EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain
Director

Brussels,
SANCO/E1/PRG/lh Ares (2011) 404736

Dear Dr Wallace,

Subject: your letter of 18 February 2011 entitled "Export of GM mosquito eggs from England: regulatory compliance"

I thank you for your letter of 18 February 2011 related to regulatory compliance of exports from England of GM mosquito eggs with Regulation (EC) 1946/2003[1] sent to Commissioner Dalli, who asked me to reply to you on his behalf.

In your letter, you refer to the reply of Commissioner Dalli to written question E-11169 of 1.2.2011 and ask him to instigate a process by which consistency with Directive 2001/18/EC for risk assessments associated with transboundary movement may be assessed in future by EFSA or the equivalent bodies in Member States.

I would like to underline that the purpose of Regulation 1946/2003 is to ensure compliance with the obligations provided by the Cartagena Protocol of Biosafety (CPB) regarding transboundary movements of GMOs and, more specifically, exports of GMOs to third countries. Accordingly, and as stated in the reply to written question E-11169, Regulation 1946/2003 provides that exports of genetically modified organisms (GMOs) intended for deliberate release into the environment should be notified to the competent authority of the Party or non-Party of import to the CPB, allowing it to make an informed decision prior to the first transboundary movement of a GMO for deliberate release into their territory. Annex I of Regulation 1946/2003 specifies the information requirements of a notification of exports of GMOs intended for deliberate release into the environment in third countries under Article 4 of the Regulation. These requirements include the provision of a previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC, mirroring the requirements of the CPB to provide "a previous and existing risk assessment report consistent with Annex III [of the CPB]". This documentation requirement was quoted in the reply to E-11169.

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[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:287:0001:0010:EN:PDF

In this context, it is important to recall that Regulation 1946/2003 places the responsibility for making the notification to the party or non-party of import and for the accuracy of the information that it contains on the exporter. Moreover, Regulation 1946/2003 requests the exporter to declare that the information it submits to fulfil the requirements of Article 4 of the Regulation is factually correct. In this regard, I would like to point out that there is no EU procedure established for an environmental risk assessment of the release of a GMO in a third country to be carried out by EFSA and by the Member States (as it exists for authorisations to cultivate GMOs in the territory of the EU), neither for the Commission to assess the accuracy of the information provided by the exporter, including the scientific soundness of the risk assessment.

Following the receipt of question E-11169 the Commission checked whether the exporter had *prima facie* respected the general documentation requirements of Regulation 1946/2003 and of the Cartagena Protocol on Biosafety to notify the export, including the provision of a risk assessment, and the receipt of the consent of the party or non-party of import before proceeding with the first transboundary movement. On the face of it, these notification requirements had been respected according to the information provided to the Commission. As a result, we do not consider necessary a revision of the reply of Commissioner Dalli to this written question.

Your letter raises a number of additional concerns regarding the detail of the handling of this specific case, including by the Competent Authority of the United Kingdom. Regulation 1946/2003 provides for Member States to ensure that the provisions of the regulation are duly implemented. The Commission was informed of the issuance by the UK government of additional guidance for exports of GMOs to third countries in the context of the implementation of the Regulation 1946/2003 in 2007. This additional guidance aimed precisely at ensuring that exporters respected the notification provisions of the Regulation. The Commission will transmit your letter to the United Kingdom Competent Authority for follow up of the various aspects related to the handling of this transboundary movement that are mentioned in your letter.

As regards your requests to create a public register for the publication of transboundary information provided under Regulation (EC) No 1946/2003 and related guidance, the exporter has to send a copy of the notification, the acknowledgement of receipt and the decision of the importing country to the competent authority of the Member States from which the GMO is exported and to the Commission and keep a record of the notification for a minimum of five years. Article 6 of this Regulation states that the Commission will make these documents available to the public in accordance with the European Union rules on access to environmental information, namely Regulation (EC) 1367/2006[2] (Aarhus Regulation). The Aarhus Regulation transposes into the EU internal legal order the Aarhus Convention ("on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters"). This Regulation grants the right to everyone to receive environmental information that is held by public authorities. Applicants are entitled to obtain this information within one month of the request and without stating any specific reason for such request.

Commission Decision 2004/204/EC, which you mention in your letter, makes reference to information accessible according to Regulation (EC) No 1946/2003 and Regulation (EC) No 1049/2001 of the European Parliament and the Council of 30 May 2001

[2] OJ L 264, 25.9.2006

regarding public access to European Parliament, Council and Commission documents but does not establish a public register for those. In fact, even without the existence of a dedicated public register, there is already a considerable amount of information transmitted to the Biosafety Clearing House (BCH) as part of the implementation of Regulation (EC) No 1946/2003. More specifically, this includes information concerning the use within the EU of GMOs that may be subject for transboundary movements for direct use as food or feed or for processing. The EU and its Member States collaborate in the continuous improvement of this information mechanism.

Against this background, the current system seems to be appropriate to meet the objectives of the EU legislation and of the Cartagena Protocol on Biosafety. Therefore, the Commission does not plan at this stage to create a public register but takes nevertheless note of your views in this respect.

Furthermore, you ask for the introduction of clear time limits to Article 6 of Regulation 1946/2003. Timelines are already provided for the party of import to provide its written consent, which exports should await before the transboundary movement takes place. These provisions mirror the obligations established in the Cartagena Protocol on Biosafety to ensure prior informed consent by third parties. The Commission will examine in the context of the implementation of the CPB whether there are more general needs to improve the operation of its notification provisions.

Finally, I would like to cast light to the fact that Regulation 1946/2003 provides that the exporter should send a copy of the notification documents to the competent authority of the Member State from which the GMO is exported and to the Commission, without however providing that this should be done prior or after the first intentional transboundary movement. The transmission of copies of the notification documents to the Commission is not a procedural nor a substantial requirement but has rather a purpose of record keeping

I would like to reassure you that I take duly note of your concerns related to the implementation of Regulation 1946/2003 and whether it is fit for its purpose and will consider if there are more general points to be addressed as part of the practical implementation of the Cartagena Protocol on Biosafety.

Yours sincerely,

Eric Poudelet

Copy: UK CA Authority