Ref. JA/TK/EU/3272

Commissioner Kyprianou
EUROPEAN COMMISSION
DG Health and Consumer Protection
B-1049 BRUSSELS

07 November 2007

Dear Commissioner Kyprianou

You will recall I recently asked a series of Parliamentary questions of you in relation to lengthy delays in the EU approvals process for new GMO varieties.

While I understand the Maize variety Herculex has finally been approved through the comitology procedure, I believe this debacle represents only the tip of the iceberg, should urgent action not be taken to overhaul the approvals system for GMO's.

I wish to commend to your attention the recent DG AGRI Report, *'Economic Impact of Unapproved GMO's on EU Feed Imports and Livestock Production'* .

According to this Report, European livestock production could be decimated should asynchronous approval persist between the EU and major third country feed exporters. The Report warns that trade is likely to be affected significantly in the next 2 years in relation to GM soybean variety Mon 89788, which will be cultivated outside of the EU in the next year, and come on stream for sale in 2009/2010.

The Medium scenario is predicted at a price increase of 60% in 2009/2010 for soybean/soybean meal products as a direct result of asynchronous approval.

The outlook for the intensive sectors is not good. Severe shortages of soya could result in a drop in EU poultry production by 44% by 2010 under the predicted worst case scenario according to the Report. In relation to the pig meat sector, the EU could become a net importer of pig meat, while imports of beef could increase by as much as fourfold as a result of trade disruptions cause by asynchronous approval.

Commissioner, this report highlights the very real and imminent dangers which EU livestock production is facing, should urgent action not be taken to improve the speed to which new GMO varieties are approved. The Herculex approvals procedure serves as a case study as to the disruption to trade that can result by having an overly bureaucratic approvals procedure in place.

I believe wider trade considerations must not be disregarded in your deliberations as to the role of DG SANCO, as this Report highlights the full extent to which EU produce will almost certainly be displaced by Non-EU, GM positive produce should prevarication and delay continue to undermine EU agriculture's competitiveness.

Therefore, will you adopt the findings of the DG AGRI Report I have highlighted, and what action do you intend to take on the back of it?

For your information, I will also be writing to EFSA on similar lines, asking for that organisation to play its full part in speeding the approvals process of GMO's.

I would ask you to reply to me at your earliest convenience.

Yours sincerely

James H Allister QC MEP

JA/TK/EU/3272

MARKOS KYPRIANOU
MEMBER OF THE EUROPEAN COMMISSION

Brussels, 20. 12. 2007
D(2007)2054

Dear Mr. Allister,

Thank you for your letter of 7 November 2007 concerning the asynchronous authorisations for GMOs and its impact on the EU livestock industry.

Let me start by reiterating what I have already indicated in my reply to your parliamentary questions (QE 4225/07 – 4227/07). The timeline for the authorisation procedure of GM food and feed is clearly defined by Regulation (EC) No. 1829/2003[1] and applies on the condition that the dossiers submitted by the companies are valid (i.e. complete in terms of the information required) and that the safety of the products can be judged upon. For most of the applications these conditions were not completely met and this situation has nearly always obliged EFSA to a particularly long completeness check and/or to stop the clock of the six month evaluation period to request further information from the applicant.

The Commission is committed to the correct application of the EU legislative framework with respect to the timeline foreseen by the legislation. In particular whenever possible the Commission has forwarded the proposal for a decision to the Standing Committee within the three-month period foreseen by the legislation. When this has not been the case, it has been because of well justifiable reasons linked to the need to clarify specific aspects of the risk assessment such as the presence of an antibiotic marker gene (in the case of a GM amylopectin potato and of some maize hybrids containing MON 863) or the evaluation of a new scientific study published by Professor Seralini in an international journal (in the case of the same maize hybrids).

It is certainly true that our authorisation procedure is very strict, demanding and thus, on average, may take longer than the procedures of other countries. The Commission is not however ready to compromise on the quality of the scientific assessment and will implement its legislative framework which is based on the principle that GM food, feed and seed can be put on the market only if evaluated as safe and appropriately approved.

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[1] Regulation (EC) No 1829/2003 of the Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

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In line with the COM's Action Plan, discussions are ongoing between the Commission and European Food Safety Authority to verify whether there is any possible step to take in order to make efficiency gains in the authorisation procedure. One of the elements which have been highlighted is the need to better communicate to applicants the requirements for the authorisation in order to improve from the start the quality of dossiers, thus shortening certain phases of the process. Furthermore the Authority has recently taken the commitment to carry out the validity check within 6 weeks from the submission of the application, thus creating the conditions for a relevant reduction of the timeline of the authorisation procedure.

Furthermore, it is important to highlight that the lack of support from Member States in the relevant regulatory committee and subsequently in the Council forces the Commission to pass so far every dossier through the whole comitology procedure. Support from Member States could significantly shorten the timeline of the authorisation process.

Finally, concerning the report of the Directorate-General for Agriculture that you mention in your letter, I would like to reassure you that the Commission is well aware that the issue of asynchronous authorisations has economic repercussions for the feed and livestock industry. In this respect, an informal discussion took place in the margins of the Agriculture Council on 26 November at which both Commissioner Fischer Boel and myself were present.

I believe that the most appropriate way forward is to explore innovative ways to handle the asynchronous authorisations at international level, for instance by concluding agreements with some producing countries in order to better synchronize the commercialisation of GMOs in third countries with our authorization system, but also helping them to improve their rules on co-existence of GM and non-GM crops and the respective segregation measures. International cooperation on criteria, data and procedures could also be used as a tool to promote our standards.

I am confident that if we manage to achieve effective agreements with Third Countries, especially those which have high stake in the EU markets, at least part of the problem could be solved. The other part would request better support from Member States for the existing authorisation system, thus allowing authorisations of new GMOs to be taken quicker and in a less contentious environment.

Yours sincerely,