicology Letters. Dr. Ladics has co-authored over 160 abstract, journal, and book chapter publications in the field of Immunotoxicology and Allergy.

Alan Raybould

Alan Raybould is a Science and Technology Fellow in the Product Safety department at Syngenta's Jealott's Hill International Research Centre in the United Kingdom, and a visiting Professor in the School of Biological Sciences in the University of Southampton. Alan joined Syngenta in November 2001, and his current job involves leading the preparation of environmental risk assessments as part of worldwide regulatory submissions for Syngenta's transgenic crops. His research interests include the development of efficient and effective environmental risk assessments for transgenic crops with stacked traits, predictive ecological modelling of the effects of agricultural management on ecosystem services, and the development of regulatory policies that encourage agricultural innovation and environmental protection.

Before joining Syngenta, Alan was a Principal Scientific Officer at the UK's Centre for Ecology and Hydrology, where he led a research group developing methods for estimating gene flow among populations of wild plants, and studying the ecological genetics of insect and virus resistance in wild relatives of crops.

Jonathan Philipps

Currently Regulatory Affairs Pipeline Strategy Lead for Monsanto based in St Louis, USA. Accountable to develop and execute cross-cutting regulatory strategies for Monsanto Biotech pipeline programs. Previously worked in Auckland, New Zealand for Genesis R&D Corp Ltd under contract to ArborGen LLC, South Carolina, USA to improve wood quality traits and Fonterra dairy company to improve pasture grass. Before joining Monsanto I was an Assistant Professor in Molecular Plant Biotechnology at Bonn University, Germany.

Boet Glandorf

Dr. Boet Glandorf has a PhD in plant pathology and has practical experience in performing field trials with GMM in the Netherlands and the US for several years. Since 2000 she works as a senior risk assessor at the GMO office of the Dutch National Institute of Public Health and the Environment. She is responsible for the environmental risk assessment of field trials and commercial release with GM plants and for the implementation of post-market monitoring. She functions as a scientific expert for the Ministry of the Environment for all aspects concerning environmental risk assessment of

GM plants.
She was part of several technical working groups of the European Commission, is a member of scientific committees of several national research projects and gives lectures and training in risk assessment of GMO's. She is also functions as a member of working groups of the EFSA GMO and FEEDAP Panel, involved in the molecular characterization of GM micro-organisms and GM plants

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EMAIL FROM EUROPABIO TO GM TEAM & OTHER WORKSHOP PARTICIPANTS 11/2/14

Subject: EuropaBio workshop - Scientific aspects of comparative assessments for GM plants and their use in risk assessment

Dear workshop participant,

Thanks for your registration. EuropaBio is pleased to welcome you next week on Tuesday 18 February and Wednesday 19 February at the EuropaBio workshop on comparative assessments of GM plants.

The workshop will take place at The Hotel, Boulevard de Waterloo 38, 1000 BRUSSELS. A map is available at the following link.

Enclosed you can find the updated programme of the workshop. Please note that registration on Tuesday starts at 08:15. Tuesday evening, after the workshop, a cocktail is organised at the Hotel. Afterwards, for those that registered, dinner will take place at 19:30h in Cospaia (Capitaine Crespel 1, 1050 Brussels), which is located at walking distance from the Hotel.

Don't hesitate to contact me, should you have any further questions.

Best regards,

SECRETARY OF STATES LETTER TO EUROPABIO AFTER 22/1/14 GROWING VOICES EVENT

Thank you for your letter of 10 January about EU decisions on the authorisation of GM products.

As I made clear in my speech at the 'Growing Voices: Healthy Food' event on 22 January, the UK Government believes strongly that GM regulatory decisions should be based on the scientific evidence. We will therefore be voting in favour of authorisation for 1507 maize, given the clear opinion of EFSA and the independent scientific group that advises UK Ministers on this subject.

I will continue to argue for the EU regime to operate so that safe GM products are approved without unjustified delays, and for all our EU partners to recognise that this is important for several reasons, including innovation, sustainability, economic growth, trade and the future competitiveness of EU agriculture.

EMAIL FROM EUROPABIO TO GM TEAM 9/12/13

Subject: GM traces in seeds

Dear Mike,

Please find attached a DRAFT report which we were zorking on with the European Seed Association early this year, regarding GM traces in seeds, more precisely the (inter-twined) issues of

- A long discussed labelling threshold for approved GM seed in conventional seed batches
- A technical solution for as yet non approved GM seed in batches of conventional or approved GM Seed.

Hope this is useful. As it is only a draft document, there may be some typos etc. in there.

Please don't hesitate to get in touch with any questions.

Best regards

ADVENTITIOUS PRESENCE IN SEEDS REPORT ATTACHED

LETTER FROM SECRETARY OF STATE TO EUROPABIO OCTOBER 2013

SOS CASE 324435 – EUROPABIO & ABC

Thank you for your letter of 30 September.

As you'll appreciate from the speech that I gave in June, the UK Government shares your concern about the operation of the EU regime for GM products. I am clear that the responsible use of GM technology can make an important difference to the future of agriculture and contribute to economic growth. We therefore want an EU framework that enables rather than hinders its development, one that encourages innovation and investment by offering a timely, predictable route to market for safe products. This is the view that we will continue to argue in public, both in the UK and in EU discussions.

I have noted your comments about not pursuing the GM cultivation dossier and realise that the proposal on the table is less than ideal. I would however like to keep open the possibility that a worthwhile solution might still be found, especially if an option is negotiable that would address the concern about post-approval opt-outs. My view remains that it would be very helpful to achieve a new understanding at EU level that allows for GM cultivation at least in those countries that are open to this.

Finally, I can confirm that your recommended improvements to the EU regime are all points that we have been raising ourselves. We will continue to call for action and work with other like-minded Member States to try and make substantive progress

EuropaBio
The European Association for Biotechnology

abc
AGRICULTURAL BIOTECHNOLOGY COUNCIL
promoting fair debate on behalf of the UK agricultural biotechnology industry

Rt Hon Owen Paterson MP
Department for Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London
SW1P 3JR

30 September 2013

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

Dear Mr Paterson,

EuropaBio and the Agricultural Biotechnology Council (abc) represent biotechnology companies, including in the pharmaceutical, industrial, food and agricultural sectors, who jointly contribute billions to the EU economy, and are a major motor of job creation given the large SME base.

We are writing to you to register our concern about the implementation of agreed EU policies related to biotechnology in agriculture, which we believe are increasingly at odds with political goals such as growth, job creation, innovation, and investment. During these uncertain economic times, the regulatory uncertainty experienced by our companies and the resulting threat to investments in the UK and the EU as a whole are particularly regrettable.

It has been extremely encouraging to hear you reiterate the Government's commitment to unlocking the potential of British agricultural science, throughout the past year. We cannot emphasise enough the vital role which this vocal leadership plays in encouraging the rest of Europe to defend a science-based approach to policy making; leadership which is backed up by the commendable work your officials are carrying out on the ground. We would therefore like to ask that you continue to set the agenda, and for your continued support in implementing a number of required improvements listed below.

Nationalisation proposals
We recognise past political efforts to achieve progress on cultivation of GM crops in the EU. We strongly support the principle of a "Community authorisation system" based on science, and we can accept the concept to grant freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory. However, the implementation needs to be compatible with European law, good governance, predictability and workability, and science-based decision-making. Unfortunately, all the proposals considered to date were only partly compatible, because they included post approval opt-outs which would undermine the scientific evaluation of our products and the credibility of the system. In our opinion, the nationalisation proposal should not be pursued further, and efforts should focus on implementing EU law by putting GM products with a positive safety assessment to the vote whether for cultivation or for import.

In the past we have indicated that we 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

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commercial sense to market specific products for cultivation, but only in the context of the framework of the existing legislation and not as part of any package that would include any form of post-approval opt-outs.

Unexploited economic potential

Genetically Modified (GM) crops are being grown on 12% of the world's cropland. Our clothes 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]. According to the Agricultural Technologies Strategy, the entire agri-food supply chain is estimated to contribute £96 billion or 7% of GVA. The UK Government has repeatedly recognised that biotechnology plays an important role in economic growth. However, as a result of the malfunctioning system for GM import authorisation 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[ii]. Regarding planting of GM crops, EU and UK 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.[iii]

Problems with improper implementation of the regulatory system

The EU has a solid legal framework regarding agricultural biotechnology, but in practice, the process for authorising 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[iv] 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 authorisation 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.[v] The backlog of GM dossiers pending authorisation already exceeds the number of authorisations received, and continues to grow quickly.

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 authorisations granted by governments around the world, and by various reports and studies published by the EU and others. It is challenging to reassure the public about safety when some national governments persistently vote against the scientific consensus expressed within EFSA positive opinions. While the European Commission has been defending, to a certain extent, the science-based system, it is regrettable that some of its recent initiatives have contributed to undermining the best scientific advice and evidence (e. g. failure to put risk assessed products to the vote within the legal timelines[vi]).

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. This move goes against the EU's science-based system given that this implementing regulation introduces non-scientific, politically driven criteria 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[vii] who have opposed the adoption of such a Regulation over a number of years. The result is a disproportionate increase in the regulatory burden and 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.

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

1. Ensure that decisions are taken on the basis of science-based risk assessment and not based on public perceptions of risk. This applies particularly when Member States vote at committee level on risk assessed GM products.
2. Promote more efficient GM authorisations, by insisting that risk assessed products be put to the vote in accordance with the timelines set out in EU legislation and that more efficient procedures be put in place (e. g. written procedure at Appeal Committee stage).
3. Protect international commodity trade by speedily introducing the planned harmonised sampling and testing protocol for food ("technical solution") to achieve more legal certainty for economic actors and authorities when implementing the current zero tolerance principle. The EU should also be encouraged to actively participate in on-going international efforts to address the challenge of low level presence spurred by FAO, OECD and the Global LLP Initiative.
4. Protect the internal market by enacting a technical solution for seed, and a labelling threshold for the adventitious presence of GM seeds in non GM seed lots, as repeatedly and unanimously requested by Ministers since 2006. Divergent national approaches are distorting the internal market for seeds considerably, and there is an important lack of legal certainty.
5. Clearly communicate that EU-authorised products are as safe as conventional crops.

A negative precedent affecting other regulated sectors
The systemic institutional failure described in this letter may be specific to the field of agricultural biotechnology. However, the fact that undue political interference is more and more prevalent in EU approval processes is increasingly felt among many regulated industries. 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 have addressed a similar letter to Commission President Barroso and Commissioner Borg, and to a number of ministers from other Member States. We remain at your disposal for any further information and thank you in advance for your kind attention.

Yours sincerely,

Nathalie Moll,
Secretary-General EuropaBio

Dr Julian Little
Chair, Agricultural Biotechnology Council

[i] http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/42837897.pdf
[ii] 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*
[iii] http://www.ncbi.nlm.nih.gov/pubmed/21272674
[iv] *"Planting the Future"*, European Academies Science Advisory Council (EASAC), www.easac.eu
[v] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-004184&language=EN
[vi] http://www.europabio.org/positions/49-years-undue-delays-eu-approval-gm-products
[vii] *"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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EAMIL FROMEUROPABIO TO GM TEAM 16/9/13

Dear --------,

As agreed, this is the link to the CLI compact:

http://www.croplife.org/the_compact in which the big 6 companies voluntarily offer States a legally binding mechanism for seeking redress from a responsible party should a GMO release ever cause damage to biological diversity.

Please let me know if I have forgotten to send you anything we agreed on last week.

Best regards

SEE ATTACHED DOCS:

HARMONISED POST MARKET ENVIRONMENTAL MONITORING PLAN FOR CULTIVATION IN THE EU – SEPTEMBER 2013

HARMONISED INSECT-RESISTANT MAIZE PLAN – SEPTEMBER 2013

FARMER QUESTIONNAIRE

LETTER FROM EUROPABIO TO COMMISSIONER BORG 2/9/13 – SEE ATTACHED

.EMAIL FROM EUROPABIO TO GM TEAM 17/4/13

Subject: RE: Follow up from Brussels meeting

Dear

thanks a lot for your quick reply, we're available to meet (almost) any time on 30 April, please let us know which time fits you best.

- **Regarding the environmental focus**, the most impressive numbers I found are from farming first regarding US agriculture:

In the United States, land use per unit of production has decreased since 1980 for corn (-30%), cotton (-30%), and soybeans (-35%), which are predominantly GM varieties in the USA today (ca. 90%). In the USA, soil erosion per unit of production has decreased by about two thirds since 1980 for maize, cotton and soybeans, which are predominantly GM. Emissions have already been massively reduced in US agriculture since 1980 for corn (-36%), cotton (-22%) and soybeans (-49%).

- **Regarding the development angle**: we absolutely agree that NGO influence is important, but it may also be a difficult one to put one's finger on as you rightly mention. On this, we would think Sir Brian and David Bennett are probably the best people to talk to. Several chapters of their book "Successful Agricultural Innovation in Emerging Economies" touch on this.

- **Regarding geographical scoping**, please be aware that our EuropaBio board met the new Commissioner in the second half of March and renewed our "offer", however there has never been any meaningful reply on this from the Commission, or rather more concretely, the idea was dismissed by them in the past. Your question is pertinent whether this will actually be tried in practice any time soon. We hope to be able to tell you by 30 April.
Excerpt from our leave behind to Commissioner Borg:
Industry accepts the principle behind Barroso's approach: "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". The last

Danish proposal provides for "*freedom for Member States",* but undermines the "*system based on science*",

because it allows post approval opt-outs based on non-scientific grounds. Such opt-outs undermine the scientific

evaluation and many national decision-makers believe the grounds will not withstand scrutiny in Courts and the

WTO. Opt-outs at any time create a fully unpredictable and therefore unworkable market.

"Alternative proposal. If it helps to achieve the Barroso vision, and to unblock the approval system, the seed

companies are open to dialogue with individual Member States, on a product-specific basis. The Commission has

indicated that geographic determination by the applicant is already possible and legal, and any such agreed

determination could be included in product approval decisions, by way of limitations where the product will be

cultivated. The seed 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 the existing approval system, 2) it allows each Member State to

achieve its political objective regarding GM cultivation, 3) it can be achieved immediately, 4) it requires no legislative

change (thus no co-decision), 5) it allows farmers access to a technology in some states."

Best regards

EMAIL FROM GM TEAM TO EUROPABIO 17/4/13

Subject: RE: Follow up from Brussels meeting

Thanks

I think we've captured most of these points in material we've developed but it's very useful to see all this together in one place – a few quick, minor reflections

- We prefer the word 'focus' to 'spin'
- If the national decision making proposal ever secured agreement we'd have to contemplate a regional approach in the UK given the stances adopted by Scotland, Wales and Northern Ireland so have already thought through the consequences of this. We concluded that regional opt-outs would be far more preferable than the UK voting in favour of a product application and then submitting a request as competent authority for a regional ban (e.g. in Wales/Scotland/Northern Ireland or all 3) that we'd know could be vulnerable to legal challenge.
- I completely agree about the trade barrier issues resulting from the operation of the entire regime (food/feed/seed) and recognise that this is the short term imperative to be resolved. We'll have to see how hard the US push for this in FTA talks. Linked to that you may have seen that most of our retailers now have dropped their blanket non-GM eggs and poultry supply chain policies as a response to global soya trading realities. We're monitoring the effects of that closely.
- One angle I perhaps expected to see in your list was the developmental one, particularly following the event in Brussels (which was perhaps dominated by trade considerations for understandable reasons). We've received (mostly anecdotal) evidence that negative European attitudes to GM are generating resistance to the technology in the parts of the world which most need access to agricultural innovations, particularly sub-Saharan Africa. For example, farmers may avoid using GM crops in fear of being locked out of certain (non-GM) European markets. Some decision-makers in the developing world may also ban GM crops in reaction to the perceived European view that GM crops are inherently "unsafe". The potential crucial benefits of improved crop varieties on a global scale sometimes get ignored in EU-centric GM debates because currently we're largely insulated from food price/supply shocks etc but it's worth shining a light on this as one consequence of the EU situation beyond our borders. And when you factor in the reports (including one from the Indian speaker at your event) about the damage caused by European anti-GM NGOs actively campaigning / scaremongering in the developing world it becomes an even more stark point – particularly if we talk in terms of 'Hunger' as opposed to the slightly more opaque term 'food security'.

Finally, I'd be interested to know if you or ------- have had any further discussions with companies about potentially introducing (or reintroducing) cultivation applications with geographically limited

scope as a way of testing whether or not the stage-1 opt-out approach could be made to work under the current rules without the need for a legislative proposal. This may be the only way of prompting progress this side of the EU elections so would be good to know what your latest thinking is as it's something I'm keen to investigate further as a possible way forward – particularly once the Pioneer 1507 outcome is known. I'm expecting to be in Brussels for a half day meeting on 30 April so could arrange my travel plans to include a quick catch-up meeting with you if you're both available?

Please let me know – and let's keep in touch.

EMAIL FROM EUROPABIO TO GM TEAM 17/4/13

Subject: Follow up from Brussels meeting

Dear ,

Following up from our meeting in Brussels on 7 March, please find below our slightly delayed input. You have probably already thought of these points.

- We would generally advise to give the message a strong environmental (but of course also innovation and competitiveness) spin; and ideally a focus not only on cultivation in the EU, but also on the need to address the trade barriers.
- With regard to "nationalisation", we would generally advise caution in messaging, even if it may appear tempting at first sight to link the GM issue with a "devolution from Brussels" agenda (consider that "nationalisation" may in fact become "regionalisation", the German Laender have recently formally requested a guarantee to be allowed to put regional opt outs in place under nationaliation).

A possible line of argumentation could include some of the following:

1) **Biotech has long arrived in every-day applications.** Eg. washing powders which allow washing at lower temperatures, Pharmaceuticals such as insuline, but also food applications produced with the use of GM microorganisms.

2) **Product safety of biotech crops has been confirmed over and over again**, so there is no scientific basis for reluctance. Ethical or ideological reluctance cannot be a reason to prevent

3) Biotech Crops, while not a "silver bullet", do have a very large potential to help boost agricultural productivity and reduce the environmental impact of agriculture.

4) UK generally supports the very **stringent EU authorization system** for biotech crops, but this system has been blocked in practice. We need to put an end to a situation where public authorities break their own laws and undermine confidence in safe technologies and in the very institutions whose task it is to ensure that our food is safe. **The system and its credibility has been undermined by**:
    a. Certain media and public institutions increasing the visibility of unfounded scare stories.
    b. public institutions acting in clearly illegal ways (EU Commission on unduly delaying the authorization process, with a de facto moratorium on the approval of GM crops for cultivation in Europe; certain Member States by illegally banning cultivation). National bans have been backed up with "new evidence" of "unsafety" that never gets confirmed when scrutinized by the responsible risk assessing institutions.

5) There is concern that there is **a wider a trend** where Commission **policy-makers are overruling or compromising on, the best available scientific advic**e, in order to derive political benefit or attain political majorities. The negative impact includes:
    a. **Contradicts growth & innovation agenda,** and is contrary to the promotion of science and science-based industries. Moves away from closing the research to market gap, and away from turning research and innovation into jobs and growth. In the case of biotechnology, contradicts classification of biotech as "key enabling technology" in EU and various national growth programmes. It is becoming more challenging to convince companies that the EU is the best place **to innovate, invest and create jobs**. Some companies are already moving to geographies where regulatory regimes are more predictable and less politicized.
    b. **Consumer confidence** in our products and in EU procedures and agencies is weakened when science-based decision-making appears to be compromised for political benefit. Irrational fears and a polarized political climate is promoted.
    c. **Trade relations become more difficult** when restrictions and perceived non-tariff barriers are not even based on objective criteria. In the case of ag biotech, this seems particularly striking as the EU and UK are highly import dependent on certain (GM) commodities.
    d. In the case of agricultural biotechnology, **preventing EU farmers from using all available tools** to become more competitive and more environment friendly seems in contradiction with the global food security challenge, and with the need to save European tax payers money.

We hope this helps. Do by all means let us know if you need more information on any of the above points.

Best regards

SEE ATTACHED EUROPABIO LEGAL BRIEFING PAPER – FEBRUARY 2013

EMAIL FROM EUROPABIO TO GM TEAM 9/1/13

Subject: RE: EuropaBio ERAG Workshop 2013: Invitation to contribute

Dear

Many thanks for your email and interest in the workshop.

Unfortunately we have not received your fax. Would you be able to send the form by email or again by fax (003227354960) ?

Best regards,

EMAIL FROM GM TEAM TO EUROPABIO 3/1/13

Subject: RE: EuropaBio ERAG Workshop 2013: Invitation to contribute

Dear

I hope that you have received a FAX confirming that I can participate in the ERAG workshop on 27/28 Feb. Please let me know if it hasn't arrived.

Regards,

EMAIL FROM PERSEUS TO GM TEAM 2/1/13

Subject: EuropaBio ERAG Workshop 2013: Invitation to contribute

Dear ----------I,

27 and 28 February have now been set as dates for the EuropaBio Workshop on "Environmental Risk Assessment of GM crops in practice". Attached you will find an official invitation letter from EuropBio to contribute to this event, the draft programme and a registration form.

Given the limited timeframe to finalize the programme, we would appreciate a quick confirmation.

For practical, logistical matters you are kindly invited to contact me directly. For the topics of the meeting, ---------- will be your contact person.

Looking forward to your participation in a successful workshop.

SEE ATTACHED REPORT ON DELAYS IN EU APPROVALS OF GM PRODUCTS

EUROPABIO PAPER OCTOBER 2012

Key messages on ANSES and HCB opinion

PRODUCT SAFETY

- An extensive body of scientific evidence, reviewed by regulatory agencies around the globe, supports the safety of plant biotechnology in general as well as the specific safety of NK603 maize and Roundup herbicide.
- *EFSA as well as a number of national authorities such as the* German*,* Dutch*,* Romanian, French (ANSES, HCB) *and* Danish *but also the* Australian and New Zealand *authorities rejected the science of Séralini's study and agreed that there is no basis to question the previous safety evaluation of NK603 maize which says that this product is at least as safe as conventional maize.*
- The French Haut Conseil des Biotechnologies (HCB) adds to this its recommendation "for a long term, independent, contradictory and transparent study, meaning that this should be done under the umbrella of public institutions, on the health safety of Maize NK603".
- We believe the HCB and ANSES should help society understand this evidence rather than call for new long terms tests for which there is no scientific need. Methodology for assessing the safety of biotech crops is well established in the EU and globally and approved products have a long history of safe use.
- All GM crops currently on the market have proven to be safe *for human and animal consumption and for the environment*.
- Biotech crops are among the most extensively tested foods in the history of food.
- An estimated two trillion meals containing biotech-derived ingredients have been eaten around the world over the last 15 years without a single substantiated case of ill-health.

EU RISK ASSESSMENT

- In the EU, GM products go *through one of the most stringent risk assessments in the world, before entering the market. They do so only after it is concluded that they are at least as safe as their conventional counterparts.*
- *The GMO risk assessment is the central element of the science-based authorization procedure, and is carried out by the European Food Safety Authority (EFSA).*
- *The product in question has been approved for consumption in 10 countries in addition to the European Union, including Argentina, Australia, Brazil, the United States, Japan, Mexico and New Zealand.*

NEED TO REFORM EU RISK ASSESSMENT ON GMOs?

- *A flawed study cannot be the basis for serious political decisions as to whether the EU risk assessment needs to be further reformed.*
- *In France, unlike almost all EU countries, a very high level of attention has been given to a flawed study.*
- *The EU authorisation system for GMOs was put in place based on legislation decided by the European Parliament together with the Member States including France. All actors including France agreed that the risk assessment must be science based. EU risk assessment has been continually evolving in line with scientific progress.*
- *The EU risk assessment system for plant protection products has historically evolved as a distinct regulatory framework, which is also known to be one of the strictest of its kind world-wide. The EU plant protection legislation was only reviewed very recently, in a lengthy process, with the full involvement of France.*
- *The European Court of Justice has found that the scientific rationale provided by the French government to limit GMO has been scientifically flawed. National governments that ban products based on perception rather than based on solid scientific evidence will run the EU internal market and the WTO into severe difficulties.*

NEED FOR LONG TERM STUDIES?

- In a written answer to a parliamentary question by Eric Andrieu MEP (Socialist, France) on 22 October 2012, the European Commission states that "*a number of long-term studies have already been performed on GMOs as indicated in a paper published in April 2012 in the "Food and chemical Toxicology" journal. This paper reviewed 12 long-term feeding studies going from 182 days to 2 years, and 12 multigenerational studies (from 2 to 5 generations).*"
- *Several long-term studies have concluded that biotech crops pose no food safety risks, including:*
    - *A 2008 two-year rat feeding study by Y. Sakomoto et al. found that biotech soybeans pose no health risks.*
    - *A 2012 assessment by C. Snell et al. reviewed 12 long-term feeding studies of biotech maize, potato, soybean, rice, and triticale and found that biotech crops are nutritionally equivalent to their conventional counterparts and can be safely used in food and feed.*
- With regard to the stated need for independent studies, it needs to be remembered that applicant companies are currently required to produce and finance a long series of studies which take several years and usually cost millions of Euros per product. It is the key task of experts appointed by EFSA and those appointed by national including French risk assessment authorities to evaluate these studies.

Sometimes the claim is made that the data submitted by companies are not available. This is an inaccurate claim. All non-confidential data submitted can be requested from the authorizing authorities (at national level or European level). The European Commission determines, in

consultation with the applicant, which information may be considered as confidential and informs the applicant of that decision following a standard procedure. The Regulation stipulates that certain information may never be considered as confidential. Information is only considered as confidential when disclosure of this information may significantly harm a company's competitive position or if it would undermine the privacy of individuals. For NK603, as for any other GMO, this means that all data and information relevant for the safety assessment is available to the public following a standard procedure

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NOTIFCATION FROM EUROPABIO TO GM TEAM AND OTHERS

SAVE THE DATE

EuropaBio Workshop on

the risk assessment requirements for GM food and feed with respect to toxicology and allergenicity

24-25 October 2012

Brussels

The objective of the workshop is to discuss key issues related to a range of new and updated guidance documents published by EFSA over the last years for the risk assessment of GM food and feed in accordance with Regulation (EC) No 1829/2003. For example:

- Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed (2010)

- Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed (2011)

• Guidance for risk assessment of food and feed from genetically modified plants (2011)

More specifically, the focus of the workshop lies on the requirements for toxicology and allergenicity assessment. The workshop aims to bring together representatives from Academia, EFSA, the European Commission, EU Member States and industry. The workshop will provide an opportunity to achieve a common understanding among stakeholders on the requirements laid out in these EFSA guidance documents.

Please feel free to forward this information to any other appropriate representative with regard to the topic within your organization. A more detailed program and the invitation will follow soon.

To register/for further information contact ---------- Brussels Belgium

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SEE ATTACHED EUROPABIO PAPER – NEW STRATEGY ON GMOS. SEPTEMBER 2012

SEE ATTACHED – KEY MESSAGES FROM SERALINI STUDY