



Questions by Corporate Europe Observatory on EFSA Gene Drive Working Group (WG) 28/06/2019

CEO's findings

Only two experts, who also belong to EFSA GMO panel, do not have direct financial interests with gene drive developers.

It should be clarified that EFSA's independence rules make a distinction between "financial interests" and "financial investments". Whilst financial investments in the food sector result in the application of an unconditional restriction (i.e. experts are not engaged in Panel/WG activities), "financial interests" have to be assessed in application of the risk-based approach, i.e. with respect to the actual terms of reference of the scientific group where the expert is asked to cooperate at EFSA.

Two (Bonsall and Wimmer) have direct financial links with Oxitec.

Michael Bonsall: the expert did not declare financial investments with Oxitec, but research activities co-financed by the University of Oxford and Oxitec itself. These are public-private funded researches, which are considered as not posing a problem in terms of competing interests for the understanding that research activity partially funded by public funds (e.g. Horizon2020) are conducted in the public interest.

Ernst Wimmer: he holds a patent -Intellectual Property Right (IPR)- on "Universal Markers of Transgenesis" that during the assessment of the expert's declaration of interests (DoI) was identified as a conflict of interest (CoI), resulting in the impossibility for the expert to serve as chair or vice chair, since the area covered by the IPR is in the mandate of the WG

However, since the EFSA WG does not have a mandate to review specifically this patent, in application with the EFSA independence rules, the expert is eligible for membership but not for chairmanship of this WG. Indeed, his eligibility is restricted to "membership".

Two (Crisanti and Mumford) have direct financial links with the Bill & Melinda Gates Foundation, which has been funding international lobby work to avoid a moratorium on the technology.

Andrea Crisanti and John Mumford: the experts are engaged in research activities funded by the Bill & Melinda Gates Foundation, and they declared that the overall amount of private funding received for research activities conducted in the areas of concern is below the threshold of 25%. This implies that these activities do not represent a source of potential CoIs.





Two (Bonsall and Crisanti) have received research funding from the US' DARPA for transgenic mosquito work.

Michael Bonsall and - Andrea Crisanti: both experts are engaged in research activities funded by DARPA, and they declared that the overall amount of private funding received for research activities conducted in the areas of concern is below the threshold of 25%. This implies that these activities do not represent a source of potential CoIs.

One (Mumford) should not have been recruited by EFSA for the group given the agency's independence rules.

The DoI of this expert was attentively screened against the EFSA's independence rules and the expert was asked to provide additional information that eventually allowed EFSA to conclude that no CoI was identified. In particular:

- (A) The role of director of the Quinlan Dacoma LLC (food operator not growing GM crops but only conventional ones): the expert expressly declared not to be an employee of the company, but to act as director since the directorship is in the hands of his family, being the company a family business. EFSA's independence rules foresee the application of an unconditional restriction in case of "employment" by a food business operator. Since this case was expressly excluded by the expert, the fact that the company produces only conventional crops poses the interest outside the remit of the WG (i.e. no overlapping).
- (B) Managerial role in Agra-CEAS Consulting Ltd: information was asked to the expert on whether the organisation provided consultancy also on GM related matters. The expert declared that the company did not provide consultancy around GM issues since 2011, i.e. when a report was issued to DG SANCO. Since the consultancy activity of the company in area pertaining to the GM WG was older than 5 years, the interest is considered not relevant and having largely passed the cooling-off period.

All of them have financial interest in one or more commercial companies whose activity is in the remit of EFSA.

As mentioned above, the difference between "financial interests" and "financial investments" is key to check the whether the application of EFSA independence policy was done in full compliance.

Questions by CEO

Which person (or group of persons, or body) was in charge of recruiting the experts of the gene drive working group?

The expert selection process has been done according to internal rules ("Establishing, updating and closing a scientific WG") and involved the chair of the GMO Panel and the chair of the Gene Drive ERA WG. EFSA together with the chair of the WG agreed on the fields of expertise to cover and EFSA then performed literature searches to identify relevant experts based on the volume and relevance of identified scientific publications.





Three categories of expertise were identified as necessary for the WG:

- 1. Arthropod genetics/genetic control strategies in insects (focusing on mosquitoes and agricultural pests as these are the most likely cases moving to practical applications) [This expertise is covered by Crisanti (mosquitoes) and Wimmer (agricultural pests)]
- 2. Molecular biology [This expertise is covered by Nogué]
- 3. Environmental risk assessment (ecological modelling, population genetics, non/target effects, risk assessment of invasive species) [This expertise is covered by Bonsall, Firbank and Mumford]

It was agreed that this core group of experts may be complemented with additional hearing experts who have been invited on an *ad hoc* basis depending on the scientific needs identified during the activities of the WG.

Why was Dr Fabien Nogue brought in only 6 months after the rest of the group?

Dr. Nogué was part of the WG since the beginning of its activities in February 2019, as evidenced in the minutes of the Gene Drive ERA WG MTGs, available online.

Given that the gene drive topic is so controversial and has sparked such a broad debate in the scientific community, why did EFSA choose to mainly appoint experts with financial links to gene drive developers in this panel, including at least one in breach of its own independence rules?

The expert selection process was mainly driven by previously identified expertise needs (see above) and the level of expertise of experts identified through literature searches.

Johannes Frieβ and Bernd Giese are also part of the WG, as hearing experts (this updated info was not available from EFSA's website at the time of the reception of CEO's request. Updated information is available here).

Will EFSA's management keep the working group's composition unchanged now it has been made aware of this situation?

No new element has been brought forward by CEO that would justify now the re-opening of the DoIs' assessment. However, should CEO have elements not declared by the experts, we would be more than glad to follow up.

Why the dominance of experts with financial links to developers when gene drive has gathered such a broad interest in the scientific community?

As explained further up the experts' selection process was driven by previously identified expertise needs and the level of expertise of experts identified through literature searches.

With the above important clarification on the distinction between "financial interests" and "financial investments", the declared interests are not in conflict with the WG mandate. One important element we would like to bring forward to complement the above information is the stakeholders' approach taken by EFSA *vis à vis* the work of this WG: a 1-day <u>stakeholder workshop</u> was organised on the problem formulation for the environmental risk assessment of gene drive modified insects (15 May 2019, Brussels).





Through this workshop EFSA aimed to engage with stakeholders to discuss plausible environmental risks from gene drive modified insects.

The list of participants is available here. As you can see a wide variety of participating stakeholders views (as sought by EFSA) was collected. The input of workshop participants will support EFSA's expert Working Group on the environmental risk assessment of gene drive modified organisms to frame its work in the broader societal context, acknowledging the distinction between risk assessment and risk management considerations.