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Dear Commissioner

Export of GM mosquito eggs from England: regulatory compliance

I write regarding the export of genetically modified (GM) mosquito eggs by the Oxfordshire-based company Oxitec¹ from England to a number of overseas countries. GeneWatch is concerned that some of these exports may not be compliant with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which covers the transboundary movement of living modified organisms.

In your capacity as the relevant Commissioner, I urge you to take the steps outlined at the end of this letter to ensure future compliance with Regulation (EC) No 1946/2003. GeneWatch is also asking the UK Secretary of State to investigate the company's compliance and to ensure prosecution of any offence that has occurred.

Oxitec's exports of GM mosquito eggs

Oxitec has exported a number of genetically modified (GM) insects, which fall within the definition of living modified organisms (LMOs) under the Cartagena Protocol, from England to other countries. A number of exports have been for contained use only and are therefore not covered by the advance informed agreement (AIA) procedure, although a number of other requirements still apply. However, Oxitec has also made the following exports of its genetically modified OX513 strain of the *Aedes aegypti* mosquito:

1. to the Cayman Islands for open release experiments which took place in late 2009 and in 2010;
2. to Malaysia, where contained use experiments were made, followed by the development of a new strain, OX513 (My1), which was used in an open release experiment in December 2010/January 2011, following approval by the Malaysian National Biosafety Board (NBB);
3. to Brazil, where open release experiments have reportedly been approved by the Brazilian regulator CTNBio but where open releases have not yet taken place.

Malaysia, Brazil and the UK are Parties to the Cartagena Protocol and have adopted relevant biosafety laws. The Cayman Islands are not a Party to the Protocol: however,

¹ <http://www.oxitec.com/>

exports to non-Parties are covered by Article 24 of the Protocol which states that transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of the Protocol.

Regulatory requirements

The Cartagena Protocol provides the international regulatory framework for transboundary movements of living modified organisms (LMOs). It establishes an advance informed agreement (AIA) procedure for LMOs for intentional introduction to the environment, ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The relevant requirements are implemented in the EU by Regulation (EC) 1946/2003 on transboundary movement of genetically modified organisms.

Regulation (EC) No. 1946/2003 notes (paragraph 4): *“It is important to organise the supervision and control of transboundary movements of GMOs in order to contribute to ensuring the conservation and sustainable use of biological diversity, taking also into account risks to human health, and so as to enable citizens to make a free and informed choice in regard to GMOs”*.

Section 1 of Chapter II covers exports of GMOs to third parties for deliberate release into the environment. Article 4 requires the exporter to ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the first intentional transboundary movement of a GMO intended for deliberate release into the environment. The notification shall contain, as a minimum, the information specified in Annex I, which includes a previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.

Article 6 requires the party of export to be informed of the transboundary movement. It states that the exporter shall for a period of a minimum of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GMO is exported and to the Commission. Without prejudice to Article 16 (which allows some information to be kept commercially confidential), the Commission shall make these documents available to the public in accordance with the Community rules on access to environmental information.

Under Article 11, these provisions do not apply to transboundary movements of GMOs intended for contained use rather than deliberate release.

Article 12 specifies the identification and accompanying documentation required for exports of GMOs for contained use or for deliberate release. Article 13 requires the exporter to notify Parties that have taken the decision to regulate transit of GMOs through their territory.

The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004 implements Regulation (EC) 1946/2003 in England.² This designates the Secretary of State for the Department of Environment and Rural Affairs (DEFRA) as the Focal Point and Competent Authority for the purpose of the Council Regulation. The Secretary of State shall enforce and execute the provisions of these Regulations and the specified Community provisions, or direct the relevant local authority to do so, or act jointly with the local authority to enforce and execute the provisions and appoint inspectors with rights of entry to inspect premises and require the provision of information. The Secretary of State may also serve notice in writing to obtain information. It is an offence to fail to comply, fail to provide

² <http://www.legislation.gov.uk/ukxi/2004/2692/contents/made>

information, or to make false entries in records and failure to comply may lead to a fine or imprisonment.

Responses to parliamentary questions regarding Oxitec's exports

In response to a UK Parliamentary Question (PQ) on 30th November 2010, the Parliamentary Under-Secretary of State, Lord Henley, at the Department of Environment, Food and Rural Affairs (DEFRA) stated that Oxitec's shipment of GM mosquito eggs from the UK to Grand Cayman was subject to the requirements of Regulation (EC) 1946/2003, chapter II of which imposes an obligation on exporters to notify their first intended transboundary movement of a GM organism to the relevant authority in the importing country, whether that country is a party or a non-party to the protocol, and to await its consent to proceed.³ He also stated that the Cayman Islands have their own legislation which required the Cayman Islands' Mosquito Control and Research Unit (MRCU) to obtain a permit from the local Department of Agriculture to carry out the trials, and that as part of this process a risk analysis and an environmental impact assessment were carried out.

On 13th January 2011, in response to a further question, Lord Henley confirmed that DEFRA had received a copy of one notification of a transboundary movement of a genetically modified (GM) organism intended for deliberate release into the environment in a third country under Regulation (EC) 1946/2003.⁴ This notification, from Oxitec, concerned the export of mosquito eggs for the release of hatched mosquitoes in the Cayman Islands and was received on 1 December 2010. In response to the question, a copy of the risk assessment pertaining to the planned GM organism release was placed in the Libraries of the House.⁵ This document states that the risk assessment was prepared in October 2009. DEFRA also confirmed in the House of Commons on 10th January that it did not have any discussions with Oxitec prior to the trial release of genetically modified mosquitoes in Grand Cayman and that Oxitec only provided DEFRA with a copy of the risk assessment that was undertaken with the Cayman authorities following the open trial releases.⁶

On 27th January 2011, Lord Henley confirmed that the date of export of GM mosquito eggs to the Cayman Islands for release to the environment was 4 November 2009.⁷ He also stated that the shipments of mosquito eggs by Oxitec to Malaysia, Brazil, India, Singapore, Thailand, the United States and Vietnam were intended for contained use and therefore not covered by the notification requirement. In addition, he stated: "*If importing nations wish to release GM mosquitoes descended from those under contained use they will do so under their own local legislation*" and that Parties to the Cartagena Protocol would be required to notify such a decision to the Convention on Biological Diversity (CBD)'s Biosafety Clearing House.

On 1st February 2011 you responded to a further question in the European Parliament, stating that in line with the requirements of Article 4 of Regulation 1946/2003, prior to the first transboundary movement to the Cayman Islands, Oxitec made a notification with the information required in Annex I of Regulation 1946/2003, which includes a risk assessment report consistent with Annex II of Directive 2001/18/EC. According to Dalli, before proceeding with the shipment, Oxitec awaited the consent of the Government of the Cayman

³ HL Deb, 30 November 2010, c427W. <http://www.theyworkforyou.com/wrans/?id=2010-11-30a.427.0&s=cayman>

⁴ HL Deb, 13 January 2011, c450W. <http://www.theyworkforyou.com/wrans/?id=2011-01-13a.450.4&s=cayman#g450.6>

⁵ Risk analysis – OX513A *Aedes aegypti* mosquito for potential release on the Cayman Islands (Grand Cayman). Prepared – Oct 2009.

⁶ HC Deb, 10 January 2011, c25W. <http://www.theyworkforyou.com/wrans/?id=2011-01-10b.31740.h&s=cayman#g31740.q0>

⁷ HL Deb, 27 January 2011, c194W. <http://www.theyworkforyou.com/wrans/?id=2011-01-27a.194.1&s=cayman#g194.2>

Islands, which issued an import permit in August 2009. In addition, the United Kingdom Competent Authority had recently forwarded the relevant information from the exporter to the Commission, which would make these documents available to the public in accordance with the European Union rules on access to environmental information.

Information provided by the European Commission

On 3rd February 2011, GeneWatch UK received an email response from the EC (DG Sanco) containing the information provided by Oxitec under Annex I of Regulation (EC) 1946/2003 for the notification of an export by Oxitec of GM mosquito eggs to the Cayman Islands. GeneWatch had originally contacted DG Sanco on 30th November 2010 but we were initially told this issue was DG Environment's responsibility.⁸ The email states that this is the only notification concerning a transboundary movement for release into the environment by Oxitec, "*as it seems that their other exports have been for the purpose of contained use*". The annexes to the list of Oxitec's responses contain:

- Annex 1: Doc 1: An unsigned invoice to Angela Harris at MRCU for approx 50,000 eggs, with a shipment date of 4th November 2009;
- Annex 1: Doc 2: A letter to Colin Wakelin, Veterinary Officer 1, Department of Agriculture, Cayman Islands and Angela Harris (MRCU), signed by Camila Beech (Oxitec's head of regulatory affairs) and dated 11th August 2009, giving a brief (2 paragraph) description of the mosquitoes to be imported;
- Annex 2: A risk assessment which states it was prepared in October 2009. This is the same one released to the UK Parliament in January 2011;
- Annex 3: Doc 1: A draft agreement with MRCU, prepared by Luke Alphey of Oxitec, dated 18th March 2009. This is an outline only and does not include terms of use which it states are to be negotiated. It sets out a draft timetable for the trials, including identifying stakeholders and implementing a communications/engagement plan;
- Annex 3: Doc 2: Protocols for the experiments, prepared by Luke Alphey (undated);
- Annex 4: Technical background in four documents (Mosquito rearing protocol; Lab cage mating effectiveness; Eliminating tetracycline contaminants; Aedes aegypti and Aedes Albopictus: life cycles, biology and distribution);
- Annex 5: An unsigned import permit for 350,000 eggs dated 28 August 2009 on Cayman Islands Ministry of Agriculture headed paper. Consignee: Angela Harris at MRCU.

Sequence of events

Thus, according to the information provided to the UK and European parliaments and by the company:

1. The export of 350,000 GM mosquito eggs by Oxitec to the Cayman Islands was approved by the Government of the Cayman Islands in August 2009, when it issued an import permit.
2. On 2nd October 2009 Director of the Mosquito Research and Control Unit of Grand Cayman (MRCU) Bill Petrie told the Cay Compass that a final decision had not been made on the project and that a permit would also have to be obtained from the Department of Agriculture before the mosquitoes were released.⁹
3. A risk assessment for the release of GM mosquitoes on the Cayman Islands, considered by Commissioner Dalli to be consistent with Annex II of Directive 2001/18/EC, was prepared by Oxitec in October 2009 (according to the date on this

⁸ Copies of this email correspondence and the attached documents are available from GeneWatch on request.

⁹ Wilson, S (2009) MRCU set to modify mozzies. Cay Compass. 2nd October 2009.

<http://www.compasscayman.com/caycompass/2009/10/01/MRCU-looks-to-modify-mozzies/>

document). The export of 50,000 GM mosquito eggs to Grand Cayman took place on 4th November 2009.

4. A small open release trial of Oxitec's RIDL strain OX513A of *Aedes aegypti* mosquito was conducted in late 2009 and a larger release from May to October 2010, in collaboration with the MRCU: this information was included in a press release issued by Oxitec on 4th November 2010.¹⁰ No public information was made available in advance of the trial and consent from local people was not sought.¹¹
5. An evidence-gathering workshop on GM insects (in which Oxitec took part) was held on 14th October 2010, by the UK Advisory Committee on Releases to the Environment (ACRE), which provides statutory advice to Ministers in the UK and devolved administrations on the risks to human health and the environment from the release and marketing of genetically modified organisms (GMOs).¹² The European Food Safety Authority (EFSA) has not yet developed guidance for the risk assessment of GM insects under Directive 2001/18/EC.¹³
6. A notification from Oxitec concerning the export of mosquito eggs for the release of hatched mosquitoes in the Cayman Islands and was received by DEFRA on 1 December 2010, following a request for information in the UK parliament.
7. On 21st December 2010, about 6,000 GM mosquitoes were released in an uninhabited area in Malaysia, following approval for experimental releases with conditions by the National Biosafety Board on 5th October 2010.^{14,15} The release involved the OX513A (My1) strain developed by the Malaysian Institute for Medical Research (IMR) in collaboration with Oxitec, based on the OX513A strain. Further releases in inhabited areas are planned.
8. GeneWatch UK understands that experimental open releases of Oxitec's OX513A GM mosquito strain were approved by CTNBio in Brazil in December 2010, but have not yet taken place. According to DEFRA, notifications of exports by Oxitec to Brazil and other countries are not required since these exports have been made for contained use and mosquitoes descended from these imports are not subject to the notification requirements. According to the EC, the only notification made by Oxitec is the one to the Cayman Islands and all other exports were for contained use.
9. The relevant information regarding the export of GM mosquito eggs to Cayman was forwarded by DEFRA to the European Commission in January 2011, following a request in the European Parliament, and will now be made publicly available.

Questions regarding compliance with regulatory requirements

A number of important questions arise regarding compliance with regulatory requirements:

1. Whether the timing of the export notification and supply of information:
 - a. to the Cayman Islands Government, DEFRA, and the Commission is in compliance with the provisions of Regulation (EC) No 1946/2003; and

¹⁰ Oxitec & Mosquito Control Unit Cayman Islands Government (2010)

Open field trial demonstrates effectiveness of RIDL® system for suppressing a target wild mosquito population. Press Release. 4 November 2010. <http://www.oxitec.com/wp-content/uploads/2010/11/Oxitec-MRCU-press-release.pdf>

¹¹ GeneWatch UK (2010) Oxitec's genetically-modified mosquitoes: in the public interest? December 2010. http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitecbrief_fin.pdf

¹² <http://www.defra.gov.uk/acre/meetings/index.htm>

¹³ EFSA Topic: Genetically modified animals.

<http://www.efsa.europa.eu/en/gmotopics/topic/gmanimals.htm>

¹⁴ A quiet release. The Star (Malaysia). 30th January 2011.

<http://thestar.com.my/health/story.asp?file=/2011/1/30/health/7886740&sec=health>

¹⁵ National Biosafety Board Decision Application for Approval for Limited Mark-Release-Recapture Of *Aedes Aegypti* Wild Type and *Aedes Aegypti* Genetically Modified Mosquitoes OX513A(My1) NBB Ref No: Nre(S)609-2/1/3. Applicant: Institute Of Medical Research. Date of Decision: 5 October 2010. http://www.biosafety.nre.gov.my/app_field/nbb_decision.shtml

- b. to members of the public is adequate to ensure that public access to environmental information is not frustrated.

2. Whether the content of the risk assessment for Grand Cayman is consistent with Annex II of Directive 2001/18/EC;

3. Whether DEFRA's interpretation of the notification requirements for planned open releases of mosquitoes descended from exports made initially for contained use is correct: particularly in relation to Brazil, where regulatory approval for open releases of the original OX513A strain appears to have been granted.

In our view:

- Oxitec failed to notify the party of import adequately (Dept of Agriculture of the Cayman Islands), pursuant to article 4 of Regulation (EC) No 1946/2003, which requires that the risk assessment should accompany the original notification to the party of import.¹⁶ Additionally, Oxitec failed to notify the Commission, pursuant to article 6 of Regulation (EC) No 1946/2003.¹⁷

The failure to provide the risk assessment, prior to the grant of the import permit and the failure to notify the UK and Commission prior to transboundary movement, renders the process meaningless in relation to its intended purpose, namely, organising the supervision and control of transboundary movements of GMOs *"in order to contribute to ensuring the conservation and sustainable use of biological diversity, taking also into account risks to human health, and so as to enable citizens to make a free and informed choice in regard to GMOs"* (Regulation (EC) 1946/2003, paragraph 4) and *"to make sure third countries have the necessary data to make an informed decision taking due consideration of potential adverse effects to health and the environment."*¹⁸ How could the Cayman Islands government have made an informed decision without Oxitec's risk assessment?

Moreover, because Oxitec did not notify DEFRA and the Commission until a year after export, Article 6 (in relation to the Commission's responsibility to make the documents available to the public) and the European rules on access to environmental information (Directive 2003/4/EC) are completely frustrated due to unreasonable delays. How can Member States possibly observe their duty to provide access to environmental information upon request *"as soon as possible or, at the latest, within one month"*¹⁹ when they themselves do not receive that information until a year after export?

The Commission has an obligation to make all the relevant information (including risk assessment) available in accordance with article 6 of Regulation (EC) No 1946/2003. It is noted that Commission Decision 2004/204/EC²⁰ states the reason why the relevant information in respect of transboundary movements is not included in the public register is because, in principle, that information is made available through Regulation (EC) No 1946/2003. This means that the Commission is under a duty to make the relevant information, including the risk assessment, available whether it is

¹⁶ The risk assessment (dated Oct 2009) was not prepared until after the approval of import (Aug 2009). It can only be concluded that the original notification to the Dept of Agriculture of Cayman Islands did not include a risk assessment.

¹⁷ Defra notified the Commission, not Oxitec.

¹⁸ Quoted directly from the Commission, 14 Feb 2011.

¹⁹ Article 3, Directive 2003/4/EC.

²⁰ Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council.

on the public register or not. Therefore, it might as well be added to the information held on the register. In this context, this reasoning is also circular in its entirety, because the Commission is in fact unable to make the relevant information available through Regulation (EC) No 1946/2003 until it receives it, which is subject to complete uncertainty, and can, as seen by the facts described here, be over a year after export.

Only notification and publication (for example, via public registers) of the relevant information (including the risk assessment) prior to the transboundary movement, in both the exporting and importing countries will ensure the intended purpose of the regulations and public access within the EU. Accordingly, GeneWatch recommends that in the next review, the Commission introduces clear time limits to article 6 of Regulation (EC) No 1946/2003 to ensure notification to the parties of export before the transboundary movement and to make all the relevant information accessible, for example, via public registers. In the meantime, the Commission should issue guidance to enable compliance with public access requirements.

- It is incorrect for Commissioner Dalli to inform the European Parliament that the content of the risk assessment for Grand Cayman is consistent with Annex II of Directive 2001/18/EC, since there has been no expert independent determination (for example, EFSA and ACRE make determinations for commercial and experimental releases within the EU respectively); no regulatory guidance exists for the risk assessment of GM insects within the EU; and the Commissioner did not in any case receive a copy of the risk assessment until some time after the export and deliberate releases had taken place;
- In Malaysia, the in-country development of a different strain of GM mosquito for deliberate release than that originally exported may mean that the original transboundary movement did not require notification: although greater clarity is needed on this point; and compliance with Article 12 of Regulation (EC) No 1946/2003 (identification and accompanying information) is still necessary. However, a different situation applies in Brazil, where the original OX513A strain is now to be released. For living organisms, application of the notification requirements only to the first generation of a given GMO renders them effectively meaningless.

In the light of the above information, I urge you to:

- a) correct your statement to the European Parliament in which you stated that Oxitec's risk assessment report was consistent with Annex II of Directive 2001/18/EC and to instigate a process by which consistency with Directive 2001/18/EC for risk assessments associated with transboundary movements may be assessed in future by EFSA or the equivalent bodies in member states (e.g. ACRE in the UK); and
- b) create an accessible public register for the publication of transboundary notification information provided under Regulation (EC) No. 1946/2003 (this would be the easiest way for the Commission to comply with the requirements of Article 6 and the access to environmental information requirements); and to inform member states that future notifications and accompanying information must be supplied to the Commission and made publicly available within a reasonable period prior to any transboundary movement; and
- c) establish clear time limits to article 6 of Regulation (EC) No 1946/2003 to ensure notification to the parties of export before the transboundary movement and in the meantime to issue guidance to enable compliance with public access requirements; and
- d) issue guidance to the extent that notification and publication of the relevant information (including the risk assessment) is made available to the public prior to the transboundary movement, in both the exporting and importing countries.

In view of the significant public interests involved, GeneWatch plans to make this letter public.

Please do not hesitate to contact me if you require further information.

Yours sincerely,

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