Response to “The anglerfish deception”

The commentary [1] on aspects of genetically modified organism (GMO) regulation, risk assessment and risk management in the EU contains omissions, errors, misunderstandings and misinterpretations. As background, environmental risk assessment (ERA) of genetically modified (GM) plants for cultivation in the EU is conducted by applicants following principles and data requirements described in the Guidance Document (ERA GD) established by the European Food Safety Authority (EFSA) [2], which follows the tenets of Directive 2001/18/EC. The ERA GD was not referenced in [1], which wrongly referred only to EFSA guidance that does not cover ERA. Applications for cultivation of a GM plant containing the ERA, submitted to the European Commission (EC), are checked by the EFSA to ensure they address all the requirements specified in its ERA GD [2]. A lead Member State (MS) is then appointed to conduct the initial evaluation of the application, requesting further information from the applicant if required. The MS evaluation is forwarded to the EC, EFSA and all other MSs. Meanwhile, all other MSs can comment on the application and raise concerns. The EFSA GMO Panel carefully considers the content of the application, the lead MS Opinion, other MSs' concerns, all relevant data published in the scientific literature, and the applicant's responses to its own requests for further information. The Panel then delivers its Opinion on the application, which covers all the potential environmental areas of risk listed in 2001/18/EC. This Opinion is sent to the EC, all MSs and the applicant and published in the EFSA journal (efsa.europa.eu). Panel Opinions on GM plants for cultivation consider whether environmental harm might be caused, and, if so, suggest possible management to mitigate these risks, and make recommendations for post-market environmental monitoring (PMEM). The final decision on whether to allow the cultivation of GM plants, and any specific conditions for management and monitoring,

rests with the EC and MSs and is not within the remit of the EFSA.

Against this background we respond to several comments in [1]. Regarding the Comparative Safety Assessment of GM plants and whether or not further questions are asked following this assessment, the Comparative Safety Assessment, described fully in [2], is not a ‘first step’. It is a general principle that forms a central part of the ERA process, as introduced in section 2.1 of [2]. Each ERA starts with problem formulation and identification, facilitating a structured approach to identifying potential risks and scientific uncertainties; following this critical first step many further questions must be asked and addressed. In [2] it is clearly stated that all nine specific areas of risk listed in 2001/18/EC must be addressed—persistence and invasiveness; vertical gene flow; horizontal gene flow; interactions with target organisms; interactions with non-target organisms; human health; animal health; biogeochemical processes; cultivation, management and harvesting techniques. Under the Comparative Safety Assessment, following problem formulation, each of these areas of risk must be assessed by using a six-step approach, involving hazard identification, hazard characterization, exposure assessment, risk characterization, risk management strategies and an overall risk evaluation and conclusion. Indeed, far from asking “no further questions” [1], the EFSA GMO Panel always sends a sequence of written questions to the applicant as part of the ERA process to achieve a complete set of data to support the ERA evaluation (on average about ten per application).

The principle of comparative analysis in ERA—sometimes referred to as substantial equivalence in the risk assessment of food and feed—is not discredited. The comparative approach is supported by all of the world's leading national science academies [for example, 3]; none has recommended an alternative. The principle is enshrined in risk assessment guidelines issued by all

relevant major international bodies, including the World Health Organization, the Food and Agriculture Organization of the United Nations and the Organisation for Economic Co-operation and Development. Critics of this approach have failed to propose any credible alternative baseline to risk assess GMOs. The comparative analysis as described in [2] is not a substitute for a safety assessment, but is a tool within the ERA [4] through which comparisons are made with non-GM counterparts in order to identify hazards associated with the GM trait, the transformation process and the associated management systems, which are additional to those impacts associated with the non-GM plant itself. The severity and frequency of these hazards are then quantified in order to assess the levels of risks associated with the novel features of the GM plant and its cultivation.

European Parliament (EP) communications include that “the characteristics of the receiving environments and the geographical areas in which GM plants may be cultivated should be duly taken into account”. We agree, and the ERA GD [2] recognizes explicitly that receiving environments differ across the EU, and that environmental impacts might differ regionally. Therefore, the ERA GD [2] demands that such differences be fully accounted for in cultivation applications and that receiving environments be assessed separately in each of the nine specific areas of risk (see section 2.3.2). Furthermore, [2] states in section 3.5 that the ERA should consider scenarios representative of the diversity of situations that might occur and assess their potential implications. The EP communications state that “the long-term environmental effects of GM crops, as well as their potential effects on non-target organisms, should be rigorously assessed”. This is covered explicitly in section 2.3.4 of [2], and developed in the recent guidance on PMEM [5].

The EFSA is committed to openness, transparency and dialogue and meets regularly with a wide variety of stakeholders

including non-governmental organizations (NGOs) [6] to discuss GMO topics. That the EFSA is neither a centralized nor a singular voice of science in the EU is clear, because the initial report on the ERA is delivered by a MS, not the EFSA; all MSs can comment on the ERA; and EFSA GMO Panel Opinions respond transparently to every concern raised by each MS. Following publication, the EFSA regularly attends the SCFAH Committee (comprising MS representatives) to account for its Opinions. The involvement of all MSs in the evaluation process ensures that concerns relating to their environments are addressed in the ERA. Subsequently, MSs can contribute to decisions on the management and monitoring of GM plants in their territories if cultivation is approved.

In recent years, several MSs have used the 'safeguard clause', Article 23 of 2001/18/EC, to attempt to ban the cultivation of specific GM plants in their territories, despite earlier EFSA Panel Opinions on those plants. But the claim that "the risk science of the EFSA's GM Panel has been publicly disputed in Member State's justifications of their Article 23 prohibitions" needs to be placed into context [1]. When a safeguard clause (SC) is issued by a MS, the EFSA GMO Panel is often asked by the EC to deliver an Opinion on the scientific basis of the SC. The criteria on which to judge the documentation accompanying a SC are whether: (i) it represents new scientific evidence—and is not just repetition of information previously assessed—that demonstrates a risk to human and animal health and the environment; and (from the guidance notes to Annex II of 2001/18/EC) (ii) it is proportionate to the level of risk and to the level of uncertainty. It is pertinent that on 8 September 2011, the EU Court of Justice ruled that 'with a view to the adoption of emergency measures, Article 34 of Regulation (EC) No 1829/2003 requires Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment'. Scientific literature is monitored continually by the Panel and relevant new work is examined to determine whether it raises any new safety concern. In all cases where the EFSA was consulted by the EC, there has been no new scientific information presented that would invalidate the Panel's previous assessment.

Throughout [1] the text demonstrates a fundamental misunderstanding of the distinction between ERA and risk management. ERA is the responsibility of the EFSA,

although it is asked for its opinion on risk management methodology by the EC. Risk management implementation is the responsibility of the EC and MSs. Hence, the setting of protection goals is an issue for risk managers and might vary between MSs. However, the ERA GD [2], through its six-step approach, makes it mandatory for applications to relate the results of any studies directly to limits of environmental concern that reflect protection goals and the level of change deemed acceptable. Indeed, the recent EFSA GMO Panel Opinions on *Bt*-maize events [for example, 7] have been written specifically to provide MSs and risk managers with the tools to adapt the results of the quantified ERA to their own local protection goals. This enables MSs to implement risk management and PMEM proportional to the risks identified in their territories.

The EFSA GMO Panel comprises independent researchers, appointed for their expertise following an open call to the scientific community. The Panel receives able support from staff of the EFSA GMO Unit and numerous *ad hoc* members of its working groups. It has no agenda and is neither pro- or anti-GMOs; its paramount concern is the quality of the science underpinning its Guidance Documents and Opinions.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest. All the authors except M. Nuti are members of the EFSA GMO Panel; M. Nuti was a member of the Panel from 2003 to 2006 (declarations of interest available on efsa.europa.eu/en/gmo/gmomembers).

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Reply to J.N. Perry *et al*

Our respondents, eight current or former members of the EFSA GMO panel, focus on defending the EFSA's environmental risk assessment (ERA) procedures. In our article for *EMBO reports*, we actually focused on the proposed EU GMO legislative reform, especially the European Commission (EC) proposal's false political inflation of science, which denies the normative commitments inevitable in risk assessment (RA). Unfortunately the respondents do not address this problem. Indeed, by insisting that Member States enjoy freedom over risk

management (RM) decisions despite the EFSA's central control over RA, they entirely miss the relevant point. This is the unacknowledged policy—normative commitments being made before, and during, not only after, scientific ERA. They therefore only highlight, and extend, the problem we identified.

The respondents complain that we misunderstood the distinction between RA and RM. We did not. We challenged it as misconceived and fundamentally misleading—as though only objective science defined RA, with normative choices cleanly confined to