GeneWatch UK complaint to the European Ombudsman against the European Food Safety Agency (EFSA)

18th February 2013

What is the decision or matter about which you complain? When did you become aware of it?

This complaint is about:

(1) Conflicts-of-interest in EFSA's Working Group on GM Insects;
(2) Lack of expertise to enable EFSA to fulfil its mandate in relation to the development of Guidance for Environmental Risk Assessment (ERA) on GM animals;
(3) Exclusion of the risks of ingestion of GM insects, including in the food chain, from the draft GM Animals ERA Guidance issued by EFSA for consultation in June 2012.

GeneWatch UK became aware of these problems during EFSA's consultation on its Guidance for the Environmental Risk Assessment (ERA) of GM animals in 2012. We have subsequently raised these issues in correspondence with DG SANCO and with EFSA as well as in our response to the consultation document. Unlike a number of other issues we have raised, these issues cannot be addressed purely through revisions to the draft guidance, since they require prior changes in the process of developing the guidance. We received a letter from EFSA 13th January 2013 which refuses to take the necessary action on these matters.

What do you consider that the EU institution or body has done wrong?

Conflicts-of-interest in the EFSA Working Group on GM Insects

Background documentation
In 2011, EFSA set up a Working Group on GM Insects to inform its development of a Guidance Document on the Environmental Risk Assessment (ERA) of GM animals.
Minutes of the meetings, which began in June 2011, are on:
http://www.efsa.europa.eu/en/gmowgs/documents/gmoinsects.pdf
Declarations of Interest are on: https://ess.efsa.europa.eu/doi/doiweb/wg/263347

The UK biotech company Oxitec, a spin-out company from the University of Oxford, is seeking to commercialise GM insects, including GM mosquitoes and agricultural pests, and is working closely with the major international agribusiness Syngenta. GeneWatch UK has published information about conflicts-of-interest involving Oxitec in the regulatory process for GM insects in a joint NGO briefing on: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf

In 2009, the UK's Biotechnology and Biological Sciences Research Council (BBSRC) reported that Oxitec's founder Luke Alphey: "*is also working towards developing regulatory frameworks for GM insects internationally and within a number of countries including the USA*".
http://www.bbsrc.ac.uk/web/FILES/Publications/innovator_2009.pdf#search=%22oxitec%22
The BBSRC has funded Oxitec with grants totalling more than GBP 1.54 million (Euros 1.93 million), mostly for Oxitec to work in association with Oxford University, which is one of the founding investors in the company. Details in GeneWatch UK briefing on:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitecbrief_fin.pdf .

One current BBSRC grant is for Oxitec to work with Mike Bonsall of Oxford University and includes "*working with various regulatory and policy-making bodies around the world, and aim to produce a policy document that we hope will form a key part of the information that such stakeholders need to assess the risks and benefits of this new technology*". Grant No. BB/H01814X/1 Integrating ecology

and genetics for insect pest control. Dr Michael Bonsall University of Oxford £322,120. http://www.bbsrc.ac.uk/PA/grants/AwardDetails.aspx?FundingReference=BB%2fH01814X%2f1

Bonsall's conflict-of-interest meant he was required to leave the room during a discussion of Oxitec's GM insects by the UK Advisory Committee on Releases to the Environment (ACRE): see Minutes of the 134th Meeting of ACRE at Nobel House, London, Thursday, 1st December 2011 (paragraph 10.4). http://www.defra.gov.uk/acre/files/ACREMINUTES20111201.pdf which states "*Dr Bonsall declared a conflict of interest as he had been working with the company, Oxitec Ltd, on this insect. He left the room while this item was discussed*". Bonsall is a co-author on at least seven papers relating to joint projects with Oxitec on GM insects. Details are available in this joint NGO briefing: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf

Mike Bonsall has nevertheless been appointed by EFSA to its GM Insects Working Group. In his Declaration of Interests he declares the BBSRC grant but does not mention that it involves working with regulators. He declares his position as an employee of the University of Oxford but states "*Oxitec Ltd., which is a SME that develops GM insects for different applications, does not receive from nor provide any financial benefit to the University of Oxford*". This is misleading because commercialising Oxitec's GM insects will in fact benefit the university because Oxitec is one of a portfolio of university investments in spin-out companies managed by Oxford Spin-out Equity Management (OSEM), which "*manages the University's shareholdings in its spin-out companies and seeks ways of maximising the value of its equity stakes*". OSEM's portfolio is here: http://www.osem.ox.ac.uk/portfolio/index.html (Oxitec is listed under "Other Healthcare").

Although EFSA's rules on conflicts-of-interest do not discuss the issue of overall bias on committees and working groups, it is hard to see the GM Insect Working Group as reflecting overall expert opinion on this issue in an unbiased way. A number of other members of EFSA's GM Insects Working Group have undeclared links to Oxitec. At least four other members of the group have current or past links with Oxitec, having worked on joint research projects or co-authored papers (Mumford, Christophides, Bellini, Kiss) and two other members work on the IAEA's programme developing GM insects (Sait and Malacrida). Panel member John Mumford declares his role in the risk assessment project Mosqguide for GM mosquitoes, but does not mention that Oxitec is a partner in this World Health Organisation (WHO)-funded project, which has informed the WHO's draft guidelines for GM mosquitoes . Mumford (and his wife Mary Quinlan) are co-authors on three journal papers with Oxitec. Working Group member George Christophides declares his role in the EU-funded FP7 INFRAVEC project, but does not mention that Oxitec is a partner in this project; Romeo Bellini is also a partner in the INFRAVEC project (undeclared) and a co-author on a journal paper with Oxitec's Luke Alphey. INFRAVEC (Research Capacity for the Implementation of Genetic Control of Mosquitoes) is a four year research infrastructure project, which has been awarded €8.5 million in EU funding from 1st September 2009 to 31st August 2013. Iztvan Kiss is a co-author on a paper with Mike Bonsall and Oxitec's PhD student which models the genetic control of pest insects. Two other members of the Working Group, Sait and Malacrida, work for International Atomic Energy Agency (IAEA)'s programme on the use of GM insects to improve the sterile insect technique. These interests should all have been declared as past or present research funding with relevance to the development of the GM insects guidance, as required by the EFSA independence rules. In addition, Working Group member Ester Kok has previously been criticised for conflicts-of-interest in developing the risk assessment process for GM plants, due to her work with the food industry body the International Life Sciences Institute (ILSI), which established an industry task force to deal with biotechnology in 2004. EFSA's GMO Panel has also been involved in drafting the guidance and will be responsible for amending and adopting it: members of this panel include Vice Chair Gijs Kleter, who has also worked with ILSI. Details are in: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf

In GeneWatch's view EFSA's independence rules appear inadequate to address the issue of overall bias on committees: nevertheless, failure to declare interests, such as past or current research collaborations with Oxitec, is a clear breach of the rules.

Luke Alphey of Oxitec also acts as an advisor to EFSA's GM Insects Working Group. He declares his role as Chief Scientific Officer at Oxitec and that he has investments in the company and patents on its technology, but the minutes of the meetings state that his role at Oxitec was "*not deemed to represent a conflict of Interest*". Alphey acted as a hearing expert at three meetings of the GM Insects Working Group in September and October 2011 and February 2012, whilst they developed the draft guidance for ERA of the products produced by his company. EFSA's 2011 Independence Rules state that Hearing Experts may be invited to present their views irrespective of whether they hold potential conflicts of interest. However, according to Article 13 of the Expert Selection rules, "*the reasons justifying such a need for external scientific experts shall be recorded in the minutes of the meeting where that need was first identified*". No reasons for appointing an expert from Oxitec have been given in the minutes. Further, the minutes state that his interests "*were not deemed to represent a conflict of Interest for the hearing expert concerned*". It would be hard to find an individual with a greater interest in the development of guidelines on GM insects than Luke Alphey, who is a founder, patent-holder and shareholder in Oxitec, the leading company with an interest in commercialising GM insects. Further, Oxitec is not acting independently of more powerful vested interests: Syngenta has funded some of its research on GM agricultural pests (as detailed in Alphey's Declaration of Interest) and most of its management and consultants and some members of its Board (including the Chair) are ex-Syngenta staff.

Substance of complaint

Mike Bonsall has breached EFSA's rules on Declaration of Interest contained in its 2011 rules on selection of experts (http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf) because he has not submitted a valid declaration: both the role of the BBSRC grant in informing regulators of the company's views and Oxford University's role as an investor in the company have been omitted. Dr Bonsall's role as an employee of Oxford University, which holds equity in Oxitec, should have led to EFSA taking a decision not to appoint him to its GM Insects Working Group. EFSA's Independence rules (http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf) state that: "*Any conflict of interests by experts and staff carrying out activities within the remit of EFSA should be promptly identified, handled and removed without delay*".

EFSA's Independence Rules also state that the concerned persons shall not be allowed to assess, rate or review their own work. However, Mike Bonsall is also a member of UK Advisory Committee on Releases to the Environment (ACRE), which commented on the ERA guidance in its official capacity: http://www.defra.gov.uk/acre/about/membership/ . EFSA GM Insects Working Group member Jeff Bale was also a member of ACRE (although he has since been replaced) and was present at the ACRE meeting when comments on the draft guidance were discussed:
http://www.defra.gov.uk/acre/files/acre-minutes-20120712.pdf
Bonsall, Mumford, Christophides, Bellini and Kiss all are or have been involved in projects with Oxitec and, in developing the guidance, are in effect rating and reviewing their own work.

Article 33 of EFSA's Rules on Panel Operation requires Working Groups to operate independently of any external influence (http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf). Yet on 8th July 2012, the Sunday Times reported that Mike Bonsall: "*admitted he was an author of the GM animal draft safety guidelines. He confirmed there had been pressure from the biotech industry to get the rules written so that work on the safety case could begin*". Source: Clover C (2012) That buzzing is GM mosquitoes heading our way. The Sunday Times. 8th July 2012.

http://www.thesundaytimes.co.uk/sto/comment/columns/charlesclover/article1076266.ece [Subscription needed].

John Mumford, George Christophides and Romeo Bellini should have declared that they are working on joint projects with Oxitec (Mosqguide and INFRAVEC) and Istvan Kiss should have declared involvement in a past project (the BBSRC/Royal Society funded project reported in: http://www.uq.edu.au/uqresearchers/researcher/yakobl.html?uv_category=pub&pub=2501041). The reasons for appointing Luke Alphey of Oxitec as an external expert should have been recorded in the minutes and the statement that he has no conflicts-of-interest should never have been made.

These conflicts-of-interest mean that EFSA is unable to fulfil its obligations in a way that is impartial, independent and objective.

Lack of EFSA expertise to fulfil its mandate on ERA of GM animals

Background documents
EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, which also lays down the general principles and requirements of food law and procedures in matters of food safety. Paragraph (38) states: "*In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC and without prejudice to the procedures established therein*".

On 13 February 2007, the EFSA GMO Panel received a mandate from the European Commission 195 (ENV.B3 D(2007) 2004) with the request to "*develop, building on the work done in the context of the 196 Codex Alimentarius, a guideline on the safety evaluation of GM animals that would address both, 197 food/feed safety and environmental safety of this technology*". The remit of this work has subsequently expanded to include products other than food and feed such as GM insects and pets.

However, EFSA lacks expertise to comment on GMOs other than food and feed and on many non-food-chain-related health and environmental risks.

Directive 2001/18/EC covers the deliberate release into the environment of genetically modified organisms (GMOs) and includes some specific aspects which need to be considered in the ERA of in the case of GMOs other than higher plants, including, for example: potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens; and possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

An expert report commissioned by EFSA (available on: http://www.efsa.europa.eu/en/supporting/doc/71e.pdf) lists the following areas of expertise relevant to the risk assessment of GM insects: Developmental biology, Microbiology, Physiology, Parasitology, Taxonomy, Invasion biology, Quarantine biology, Applied biology (incl. applied ecology and entomology), Molecular biology, Proteomics/ transcriptomics/ genomics, Insect molecular biology, Biotechnology/transgenics, Genetics, Evolutionary genetics, Molecular genetics, Population genetics, Entomology, Insect immunity, Medical entomology/vector control, Regulatory entomology, Evolutionary ecology, Molecular ecology, Microbial ecology, Insect ecology, Community ecology (incl. symbiosis, insect-pathogen interactions),Population ecology, Behavioural ecology, Landscape

ecology, Disease ecology, Chemistry, Biochemistry, Medicine, Evolutionary medicine, Human medicine, Veterinarian medicine, Immunology, Epidemiology, Agricultural Science, Phytopathology Agricultural pest control/biological control, Toxicology, Ecotoxicology, Mathematical modelling, Bioinformatics, Geographic information science, Biosafety, (Environmental) risk assessment, Other Sterile insect technique, Monitoring, Mass rearing.

Substance of the complaint
EFSA has expertise and competence in very few of these areas.

Examples of issues that need to be considered in the case of the release of GM mosquitoes include the possibility that another species of mosquito which is also a disease-vector occupies the ecological niche vacated by the targeted species; the risk of the virus transmitted by the mosquito evolving; and complicated interactions with human immunity which mean that in some cases reducing the frequency of biting can actually increase the harm caused by a tropical disease. More information about these risks is available on:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec_unansweredQs_fin.pdf
and:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/EFSA_GWresponse.pdf
These are all issues that are way outside EFSA's area of expertise and many have been downplayed or omitted from EFSA's draft guidance on the ERA for GM animals due to this lack of competence, combined with dependence on a Working Group on GM insects that is strongly influenced by commercial interests (see above).

EFSA's lack of expertise means that it is unable to fulfil its obligations under Paragraph (38) of Regulation (EC) No 178/2002 in a way that is impartial, independent and objective. This means that EFSA is not competent to draft the Guidance it has issued on the ERA of GM animals, because too many issues fall outside its areas of competence.

The exclusion of risks of ingestion of GM insects, including in the food chain, from public consultation

Background documents
The importance of public consultations is set out in EFSA's Founding Regulation and EFSA has a consultation policy: http://www.efsa.europa.eu/en/keydocs/docs/consultationpolicy.pdf . The policy states that the consultation must clarify the consultation target audiences and the nature of relevant information.

In its September 2011 Public Consultation on Draft Guidance on the risk assessment of food and feed from genetically modified animals including animal health and welfare aspects, EFSA stated explicitly that "*Insects and other invertebrates were not taken into account, with the exception of honey bees that are used in agricultural practice*":
http://www.efsa.europa.eu/en/consultationsclosed/call/110810.htm
This statement was repeated in the final Guidance:
http://www.efsa.europa.eu/en/efsajournal/pub/2501.htm .
This document provides guidance for the risk assessment of food and feed containing, consisting of or produced from genetically modified (GM) animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GM food and feed. It states: "*In relation to the food and feed risk assessment, the underlying assumption of this comparative approach is that traditionally-bred animals have a history of consumption as food and feed for the average consumer or animal to which the animal-derived products are fed. These*

traditionally-bred animals can serve as a baseline for the food and feed safety assessment of GM animals or their products and the welfare of the GM animals". The General Principles underpinning this approach are listed on pages 8 to 9. The comparative approach is based on the concept of "substantial equivalence" developed by the WHO and OECD and taken into consideration in the "guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals" prepared in the context of the Codex Alimentarius in 2008.

Codex Alimentarius has not considered the risk assessment of GM insects in the food chain. The international body defines a "Recombinant-DNA Animal" as an animal in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, and its "Conventional Counterpart" as an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals. This comparison forms the basis of the concept of "substantial equivalence" as outlined in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals:
http://www.codexalimentarius.net/download/standards/11023/CXG_068e.pdf
Notwithstanding the many critiques of the concept of "substantial equivalence" it is clearly inappropriate to assess the risk of potentially very large numbers of GM insect eggs, larvae and adults entering the food chain on or inside crops or food derived from them. The Codex committee which developed this guidance no longer exists and there is therefore no body of work for EFSA to draw on regarding food safety issues and GM insects:
http://www.who.int/foodsafety/biotech/codex_taskforce/en/

In our response to the consultation on this Guidance, GeneWatch UK highlighted that GM insects and invertebrates (including GM bees) raised a whole range of additional issues which could not be properly considered in this document and required separate in-depth consideration:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/EFSA_animals_consul11.pdf
We did not provide any further detail in our response because EFSA had stated explicitly that GM insects were excluded from the consultation.

EFSA issued its Public consultation on the draft Guidance Document on the Environmental Risk Assessment of Genetically Modified Animals in June 2012:
http://www.efsa.europa.eu/en/consultationsclosed/call/120621.htm
This document provides draft guidance for the environmental risk assessment (ERA) of genetically modified (GM) animals to be released into the environment and placed on the EU market according to Regulation (EC) No 1829/2003 or Directive 2001/18/EC (which covers deliberate releases of GMOs into the environment).
It states, lines 267-272: "*Furthermore, although this Guidance Document does not give detailed guidance on the risk assessment of the accidental intake of GM animals not intended for food and feed uses by humans (e.g. GM insects), applicants should assess this likelihood and assess any risk by implementing principles in the Guidance Document on the risk assessment of food and feed from GM animals and on animal health and welfare aspects (EFSA, 2012a). Potential impacts of such GM animals on human health, through other routes of exposure (than ingestion), are addressed in sections 4.1.7, 4.2.6 and 4.3.9*". There is no information in the document regarding the risks of the ingestion route for GM insects. There is also no justification of the claim that the ingestion of GM insects released as part of a commercial programme should be regarded as "accidental".
The consultation also states (lines 185-186): "*The EFSA GMO Panel will not consider issues related to risk management (e.g. traceability, labelling, coexistence)*". Notwithstanding this claim, line 355 includes as one important step in the ERA process: "*Application of management strategies for risks*

from the deliberate release or marketing of GMO(s)" and the risk management step is included in every section of the draft guidance: except that management of risks to the food chain via traceability, labelling and co-existence measures are omitted.

In our response to this EFSA consultation, GeneWatch UK objected to EFSA's failure to consider the ingestion route and failure to consider food safety, consumer and trade issues for GM insects in the food chain, including traceability, labelling and co-existence:
http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/EFSA_GWresponse.pdf

Subsequent correspondence between ourselves and DG SANCO (attached) has established that the Commission takes the view that the single sentence in lines 267-272 amounts to a consultation on whether or not applicants should apply the principles developed for GM animals (i.e. "substantial equivalence" and the comparator approach) to GM insects in the food chain. DG SANCO states (in a letter to us on 11th October 2012): "*The already published guidance document on risk assessment of food and feed from genetically modified animals covers animals which are intended to be used as food and feed. Therefore, any organisms which are not intended to be used as food and feed cannot be covered under this guidance. Insects are - so far - not intended to be consumed as food in the EU and that is why they are not covered in this document.*
However, the accidental consumption of GM insects via the food chain is covered in the draft guidance on environmental risk assessment. EFSA explicitly asks applicants to assess the likelihood of accidental consumption and any linked risk for human health, stating that the general principles of food/feed risk assessment of GM animals should be followed in that case. In other words, EFSA makes clear that accidental consumption of GM insects needs to be addressed by the applicant and as a consequence it will be covered in the corresponding scientific opinion of EFSA. In conclusion, the risk of accidental consumption of GM insects via the food chain is covered in the guidance document on environmental risk assessment of GM animals."

In its letter to us on 13th January 2013, EFSA states that "*the issue of accidental ingestion of GM larvae through the consumption of fruits on which they fed is accounted for in the guidance document on the ERA of GM animals*". Yet this exposure route is not even mentioned in the consultation nor are any grounds given as to why ingestion of GM larvae should be regarded as "accidental": numbers of GM larvae in crops are expected to be high (much higher than the number of non-GM larvae present when the technology is not used) because Oxitec's GM insects are genetically programmed to die at the larval stage i.e. while they are in or on the crop.

There is no doubt that people will ingest GM insects if they are released as part of pest control programmes. Oxitec's experiments in Brazil have involved "release ratios" of GM mosquitoes to wild mosquitoes of up to 54 to one, in order for sufficient number of GM male mosquitoes to mate with wild females to seek to suppress the population. In November 2010, the Los Angeles Times reported on open releases of Oxitec's GM mosquitoes in Brazil, stating that "*Male Aedes don't bite, so being swarmed with them isn't painful, although it's impossible to talk during the liberation sessions without accidentally swallowing a few of the Frankenbugs*."
http://articles.latimes.com/2012/nov/01/world/la-fg-brazil-mutant-mosquitoes-20121102 . There is also no doubt that the ingestion route must be considered in the ERA as part of Directive 2001/18/EC requirements (Annex A, D.1), which include: "*Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s)*". The complete absence of the ingestion route from EFSA's consultation document on the ERA of GM animals is therefore difficult to justify.

However, an even bigger gap in EFSA's guidance arises in the case of GM agricultural pests, because very large numbers of dead GM insect larvae, as well as GM insect eggs and some living larvae and adults will be left in vegetables, fruit and other crops. Oxitec's GM agricultural pests have a female-killing trait: this means male offspring survive to adulthood but females mostly die at the late larval or pupal stage, in the absence of the antibiotic tetracycline (which is used to breed the insects in the lab). Species include the Mediterranean fruit fly, diamond back moth, olive fly, tomato leaf miner/borer, the Mexican fruit fly and the red flour beetle. Oxitec recently announced that its Olive fly and Mediterranean Fruit fly strains are ready for national evaluation. The company also plans to begin working on some new species from the Pacific region: the Queensland fruit fly and two species of Oriental fruit fly, native to the Philippines. References are available in: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf . The number of GM pests in the food chain could vastly outnumber existing wild pests that can end up in fruit and vegetables or other food products because Oxitec's GM insects are genetically programmed to die mostly at the late larval or pupal stage. In some cases the GM insect progeny will mostly die inside the fruit because the target pests lay eggs inside which only emerge at the adult stage (e.g. olive flies, fruit flies). In other cases, some of the larvae with bury into the fruit (e.g. tomato borers) or feed on the outside of cabbages or broccoli (diamondback moths).

Following the adoption of Directive 2001/18/EC, Member States argued that further regulation was needed to address food safety issues and to facilitate the removal of GM foods from the supply chain should new evidence of harm come to light, as well as providing consumer choice. This led to the adoption of Regulation (EC) No.1829/2003 on genetically modified food and feed and Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

Since Oxitec's dead GM insect larvae are likely to be left in foods such as vegetables and fruit, these are likely to be regarded as foods containing GMOs for the purposes of Regulation (EC) No.1829/2003. The determining criterion is whether or not material from the genetically modified source material is present in the food and feed (paragraph (16). In some cases, foods produced using GM agricultural pests (such as olive oil, tomato puree or fruit juices) might be highly processed and thus the remains of GM insects may not be visible to consumers. Yet Guidance on how to implement Regulation (EC) No.1829/2003 in the case of GM insects is entirely lacking and there has been no consultation on this issue: again EFSA seems to regard the single sentence in its consultation on the ERA for GM insects as adequate to cover this important issue.

Traceability and labelling requirements for food and feed produced using GMOS are contained in Regulation (EC) No. 1830/2003. There is again no discussion in the consultation of how these might be applied to crops produced using GM insects.

The EC has adopted a subsidiarity-based approach on coexistence of GM and non-GM crops. It has adopted guidelines to help Member States develop national legislative or other strategies for coexistence and has reported on progress in member states: http://ec.europa.eu/agriculture/gmo/coexistence/index_en.htm and is required to develop guidance on the co-existence of genetically modified, conventional and organic crops (Directive 2001/18/EC as amended by Article 47 of Regulation (EC) No. 1829/2003) and to allow member states to take appropriate measures to avoid the unintended presence of GMOs in other products. However, there is no research or guidance on the co-existence of crops produced using GM insects. This is a major omission because GM insect eggs, larvae and adults will inevitably spread from the intended area of use. In the US, experiments involving fluorescent GM bollworms in cotton fields (produced by Oxitec but sterilised using radiation rather than containing the genetic conditional lethality trait) have been halted following concerns that the use of GM bollworms breach US organic

standards. The use of GM insects by one producer could therefore clearly impact on trade, as well as raising important health and environmental issues.

In Oxitec's view GM olive flies which remain in crops should be regarded as "technically unavoidable" under EU legislation (so they do not trigger labelling requirements) and "excluded from the scope of regulations" by the Standing Committee on the Food Chain and Animal Health, in a similar manner to foods and feeds produced by fermentation with genetically modified microorganisms: http://www.biomedcentral.com/1741-7007/10/51 . It is hard to escape the view that EFSA is quietly supporting Oxitec's approach and attempting to avoid any regulation or labelling of crops and foods produced using GM insects.

Substance of complaint
EFSA's consultation on the ERA of GM insects fails to cover the ingestion route and the implications of GM insects in the food chain:

- It is unclear to consultees that the single sentence in lines 267-271 amount to a consultation on applying the principles contained in an earlier consultation to GM insects in the food chain, as EFSA and DG SANCO appear to be claiming.
- The principles outlined in the earlier consultation on GM animals in food and feed were not developed for GM insects and there is no international standard under Codex Alimentarius or elsewhere for such an approach.
- No information has been provided about the likely occurrence of large numbers of GM insect eggs, larvae and adults in the food chain if commercial releases of Oxitec's GM agricultural pests are approved. Many dead GM insect larvae will be inside or on the surface of crops because Oxitec's GM insects are not sterile but most female GM insect offspring die at the late larval stage.
- In contrast to other exposure routes, no information about possible health and environmental risks of ingesting GM insects or introducing GM insects into the food chain has been provided in the consultation.
- The important risk management measures of traceability, labelling and co-existence have been explicitly excluded from the consultation.

This means that important interests such as those of farmers, retailers and consumers have effectively been excluded from any meaningful consultation on this issue, despite important implications for health, the environment, the internal market and international trade.

Unlike many issues relevant to the ERA guidance, for which EFSA lacks the expertise and competence (see above), issues relating to food safety, consumer choice and trade fall clearly within EFSA's remit, yet EFSA appears to have abdicated any responsibility for considering or consulting on such issues in the case of GM insects. As well as implications for food safety, the lack of international guidelines under Codex Alimentarius and differences of view in member states or other countries (including the United States) will have implications for international trade and consumer choice.

What, in your view, should the institution or body do to put things right?

- EFSA's working group on GM insects must be re-constituted to remove all conflicts-of-interest and bias.
- EFSA must establish sufficient internal expertise to enable it to fulfil its obligations under Paragraph (38) of Regulation (EC) No 178/2002, or the EC must establish alternative procedures through which the expertise of other European institutions regarding environmental risk assessment and human health can play a central role in developing guidelines and assessing the ERA of GMOs other than food and feed.

- EFSA must re-formulate its environmental risk assessment guidance for GM animals with input from this independent expertise, and re-consult on it, or another European institution with appropriate expertise must carry out this task.
- This re-consultation, or an additional separate consultation, must include draft guidance for the risk assessment of the ingestion of GM insects, including in the food chain. The ingestion route is an important route for inclusion in the ERA but food chain risks are also relevant to food safety legislation and to trade and consumer choice. Risk management measures discussed in the consultation must include traceability, labelling and co-existence.

Have you already contacted the EU institution or body concerned in order to obtain redress?

GeneWatch UK raised the above points in our response to the EFSA consultation in August 2012. We wrote to DG SANCO about our concerns on 22nd August and again on 14th September. The letters were copied to EFSA's Executive Director. Copies of these letters and replies are attached. GeneWatch UK then wrote to EFSA's Executive Director on 27th November 2012 and received a reply on 13th January 2013. These letters are also attached. EFSA has taken no action in response to our complaints beyond stating that responses to the consultation will be taken into account in the final guidance. We have raised a number of issues in response to the consultation which are not included here, however the points raised here in our view require prior action i.e. mere amendments to the guidance will be insufficient, because the consultation process itself has already been compromised.