ANNEX III

Assessment of the grounds for the review of Commission Implementing Decision (EU) 2021/65[1] authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003[2]

1. Risk assessment conducted by EFSA

1.1 Risk assessment of the parental plant MON 87411

In point 2.2 of your request, you recall that part II, section 1.2.2.3 of Annex II to Regulation (EU) No 503/2013[3] requires that, when silencing[4] approaches with RNAi are used in genetically modified plants, 'off-target genes' are searched by *in silico* analysis to assess if the genetic modification could affect the expression of other genes which raise safety concerns. This provision is relevant as regards the DvSnf7 dsRNA[5], produced by the genetically modified ('GM') maize MON 87411, which is a RNAi that has silencing effects on the targeted organism (corn rootworm).

You claim that, in its scientific opinion on GM maize MON 87411[6], the European Food Safety Authority ('EFSA') admitted that there were several uncertainties as to the potential risk of DvSnf7 dsRNA and that, by not addressing those uncertainties, EFSA did not comply with the above mentioned provision.

You support your claim on three grounds:

(a) the fact that during the bioinformatics analysis of 'off target genes', the DvSnf7 dsRNA produced by the GM plant was not compared to RNA expressed in mammals and microorganisms, but only to RNA expressed in plants, is a gap in the scientific

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1 OJ L 26, 26.1.2021, p. 37-43.

2 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1–23).

3 Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1–48).

4 "Silencing" refers to the loss of gene expression.

5 DvSnf7 double stranded RNA: DvSnf7 dsRNA is expressed in the plant tissues of GM maize MON 87411, and induces, upon consumption by the corn rootworm, RNAi silencing leading to pest mortality.

6 EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. *Scientific opinion on the assessment of genetically modified maize MON 87411 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003* (application EFSA-GMO-NL-2015-124). EFSA Journal 2018; 16(6):5310, 29 pp. https://doi.org/10.2903/j.efsa.2018.5310.

information provided, but EFSA did not request such data for GM maize MON 87411 or the GM stack maize MON 87427 × MON 89034 × MIR162 × MON 87411 (hereafter "GM stack maize");

(b) the fact that EFSA did not take into consideration the concentration of DvSnf7 dsRNA and the biologically active molecules derived from it in the plants and that, as a result, the concentration of the biologically active molecules in plants was not assessed;

(c) the fact that greater uncertainties were observed in the GM maize feeding study, indicating unintended effect via the consumption of grain.

(a) First ground: alleged incomplete bioinformatics analysis of off target genes

As a first ground, you claim that the DnSnf7 dsRNA produced in the GM plants was only compared with RNA expressed in plants and not with RNA expressed in mammals and micro-organisms, and that, therefore, the analysis is not compliant with (EU) Regulation 503/2013.

The Commission does not agree that there is a gap in the risk assessment of GM maize MON 87411. As required by part II, section 1.2.2.3 of Annex II to Regulation (EU) No 503/2013, an *in silico* analysis[7] to identify potential 'off target genes' was performed by the applicant and risk assessed by EFSA as described in section 3.2.2 of the EFSA opinion on GM maize MON 87411[8]. The applicant followed the recommendations by the EFSA's GMO Panel ('GMO Panel'), described in the minutes of its 118th meeting[9], for an 'off target genes' search in plants. EFSA concluded that the *in silico* analysis did not indicate that the DvSnf7 dsRNA has an effect on 'off target genes' from GM maize MON 87411 affecting their expression that would need further assessment.

It is true that *in silico* analysis did not search for 'off target genes' in animals and humans.

However, on the one hand, the GMO Panel considers that only searches for 'off target genes' in the GM plant itself may have value for the risk assessment of GM plants[10]. This position is based on the fact that, while, in plants, a set of parameters allows for a reasonable prediction of 'off target genes', in humans and animals, these parameters do not allow for sufficiently reliable predictions.

On the other hand, EFSA took into account that fact that the scope of the application of GM maize MON 87411 covers only the placing on the market of the (imported) GM maize for food

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7 This *in silico* analysis is a bioinformatics analysis which compares the sequence of the dsRNA DvSnf7 produced by the GM maize MON 87411 to the sequence of RNAs produced by plants.

8 See *supra* footnote 6.

9 Annex II of the minutes of the 118th Plenary meeting of the Scientific Panel on GMO available at https://www.efsa.europa.eu/sites/default/files/event/171025-m.pdf.

10 Annex II to the minutes of the 118th Plenary meeting of the Scientific Panel on GMO available at https://www.efsa.europa.eu/sites/default/files/event/171025-m.pdf.

and feed uses, and not its cultivation within the EU, and that the likelihood that the genetic modification results in effects to non-target organisms is negligible in that context. In this regard, section 3.5.1.2. of the EFSA opinion on GM maize MON 87411 states that the potential of maize grains (be it GM or not) spilled during import to establish, grow and produce pollen, is extremely low and transient. Furthermore, EFSA considered that potential interactions of the GM maize with non-target organisms do not raise any environmental safety concern, because environmental exposure of those organisms to spilled GM maize grains or occasional feral GM maize plants arising from spilled GM maize grains was expected to be limited, and because ingested DvSnf7 dsRNA are degraded before entering the environment through faecal material of animals fed with GM maize. Therefore, EFSA considered that no bioinformatic analysis was necessary for non-target organisms.

The Commission takes note of the fact that you consider that the recommendations described in the minutes of the 118th GMO Panel meeting, referred to above, expose limitations in the current knowledge as regards potential off-target effects in human and livestock, and in their gut microbiome. However, as explained, EFSA took into consideration potential off-target effects in non-target organisms taking into account the existing limitations.

In view of the above considerations, the first ground of your claim must be rejected as unfounded.

(b) Second ground: lack of assessment of the concentration of DvSnf7 dsRNA and the biologically active molecules in plants

According to your second ground, EFSA did not take into consideration the concentration of DvSnf7 dsRNA and of the biologically active molecules derived from it in the plants, and, as a result, it did not assess the concentration in the plants of those molecules and based its conclusions on a mere assumption of the amount of RNAs taken up and absorbed in humans and animals.

Your claim cannot be accepted.

Contrary to your allegations, EFSA did consider all the information received for the risk assessment, including the concentration of DvSnf7 dsRNA in the plants.

For the molecular characterisation of GM plants required by part II, section 1.2 of Annex II to Regulation (EC) No 503/2013, expression of new constituents is demonstrated and risk-assessed with regard to food and feed safety. In this respect, the applicant provided in the application the measured levels of the DvSnf7 dsRNA in different plant tissues of GM maize MON 87411. EFSA examined that information and concluded that the levels of DvSnf7 dsRNA in GM maize MON 87411 tissues did not represent the levels of the deriving pool of biologically active molecules that would be present in plants and that could potentially exert off-target effects, since it is likely that plant proteins may process some of the DvSnf7 dsRNA into a pool of biologically active molecules, such as active siRNAs or silencing RNAs.

It is true, however, that EFSA did not assess human and animal dietary exposure to the DvSnf7 dsRNA and to the biologically active molecules deriving from it, but EFSA explained, in section 3.4.3.2 of its opinion on GM maize MON 87411[11], the reasons why it considered that such assessment was not useful.

EFSA recalled that DvSnf7 dsRNA and the biologically active molecules deriving from it are considered generally not to exert any biological effects on humans and animals when ingested. It explained that silencing RNAs are generally rapidly degraded shortly after ingestion, unless chemical modifications increasing their stability are introduced, and face several cellular and intracellular barriers to their absorption. Therefore, the amount of silencing RNAs absorbed upon ingestion can be considered negligible in humans and animals and limits the possibility to reach a tissue or functional location in sufficient amounts to exert any biological effect.

In the case of GM maize MON 87411, based on the information provided by the applicant, the DvSnF7 dsRNA is not chemically modified to increase stability in the plant and/or increase cellular uptake in the gastrointestinal tract and the systemic absorption following oral administration[12]. Therefore, as concluded by EFSA, the DvSnf7 dsRNA and the biologically active molecules derived from it are not able to exert any biological effects once ingested by humans and animals (other than the targeted organism (corn rootworm)).

In view of the above, your second ground cannot be accepted.

(c) Third ground: uncertainties in the GM maize feeding study

Your third ground concerns the 90- day oral repeated- dose toxicity study in rats on whole food and feed from GM maize MON 87411 provided by the applicant in accordance with the requirements of part II, section 1.4.4.1 of Annex II to Regulation (EU) No 503/2013. You allege that EFSA erred in accepting the data from that feeding study because it only included one dosage of maize as part of the diet instead of different dosages as required by EFSA's existing guidance, and because the stability of the test and control materials was not tested to determine its comparability to diets fed under practical conditions. In that regard, you refer to publications by Dávalos *et al*. (2019)[13] and by Nawaz *et al.* (2019)[14] showing that the uptake of non-coding RNA ('ncRNA') from plants via ingestion in sufficient amounts exerts effects on gene regulation in mammalian cells and that it also has impact on the host's microbiome. In addition, you claim that weight depression observed in rats fed with GM maize MON 87411 is an unintended effect linked to the consumption of the GM maize MON 87411.

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[11] See *supra* footnote 6.

[12] Section 3.4.3.2 of EFSA Scientific opinion on the GM maize MON 87411 (see *supra* footnote 6).

[13] Dávalos A, Henriques R, Latasa MJ, Laparra M, Coca M, 2019. Literature review of baseline information on non-coding RNA (ncRNA) to support the risk assessment of ncRNA-based genetically modified plants for food and feed. EFSA supporting publication 2019:EN-1688. 220 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1688.

[14] Nawaz, M.A, Mesnage, R., Tsatsakis, A.M., Golokhvast, K.S., Yang, S.H., Antoniou, M.N., Chung, G, 2019. Addressing concerns over the fate of DNA derived from genetically modified food in the human body: a review. Food Chem Toxicol, 124: 423-430 https://doi.org/10.1016/j.fct.2018.12.030.

Your ground cannot be accepted.

Concerning the fact that the applicant only tested one dose level, EFSA took note of this fact. Nonetheless it considered the study acceptable because the dose tested was close to the highest possible without inducing nutritional imbalance according to the current knowledge, and, therefore, it was in accordance with the limit test dose as described in the OECD Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption ('OECD TG 408')[15]. It should also be noted that EFSA did not identify any specific hypothesis to test the whole food and feed in a toxicological study.

Concerning the stability of the test and control materials in the 90-day feeding study on MON 87411, it is correct that it was not tested. This is a recurrent situation in 90-day feeding studies on GM plants, which the Food and Feed Working Group of the GMO Panel discussed and clarified[16]. The GMO panel concluded that, in accordance with the OECD Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items[17], the information on the expiration dates of the constituents of the formulated diets, as declared by the diet manufacturer, can be regarded as sufficient to prove their stability, provided that this information is duly documented. Moreover, identification of the event and/or of the newly expressed proteins in the test material and formulated diets after the conclusion of the in-life phase of the toxicological studies should be conducted to further corroborate their stability. In the specific 90-day feeding study on GM maize MON 87411, EFSA considered the stability of the test item adequate as, in accordance with product expiration standards declared by the diet manufacturer, the constituents of the diet (including the test and control item 'maize') were considered stable for the duration of the study.

With regard to your claim that weight depression observed in rats fed with GM maize MON 87411 is an unintended effect observed in the feeding study, EFSA concluded that those changes were not adverse based on the lack of associated findings (clinical signs and histopathological changes in the digestive tract). Moreover, these changes were of limited magnitude and/or transient in occurrence.

Based on the above considerations, your first ground must be rejected as unfounded.

1.2 New findings

In point 2.3 of your request, you mention the publication by Dávalos *et al*. (2019) as well as the publication by *Nawaz et al*. (2019), referred to above. You state that the findings from those

[15] OECD, 2018. "Repeated Dose 90-Day Oral Toxicity Study in Rodents (OECD TG 408)" in Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption, Éditions OCDE, Paris, https://doi.org/10.1787/9789264304741-23-en.

[16] Minutes of the 108th Meeting of the Working Group on Food and Feed Safety, available at https://www.efsa.europa.eu/sites/default/files/wgs/gmo/wg-applications-foodfeed-2018-2021_0.pdf.

[17] OECD (Organisation for Economic Co-operation and Development) Series On Principles Of Good Laboratory Practice And Compliance Monitoring Number 19, 2018. Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items. ENV/JM/MONO(2018)6.

papers, particularly regarding potential 'off target genes' in mammals (point 2.3.1 of your request), stability of ncRNA (point 2.3.2) and interaction in the microbiome (point 2.3.4), were not mentioned in the EFSA opinions on GM maize MON 87411 and on the GM stack maize and that these publications have to be considered as new information published after the EFSA opinions were adopted.

In addition, you claim, in point 2.3.3 of your request, that the publication by Dávalos *et al*. (2019) shows that the uptake of ncRNA from plants via the gut into human and animal cells is a fact and that it is in contradiction with the EFSA opinions on GM maize MON 87411 and on the GM stack maize. You also claim that according to that publication, plants ncRNA are chemically protected against degradation and that they have been found in many human and animal fluids, including blood and milk. Based on that information, you claim that there is a plausible hypothesis on how the additional DvSnf7 dsRNA might affect the gut microbiome community after ingestion and further research is needed to understand the impact of other exogenous dsRNA in mammalian host microbiota composition and to identify microbial targets along with their effect on physiological conditions.

Your claims cannot be accepted.

Regarding the publication by Dávalos *et al*. (2019), it is a literature review commissioned by EFSA to inform the food and feed risk assessment on the impact of ncRNA from GM plants to humans and animals. The literature data was taken into consideration by EFSA for the assessment of GM plants expressing dsRNA, in particular for the assessment of GM maize MON 87411 and the GM stack maize. However, it was not possible to cite this review before its final publication date (2019).

Nevertheless, the key elements used in the risk assessment of the ncRNA for GM maize MON 87411[18] and for the GM stack maize[19], such as its stability, are in line with the conclusions by Dávalos *et al*. (2019).

This publication presents a wide set of information and discusses the controversies on the presence of dietary exogenous RNAs in the biological fluids of humans and animals and their effects. EFSA considered the potential of the DvSnf7 dsRNA and biologically active molecules derived from it to exert any biological effects once ingested by humans and animals, in light of that information. As mentioned above, EFSA explained that, unless chemical modifications increasing the stability of silencing RNAs are introduced (which is not the case for the DvSnf7 dsRNA in GM maize MON 87411), the amount of such RNAs absorbed upon ingestion can be considered negligible in humans and animals and limits the possibility to reach a tissue or functional location in sufficient amounts to exert any biological effect.

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[18] See *supra* footnote 6.

[19] EFSA GMO Panel, Naegeli H, Bresson JL, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Álvarez F, Ardizzone M, De Sanctis G, Fernández Dumont A, Gennaro A, Gómez Ruiz JA, Lanzoni A, Neri FM, Papadopoulou N and Paraskevopoulos K, 2019c. *Scientific Opinion on the assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003* (application EFSA-GMO-NL-2017-144). EFSA Journal 2019;17(11):5848, 33 pp. https://doi.org/10.2903/j.efsa.2019.5848.

Regarding the publication by Nawaz *et al*. (2019), the information contained in this publication does not affect the conclusions of EFSA. Nawaz *et al*. (2019) reviews information that plant-food-micro RNAs can survive digestion, however, as just recalled, based on the data provided by the applicant, EFSA concluded that it is unlikely that the DvSnf7 dsRNA can survive digestion. In view of the above considerations, your claim must be dismissed as unfounded.

1.3 Authorisation of the GM stack maize and its subcombinations

In point 2.3.4 of your request, you claim firstly that the risk assessment of GM maize MON 87411 did not consider effects on the microbiome and that no data on the update of molecules from the gut were available. You also claim that, in the assessment of the GM stack maize, the publications by Dávalos *et al*. (2019) and Nawaz *et al*. (2019) were not considered. You claim that, based on the findings of those two publications, further risk assessment had to be performed to trace the fate of the artificial ncRNA after ingestion, to identify the potential target site in the microbial community in the gut and mammalian cells, and to assess the magnitude of potential effects, if identified.

Finally, you claim that a mixed toxicity, coming from a combination of DvSnf7 dsRNA, some of the newly expressed proteins (the *Bacillus thuringiensis* (Bt) proteins) and residues from spraying can have an effect on the immune system and other adverse health effects, either directly or via the microbiome, and that the GM stack maize needs to be tested in this respect.

Your claims cannot be accepted.

Regarding the effects on the gut microbiome, EFSA agrees in general on the relevance of the microbiome in the context of risk assessment. EFSA, during its assessment of the GM maize MON 87411 and of the GM stack maize expressing DvSnf7 dsRNAs, considered the potential of the dsRNA and deriving siRNAs to exert any biological effects once ingested by humans and animals, taking into account recent information including the findings of Dávalos *et al*. (2019), as explained in the above section 1.2 above.

In addition, EFSA recently launched a call for a thematic grant on the evaluation of the impact of microbiomes in risk assessment, including gastrointestinal tract microbiomes (human and domestic animals) and environmental microbiomes (plants, wildlife, soil)[20]. The microbiome is also being considered as a possible future scientific theme by the Science Studies and Project Identification & Development Office of EFSA (SPIDO)[21]. Furthermore, the need to explore the integration of microbiomes in the EFSA risk assessment is included in the draft EFSA 2027 strategy, currently under public consultation.

Regarding your claims on the mixed toxicity of the GM stack maize, risks indicating immunological health impacts were assessed by EFSA following the relevant guidelines[22] and

[20] https://www.efsa.europa.eu/en/news/new-grant-opportunity-microbiomes-and-plant-pests.

[21] https://www.efsa.europa.eu/en/events/event/79th-advisory-forum-meeting, item 2.5.

[22] EFSA GMO Panel, 2011. Scientific *Opinion on Guidance for risk assessment of food and feed from genetically modified plants*. EFSA Journal 2011;9(5): 2150, 37 pp. https://doi.org/10.2903/j.efsa.2011.2150.

Regulation (EU) No 503/2013. In the case of GM plants developed by stacking, one of the focus in the assessment is on the potential for interactions/combinatorial effects between the single events[23]. In the GM stack maize, there was no indication of an interaction that may affect the integrity of the combined events. The newly expressed protein levels in different parts of the plant, as determined for the GM stack maize and the corresponding single events, were comparable in all tissues. The only exception were the levels of the protein CP4 EPSPS, but those were expected to be different because of the combination of events MON 87427 and MON 87411, both producing this protein, in the GM stack maize. This difference in CP4 EPSPS protein levels was assessed and EFSA concluded that it did not raise any safety concerns. Moreover, EFSA assessed the potential impact of the DvSnf7 dsRNA on the levels of the newly expressed proteins by comparing the protein expression levels in GM stack maize and the respective single events. These data indicated that there was no such an impact. In addition, EFSA did not identify a hypothesis, mentioned in the second paragraph of section 1.4.4.1 of part II of Annex II to Regulation (EC) No 503/2013, that could require the investigation of the GM stack maize as whole food and feed, for example, in animal feeding studies. Therefore, EFSA considered that no animal studies were necessary to support the food and feed safety assessment of GM maize MON 87411. Further information on the use of animal studies for the assessment of health risks associated with the consumption of products derived from genetically engineered plants with a combination of traits may be found in section 3.4.2.2. of the EFSA technical report 'Assessment of the outcomes of the project "Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland" (RAGES)'[24]. Furthermore, because none of the newly expressed proteins in the GM stack maize showed potential for allergenicity, considering current knowledge, EFSA considered that no reasons for concern are expected regarding the simultaneous presence of these newly expressed proteins and DvSnf7 dsRNA in the GM stack maize.

Finally, concerning your claim on the need to assess the possible effects of a combination of DvSnf7 dsRNA, Bt proteins and residues from spraying, the Commission would like to clarify that under Articles 4(1)(a) and 16(1)(a) of Regulation (EC) No 1829/2003, GM food and feed must not have adverse effects on human health, animal health or the environment. However, these conditions for the authorisation of GM food and feed under Regulation (EC) No 1829/2003 do not cover the assessment of the potential effects of pesticide residues on human health, including possible cumulative effects.

This has been confirmed by the EU Court of Justice in its judgment of 12 September 2019 in Case C-82/17 P, *Testbio Tech and Others v. Commission* (par. 106 and 107), which upheld the General Court's interpretation that the assessment of the effects of pesticide residues on health is not covered by Regulation (EC) No 1829/2003 but by Regulation (EC) No 396/2005 on maximum residue levels ("MRLs") of pesticides in or on food and feed of plant and animal origin (Case T-177/13, par. 233 and 289). The safety of GM food and feed products with a

[23] EFSA scientific opinion on GM maize MON 87427, MON 89034, MIR162 and MON 87411 (see *supra* footnote 19).

[24] EFSA, Gennaro A, Álvarez F, Devos Y, Fernandez Dumont A, Gómez Ruiz JÁ, Lanzoni A, Paoletti C, Papadopoulou N, Raffaello T, Waigmann E, 2020. *Assessment of the outcomes of the project "Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland" (RAGES)*. EFSA supporting publication 2020:EN-1890. 31 pp. https://doi.org/10.2903/sp.efsa.2020.EN-1890.

possible presence of pesticide residues is therefore guaranteed by the combined application of Regulations (EC) No 1829/2003 and (EC) No 396/2005.

In any event, Regulation (EC) No 396/2005 applies to pesticide residues on all food and feed placed on the market in the EU and whether they are conventional or GM products. As any other food and feed, GM products placed on the EU market have to comply with the corresponding MRLs under Regulation (EC) No 396/2005.

In view of the above considerations, your claims must be rejected as unfounded.

2. Detection methods and post-market monitoring requirement in the Commission Implementing Decision

In point 3.2 of your request, you claim, firstly, that the detection methods provided by the applicant should not have been accepted because they do not allow, under practical conditions, to identify the GM stack maize in question and to distinguish it from other already authorised stacked or single events that inherit the same gene constructs and can be mixed in the diets. Secondly, you indicate that the post-market monitoring plan should have included some pieces of information, such as import volumes and volumes used in the EU. Finally, you make a number of observations regarding where and how environmental monitoring should be carried out.

Regarding the first claim, in accordance with Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, the applicant must provide the methods of detection, sampling and identification of the transformation event, in accordance with the requirements set out in Article 8 and Annex III to Regulation (EC) No 503/2013.

For GMOs with stacked events, the Commission's Joint Research Centre ('JRC'), which is the European Union Reference Laboratory for GM food and feed ('EURL GMFF')[25], carries out a verification study to assess the performance of the event-specific methods previously validated on parental lines, to detect and quantify the transformation event(s) on DNA from the stacked GMO containing several transgenic events. The results of the EURL GMFF verification are available online[26].

The detection methods validated by the EURL GMFF for the purpose of carrying out its tasks pursuant to Regulation (EC) No 1829/2003 are event-specific. Therefore, by applying several of such methods, it is possible to appropriately identify multiple GMO events in a food or feed sample, may the events correspond to different GMOs or to the same GMO. However, distinguishing between the potential presence of an equimolar mixture of single-event GMOs and a stacked-event GMO in a food or feed product usually requires additional information besides the laboratory measurement results.

[25] The JRC/EURL GMFF is in charge of testing and validating the methods of detection and identification proposed by the applicants in accordance with Articles 6(3)(d) and 18(3)(d) of Regulation (EC) No 1829/2003.

[26] Available at https://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx.

In any case, in your request, you do not provide any evidence to support your claim that the GM maize in question cannot be distinguished from other GM stacked or single events. Therefore, your allegation on this point must be rejected.

As regards your second claim, the Commission notes that, in accordance with Article 5(3)(k) of Regulation (EC) No 1829/2003, the application for authorisation may include, *'where appropriate, a proposal for post-market monitoring regarding the use of the food for human consumption'*. Article 6(5)(e) provides that post-market monitoring requirements may be imposed (*'where applicable'*), *'based on the outcome of the risk assessment'*. In the case at hand, the applicant did not propose a post-market monitoring regarding the use of the GM stack maize in food, and EFSA in its opinion did not identify the need for such monitoring on the basis of the risk assessment. Your request does not provide any argumentation or evidence showing that such a monitoring was needed based on the outcome of the risk assessment.

Finally, concerning the monitoring plan for environmental effects, the Commission notes that, as stated in recital 8 of Commission Implementing Decision (EU) 2021/65, EFSA concluded that the plan submitted by the applicant, consisting of a general surveillance plan, was in line with the intended uses of the products. In your request, you simply mention aspects, including where and how environmental monitoring should be carried out, which were not included in the plan, without providing any argumentation or evidence as to the reasons why they should have been included or as to the way in which they were at odds with the requirements of Annex VII to Directive 2001/18/EC[27].

Based on the above considerations, the Commission is of the view that your claims regarding the detection methods and the post-market monitoring requirement in Commission Implementing Decision (EU) 2021/65 are unfounded.

[27] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1–39).