Scientific Panel on GMO

Minutes of the 108th Plenary meeting of the Scientific Panel on GMO

13-14-15 July 2016, Parma

(Agreed on 16 August 2016 by written procedure)

Participants

- **Panel members**:

Josep Casacuberta, Adinda De Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Nielsen, Hanspeter Naegeli, Fabien Nogue, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal.

- **EFSA:**

GMO Unit: Fernando Alvarez, Michele Ardizzone, Herman Broll, Chiara Belvederi, Fabrizio Chiaramonte, Yann Devos, Antonio Fernández Dumont, Niccolò Franceschi, Andrea Gennaro, Anna Lanzoni, Franco Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, Regina Selb, Elisabeth Waigmann.

Other EFSA Units/Directorates: Juliane Kleiner (REPRO Directorate) for item 8.1 and Dirk Detkens (LRA Unit / RESU Directorate) for item 9.1, Kirsten Haupt (RISKCOM Unit / COMMS Directorate) for items 5.1 and 8.2, Flavio Fergnani (RISKCOM Unit / COMMS Directorate) for item 9.2, James Ramsay (EXREL Unit / COMMS Directorate) for item 5.1.

- **European Commission observers:** Kaja Kantorska (DG SANTE).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** Hildegard Przyrembel for item 5.2; Kim Esbensen and Claas Wagner for item 8.3.

1 Welcome and apologies for absence

The Chair of the EFSA GMO Panel welcomed the participants. Apologies were received from Andrew Nicholas Birch.

2 Adoption of agenda

The agenda was adopted without changes.

3 Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[2], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4 Agreement of the minutes of the 107th Plenary meeting held on 18-19 May 2016, Parma

The minutes of the 107th Plenary meeting held on 18-19 May 2016 were adopted and will be published on the EFSA website at: Event: 107th plenary meeting of GMO Panel.

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 Application for authorisation of genetically modified maize Bt11 x 59122 x MIR604 x 1507 x GA21 for food and feed uses, import and processing and all sub-combinations independently of their origin, except for 1507 x 59122 submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2011-99) (EFSA-Q-2011-00894)

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for discussion and possible adoption. It was previously presented to the EFSA GMO Panel at its 107th Plenary meeting on 18-19 May 2016 (see minutes here).

A minority opinion concerning the risk assessment of subcombinations for which no specific data were provided, was presented. The minority opinion was shared with all members of the EFSA GMO Panel in advance of the meeting and extensively discussed during the meeting.

The following aspects were considered in the discussion:

i) *Approach for risk assessment of subcombinations*.

It is foreseen in the EFSA guidance document on Risk assessment of genetically modified plants containing stacked transformation events (2007)[3], and also in the Implementing Regulation 503/2013[4], that applicants can provide either a scientific argumentation or specific data to support the risk assessment of subcombinations[5].

The 2007 guidance document states in the Introduction: "*As long as each event in the highest number of stacked events has been risk assessed, the risk assessment of the stacked events might also be applicable to GM stacks containing fewer of these events. Thus a single risk assessment of such a stack could cover all combinations with fewer of these events. However, applicants need to take into account the potential impact of any*

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[2] http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf
[3] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2007.512/epdf
[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF
[5] Subcombinations are stacks that contain any combination of fewer events than those present in the highest stack covered by the application.

reduction in the number of events involved and should provide scientific argumentation for the absence of specific data on the stacked events with a lower combination of events."

The Implementing Regulation states in Annex II, 2.2.: "*….the application shall include all subcombinations independently of their origin which have not yet been authorised. In such a case, the applicant shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations or, in the absence of such scientific rationale, provide the experimental data.*"

It was noted that in the case of Application EFSA-GMO-DE-2011-99 the applicant has provided a scientific argumentation for the safety of subcombinations, in line with the provisions foreseen in the EFSA 2007 guidance document on stacked transformation events. It was further noted that all the single events have already been risk assessed by EFSA, and that the applicant has provided a full data package for the 5-event stack. Furthermore, five subcombinations not covered by the scope of Application EFSA-GMO-DE-2011-99 were previously assessed by the EFSA GMO Panel as stand-alone dossiers.

ii) *Expression levels of Cry proteins in the subcombinations*

In the minority opinion, the considerations regarding the expected expression levels of the Cry proteins in subcombinations are questioned. During the discussion at the EFSA GMO Panel Plenary meeting, the considerations of the EFSA GMO Panel as detailed in the scientific opinion were further clarified, as follows: it was noted that no indications of interactions between the events based on the biological functions of the newly expressed proteins that would raise a safety issue were identified. Comparison of the levels of the newly expressed proteins between the five-event stack and each of the single events did not reveal an interaction that manifests at protein expression level. In addition the data on genetic stability and protein expression for five subcombinations previously assessed as stand-alone dossiers and not included in the scope of this application, do not show any evidence of interactions. Therefore, there is no indication to suggest that the presence of one protein may mask or enhance the effects of the others and there is no reason to expect interactions that would alter the expression levels of these proteins in the twenty subcombinations included in the scope of this application.

iii) *Potential adjuvanticity of Cry proteins in GM plants*

In the minority opinion, the potential adjuvanticity of some Cry proteins at high doses was highlighted. During the discussion at the EFSA GMO Panel Plenary meeting, it was noted that the Food and Feed WG has discussed extensively the potential adjuvant capacity reported for some Cry proteins when applied at relatively high doses, by reviewing literature available on the topic (e.g. Vazquez-Padron et al 1999[6]; Moreno-Fierros et al 2003[7]; Rojas-Hernandez et al 2004[8]; Guimaraes et al 2008[9]; Reiner et al

[6] Vazquez RI, Moreno-Fierros L, Neri-Bazan L, de la Riva GA and Lopez-Revilla R, 1999. *Bacillus thuringiensis* Cry1Ac protoxin is a potent systemic and mucosal adjuvant. Scandinavian Journal of Immunology, 49, 578–584.

[7] Moreno-Fierros L, Ruiz-Medina EJ, Esquivel R, Lopez-Revilla R and Piña-Cruz S, 2003. Intranasal Cry1Ac protoxin is an effective mucosal and systemic carrier and adjuvant of *Streptococcus pneumonia polysaccharides* in mice. Scandinavian Journal of Immunology, 57, 45–55.

[8] Rojas-Hernandez S, Rodriguez-Monroy MA, Lopez-Revilla R, Resendiz-Albor AA and Moreno-Fierros L, 2004. Intranasal co-administration of the Cry1Ac protoxin with amoebal lysates increases protection against *Naegleria fowleri* meningoencephalitis. Infection and Immunity, 72, 4368–4375.

[9] Guimaraes VD, Drumare MF, Ah-Leung S, Lereclusb D, Bernard H, Cre´minon C, Wal JM and Adel-Patient K, 2008. Comparative study of the adjuvanticity of *Bacillus thuringiensis* Cry1Ab protein and cholera toxin on allergic sensitisation and elicitation to peanut. Food and Agricultural Immunology, 19, 325–337.

2014[10]; Andreassen et al 2015[11]). It was recalled that EFSA and other risk assessment bodies have also previously commented on the potential adjuvant capacity of Cry proteins in the context of GM plants (EFSA/GMO/472[12]; VKM report on adjuvanticity[13]). During the discussion at the EFSA GMO Panel Plenary meeting, it was further highlighted that adjuvanticity of Cry proteins is a matter of scientific debate where most of the groups agreed on the limited and contrasting evidence available for such an activity (reviewed by Rubio-Infante and Moreno-Fierros 2015[14]; Joshi et al 2016[15]); for example, little is known regarding a dose-response relationship for the potential adjuvant activity of Cry proteins. However, it has been experimentally shown that at the range of expression levels of Cry proteins observed in GM plants, no adjuvant effect was observed (e.g. Reiner et al 2014). Consequently, on the basis of current knowledge, EFSA and other risk assessment bodies (e.g. VKM) concluded that at the range of expression levels of Cry proteins observed in the GM plants assessed, the Cry proteins would not raise a safety concern.

iv) *Data on expression levels of newly expressed proteins in subcombinations*.

In the minority opinion, it is stated that the EFSA GMO Panel "*does not require that additional specific data shall be provided to EFSA to guarantee the safety of these 20 subcombinations should they be produced and imported to the EU market in the future*." During the discussion at the EFSA GMO Panel Plenary meeting, the following points were raised: for the subcombinations included in the scope of this application, no specific data were submitted. For these subcombinations, the EFSA GMO Panel has drawn conclusions on a weight-of-evidence approach, including evidences summarized in Point ii) above. Due to the absence of specific data, uncertainties remained. To reduce these uncertainties and confirm assumptions made for the assessment of these subcombinations, the EFSA GMO Panel considers that the applicant should provide relevant information, if these subcombinations were to be created via targeted breeding approaches and imported into the EU in the future. This information should focus on expression levels of the newly expressed proteins. Furthermore, it was underlined, that in the case of Application EFSA-GMO-DE-2011-99 this request would also cover uncertainties linked to a potential adjuvanticity of some Cry proteins at relatively high doses. Therefore, contrary to what is stated in the minority opinion, the very unlikely possibility of a risk for the consumers would be mitigated.

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[10] Reiner D, Lee R-Y, Dekan G and Epstein MM, 2014. No adjuvant effect of *Bacillus thuringiensis*-Maize on allergic responses in mice. PLoS ONE 9(8): e103979.

[11] Andreassen M, Bohn T, Wikmark OG, Van den Berg J, Lovik M, Traavik T and Nygaard UC, 2015. Cry1Ab protein from *Bacillus thuringiensis* and MON810 cry1Ab-transgenic maize exerts no adjuvant effect after airway exposure. Scandinavian Journal of Immunology, 81, 192–200.

[12] EFSA (European Food Safety Authority), 2009. Bilateral technical meeting between members of the Panel on genetically modified organism and the VKM Norwegian delegation- Adjuvanticity of Cry proteins. EFSA/GMO/472, 1–2.

[13] VKM (The Norwegian Scientific Committee for Food Safety), 2012. Summary of the health risk assessment of the adjuvant effects of Cry proteins from genetically modified plants used in food and fodder. Opinion of the panel on genetically modified organisms of the Norwegian scientific committee for food safety. VKM pp. 9. Doc. no: 11-313-4. ISBN: 978-82-8259-072-3.

[14] Rubio-Infante N and Moreno-Fierros L, 2016. An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals. Journal of applied toxicology, 36, 630–648.

[15] Joshi SS, Barnett B, Doerrer NG, Glenn K, Herman RA, Herouet-Guicheney C, Hunst P, Kough J, Ladics GS, McClain S, Papineni S, Poulsen LK, Rascle JB, Tao AL, van Ree R, Ward J and Bowman CC, 2016. Assessment of potential adjuvanticity of Cry proteins. Regulatory Toxicology and Pharmacology, 79, 149–155.

v) *Points raised by the European Commission*:

While the European Commission does not in any way wish to compromise independence of the scientific advice and debate, it maintains that divergent views and minority opinions must be purely scientific and factual. Furthermore, the European Commission explained to the EFSA GMO Panel that it has followed in the past the Panel's recommendations on the subcombinations and will continue to do so in the future by inserting specific conditions in its proposals for the authorisation for placing on the market of relevant GM stacks.

vi) *Current status and applicability of the Draft Guidance Document on Uncertainty in Scientific Assessment*.

In the minority opinion it is stated that an uncertainty analysis in line with the EFSA Draft Guidance Document on uncertainty should have been made for the risk assessment of the 20 subcombinations. During the discussion at the EFSA GMO Panel Plenary meeting, the current status of this Draft Guidance Document was summarised. The EFSA Draft Guidance Document on uncertainty has been developed by the Scientific Committee to horizontally support EFSA's risk assessment and provides information on quantitative and qualitative tools for uncertainty analysis. It has undergone a public consultation during summer 2015 and is currently in a trial phase during which its applicability is tested on dedicated risk assessment questions. Following this trial phase, the Draft Guidance Document will be revised. Thus, this guidance document has not yet been developed into its final form and does not have to be routinely applied at the moment. However, EFSA experts can acknowledge uncertainty and apply tools described in the Draft Guidance Document on a case-by-case basis, at their discretion. In this case, the EFSA GMO Panel has acknowledged uncertainties due to the absence of specific data for the subcombinations, and requested that data on expression levels of newly expressed proteins should be provided if these subcombinations were to be created via targeted breeding approaches and imported into the EU in the future.

vii) *Role of EFSA experts in the risk assessment*.

In the minority opinion it is stated that the role and remit of EFSA experts should be limited to check the validity and relevance of the data provided, and the reliability of the outcomes of the safety assessment performed by the applicant. During the discussion at the EFSA GMO Panel Plenary meeting, it was recalled that EFSA experts review all available relevant information, either provided/produced by applicants or other third parties. Taking into account and weighing all the available information, EFSA experts reach their conclusion by collegial decision making. In the respective scientific opinions, EFSA experts should provide the scientific rationale leading to their conclusion. In the case of Application EFSA-GMO-DE-2011-99, the EFSA GMO Panel explained in its scientific opinion that it has reached a conclusion on the subcombinations by weight of evidence approach that takes as a starting point results of the assessments of the single events, the data generated for the five-event stack maize, and all the data available for subcombinations previously assessed by the EFSA GMO Panel as stand-alone dossiers but not included in the scope of this application.

Following the discussion, the EFSA GMO Panel voted in favour of adopting this scientific opinion with the exception of one expert who maintained a minority opinion.

Abstract

In this opinion, the EFSA GMO Panel assesses the five-event stack maize and twenty of its subcombinations independently of their origin. The EFSA GMO Panel has previously assessed the five single events that are combined to produce this five-event stack maize Bt11 × 59122 × MIR604 × 1507 × GA21 and did not identify safety concerns. No new data on the single events, leading to a modification of the original conclusions on their safety, were identified. The molecular, agronomic, phenotypic and compositional data on the five-event stack maize did not give rise to safety concerns and there is no reason to expect interactions between the single events impacting on the food and feed safety of the five-event stack maize. Considering the scope of the application (no cultivation), routes of exposure and limited exposure levels, the Panel concludes that this five-event stack maize would not raise safety concerns in the event of accidental release of viable grains into the environment. The EFSA GMO Panel concludes that the five-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. For the 20 subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded that they are expected to be as safe as the five-event stack maize. For the subcombinations included in the scope of this application that could be produced by conventional crossing through targeted breeding approaches, no specific data were submitted. To reduce these uncertainties and to confirm assumptions made for the assessment of these subcombinations, the EFSA GMO Panel considers that the applicant should provide relevant information, if these subcombinations were to be created via targeted breeding approaches and imported into the EU in the future. In this case, this information should focus on expression levels of the newly expressed proteins.

A minority opinion expressed by an EFSA GMO Panel member is presented in Annex to this opinion.

The scientific opinion, together with the minority opinion, will be published on the EFSA website at: EFSA Journal.

5.2 Application for authorisation of genetically modified soybean 305423 x 40-3-2 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2007-47) (EFSA-Q-2007-175)

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for discussion and possible adoption. The focus of the discussion was on the comparative analysis and the nutritional assessment.

Abstract

The EFSA GMO Panel previously assessed the two single events combined to produce soybean 305423 × 40-3-2 and did not identify safety concerns. No new data on the single events affecting the original conclusions were identified. Based on the molecular, agronomic, phenotypic and compositional characteristics, the combination of soybean events 305423 and 40-3-2 in the two-event stack soybean did not raise concerns regarding food and feed safety or nutrition. The combination of the newly expressed proteins in the two-event stack soybean did not raise human or animal health concerns. No compositional differences requiring further assessment were identified between soybean 305423 × 40-3-2, the non-GM comparator, additional comparators and the non-GM commercial soybean reference varieties, except for the altered fatty acid profile (consistent with the intended trait). Nutritional assessment of food products from soybean 305423 × 40-3-2 identified no concerns for human health and nutrition. There are no concerns

regarding the use of feedingstuffs from defatted toasted soybean 305423 × 40-3-2 meal. There are no indications of an increased likelihood of establishment and spread of occasional feral soybean plants, unless these are exposed to acetolactate-synthase-inhibiting or glufosinate-ammonium-based herbicides. Risks associated with the unlikely, but theoretically possible, horizontal transfer of recombinant genes from soybean 305423 × 40-3-2 to bacteria were not identified. Considering the scope of the application, interactions with biotic and abiotic environments are not considered a relevant issue. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean 305423 × 40-3-2. The EFSA GMO Panel is of the opinion that soybean 305423 × 40-3-2 is as safe as the non-GM comparator and non-GM commercial soybean varieties with respect to potential effects on human and animal health and environment in the context of its scope. The EFSA GMO panel recommends a post-market monitoring plan.

The EFSA GMO Panel voted unanimously in favour of adopting this scientific opinion, which will be published on the EFSA website at: EFSA Journal.

5.3 Application for authorisation of genetically modified soybean DAS-68416-4 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2011-91) (EFSA-Q-2011-00052)

Not discussed due to lack of time.

5.4 Application for authorisation of genetically modified maize Bt11 x MIR162 x 1507 x GA21 for food and feed uses, import and processing and sub-combinations independently of their origin submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2010-86) (EFSA-Q-2010-01087)

Not discussed due to lack of time.

5.5 Self-task mandate of the EFSA GMO Panel to establish a new working group activity to develop supplementary guidelines for the allergenicity assessment of GM plants to incorporate new developments (EFSA-Q-2014-00547)

The draft guidance was discussed in the specific GMO Working Group and at the 107th GMO Plenary meeting.

The EFSA GMO Panel endorsed the draft guidance document on Development of Supplementary Guidelines for the Allergenicity Assessment of GM plants.

The draft guidance has been placed at EFSA Call: Public consultations on 26 July 2016 for a 8-week public consultation.

5.6 Application for authorisation of genetically modified maize 1507 x 59122 x MON 810 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2011-92) (EFSA-Q-2011-00116)

Not discussed due to lack of time.

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

None.

6.2 Annual PMEM reports

None.

6.3 Other Requests and Mandates

None.

7 Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA and the European Commission

7.1 Scientific Committee and other Scientific Panels

None.

7.2 EFSA including its Working Groups/Task Forces

7.2.1 Feedback from LLP WG

A member of the GMO unit and a member of the EFSA GMO Panel provided feedback on the current status of development of the activities in the LLP Working Group (EFSA-Q-2015-00433, M-2015-0155). In particular they presented the preparatory work conducted to support the activities of the working group, and shared with the EFSA GMO Panel the strategy proposed.

7.3 European Commission

None.

8 Other scientific topics for information and/or discussion

8.1 Risk assessment frame and approach

The Head of the REPRO department discussed the risk assessment frame and procedure with the EFSA GMO Panel, in particular as linked to the aims in developing an opinion, the expectation and responsibility of Panel experts when developing and adopting an opinion, and procedural aspects linked to minority opinions.

8.2 Sub-combinations

Following discussion on the risk assessment of sub-combinations obtained via natural segregation and of the sub-combinations obtained by targeted breeding approaches at its April and May Plenary meeting, the EFSA GMO Panel further discussed its approach. Further discussion is needed.

8.3 Outcome from the contract (OC/EFSA/GMO/2013/04)

The contractor was invited to provide the EFSA GMO Panel with an overview of the works performed under the EFSA contract on *Development and harmonisation of reliable sampling approaches for generation of data supporting GM plants risk assessment (OC/EFSA/GMO/2013/04)*

9 Any other business

9.1 Election of a new vice chair of the EFSA GMO Panel and nomination of a new Chair for ENV WG

Following the resignation of Achim Gathmann as vice-Chair of the EFSA GMO Panel and Chair of the standing working group on GMO Applications Environment in May 2016, the election of a new Vice-Chair took place following the guidelines laid down in the Decision of the EFSA Management Board concerning the establishment and operations of the

Scientific Committee, Scientific Panels and of their Working Groups[16], the Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work[17], and the Decision of the Executive Director on Declarations of Interest[18].

Huw Jones was elected Vice-Chair of the EFSA GMO Panel.

Antoine Messéan and Adinda de Schrijver were subsequently nominated respectively Chair and Vice-Chair of the standing working group on GMO Applications Environment.

9.2 Media request guidelines

A member of the GMO unit gave a brief presentation on EFSA media guidelines.

9.3 Feedback from GMO Scientific Network meeting, 30 May – 1 June 2016

A member of the GMO unit provided an overview "6th meeting of the EFSA scientific network for risk assessment of GMOs" that took place in Parma on 31 May and 1 June 2016.

9.4 Quality review at EFSA

A member of the GMO unit provided an update on Quality review at EFSA on the ISO9001 certification that is expect to receive the final certification in fall 2016.

9.5 EFSA Strategy 2020: identification of thematic research projects

The Head of the GMO unit gave an overview of the EFSA Strategy 2020 and encouraged the EFSA GMO Panel to identify potential thematic research projects that address issues relevant to EFSA and that can be anchored to EFSA's own priorities, taking into consideration the criteria for the 2018-2020 Work programme.

9.6 Next step in the uncertainty analysis

The Head of the GMO unit explained that in the frame of the development of the EFSA Guidance Document on uncertainty, a trial period for testing the uncertainty analysis on selected outputs is foreseen. For GMO, it was decided to use a PMEM report as test case.

The EFSA GMO Panel was also informed that further trainings on uncertainty will be organised as needed.

9.7 Paperless experts' reimbursements process

A member of the GMO unit provided an overview on the administrative issue related to meeting attendance reimbursement.

[16] http://www.efsa.europa.eu/sites/default/files/assets/paneloperation.pdf
[17] http://www.efsa.europa.eu/sites/default/files/assets/expertselection.pdf
[18] http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the SDoI filled for the present meeting, Philippe Guerche declared an interest for Item 5.3 in relation to previously declared annual declaration of interest (ADOI): Mr Guerche commented on dossiers submitted to EFSA including Application for authorisation of genetically modified soybean DAS-68416-4 for food and feed uses, import and processing (EFSA-GMO-NL-2011-91) submitted to EFSA under Regulation (EC) No 1829/2003 by Dow AgroSciences, in his capacity of member of the French High Council for Biotechnology (FSO), which advises the French government on GMOs. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[19] and the Decision of the Executive Director on Declarations of Interest[20], and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of the agenda items 5.3.

[19] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[20] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014