ANNEX I – GENERAL LEGAL FRAMEWORK

Part 1 of your request for internal review entitled “General Legal framework” describes the legal framework, which in your view is applicable to Commission Implementing Decision 2015/687/EU of 24 April 2015 authorising the placing on the market of food and feed containing, consisting of, or produced from genetically modified oilseed rape MON 88302 and which should, in your opinion, serve as a basis for the verification of the compliance of the proper implementation of EU legislation on genetically modified organisms (GMOs).

You also allege that Regulation (EC) 1829/2003 on genetically modified food and feed and Directive 2001/18/EC on the deliberate release of GMOs in the environment¹ are “violated or disregarded by the market authorisation”, and that the precautionary principle enshrined in Regulation (EC) 178/2002² is “undermined”³.

In particular, you claim that “on the way in which the risk assessment was carried out by EFSA falls short of the legal requirements governing genetically modified foods and feeds within the EU pursuant to both Regulation 1829/2003 and 178/2002 and Directive 2001/18 require”. You add that the “environmental risk assessment carried out by EFSA, and upheld by the Commission, fails to meet the requirements of Directive 2001/18” and that “EFSA also failed to recommend, and the Commission failed to impose, any monitoring requirements pursuant to the GM Regulation on the use of MON 88302 as food and feed”⁴.

Before entering into the substantial elements of your claims, the Commission would like to react to certain statements made in this Part of your request that it cannot share.

1. Your allegations in point I (b) as regards the applicability of the requirements of Articles 13 and 19 of Directive 2001/18/EC

In the introduction and different parts of point I (b) of your request, you mention the application of the requirements of Directive 2001/18/EC applicable for a written consent in accordance with Article 19 of the Directive to be granted, and you cite the need to the application to fulfil the conditions of Article 13 of the Directive (which refers to the "notification procedure").

The Commission wishes to make clear that the genetically modified oilseed rape MON 88302 is authorised for food and feed and other uses than food and feed except cultivation by Commission Implementing Decision 2015/687/EU adopted pursuant to Regulation (EC) 1829/2003 on genetically modified food and feed (GM food and feed), and not under Directive 2001/18/EC.

³ Page 1 of your letter to Commissioner Andriukaitis of 9 June 2015.
⁴ Page 2 of the Technical background of the request for internal review.
According to the European Court of Justice of the European Union\(^5\), Regulation (EC) No 1829/2003 constitutes an implementation of Article 12 (1) of Directive 2001/18/EC which provides that Articles 13 to 24 of Directive 2001/18/EC do not apply “to any GMO as or in products as far as they are authorised by Community legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements (...) at least equivalent to those laid down in this Directive.”

Regulation (EC) No 1829/2003 mirrors this provision in its Articles 5 (5) and 17 (5), which both explicitly indicate that Articles 13 and 24 of Directive 2001/18/EC do not apply to GM food and feed containing or consisting in GMOs that comply with the requirements set out in Regulation (EC) No 1829/2003.

It follows that all references to Articles 13 and 19 of Directive 2001/18/EC in your request for internal review are irrelevant for the examination of the compliance of Commission Implementing Decision 2015/687/EU with Regulation (EC) No 1829/2003.

2. Your allegations as regards the environmental risk assessment (ERA) performed in the framework of the authorisation of the genetically modified oilseed rape MON 88302 regarding the effects on human and animal health.

You claim that "the environmental risk assessment has to include all effects which the placing of a GMO on the market may have on human health, including any possible cumulative effects" of GM plants on which herbicides have been sprayed and that "this also includes the potential effects of the use of herbicides or pesticides on the GMO plant or product"\(^6\). In answer to these allegations, the Commission would like to make the following observations:

2.1 On the claim that the environmental risk assessment must include all effects that a GMO placed on the market can have on human health, including any possible cumulative effects

The Commission does not agree with this allegation. It must indeed be recalled that the environmental risk assessment and the food and feed safety assessment serve different objectives, reflected in Regulation (EC) No 1829/2003 as follows:

- According to Articles 5 (3) and (4) and 17 (3) and (4) of Regulation (EC) 1829/2003, applicants are required to submit data demonstrating the human and animal health safety of the GM food and feed, including data on molecular characterisation, comparative assessment, toxicity, allergenicity, and nutrition. The objective is to assess all possible effects on human and animal health due to the consumption of GM food and feed.

- In addition, in case of food and feed containing or consisting of GMOs (living GMOs), Articles 5(5)(a) and 17(5)(a) of Regulation (EC) No 1829/2003 impose an environmental risk assessment, with the objective to assess the environmental and health impacts due to the release of GMOs in the environment.

In order to ensure that the environmental risk assessment of these GMOs is performed on the same criteria than any other GMOs falling under Directive 2001/18/EC, these

---

5 Judgement Monsanto SAS a.o, joined cases C-58/10 to C-68-10 of 8 September 2011. See point 47 of the judgement.
6 Page 8 of the Technical background of the request for internal review.
articles refer to Annexes II (for principles of the environmental risk assessment), III and IV (for the information to be supplied in the technical dossier) and Annex VII (for the monitoring) of Directive 2001/18/EC.

The two risk assessments are distinct and should not be confused, as explained in Recital 33 of Regulation (EC) No 1829/2003/EC:

"Where an application concerns products containing or consisting of a GMO, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under Part C of Directive 2001/18/EC (…), or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC (…)."

In light of these elements, the Commission cannot agree with your claim that the environmental risk assessment to be performed in accordance with the principles of Annex II of Directive 2001/18/EC must cover “all effects that the GMO products may have on human health or animal health.”

In fact, the objective of the environmental risk assessment to be performed in accordance with the principles of Annex II of Directive 2001/18/EC is to assess the effects on health and the environment of the release of the GMO into the environment. In this context, Point D of Annex II (“Conclusions on the potential environmental impact from the release or the placing on the market of GMOs”) describes the elements to be taken into account for the assessment of the health aspects in the context of an environmental assessment:

"possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMOs and persons working with, coming into contact with or in the vicinity of the GMO release(s)."

This assessment, which focuses on the protection of workers and persons in contact or in the vicinity of a GMO release, is clearly different from the safety assessment carried out under Regulation (EC) 1829/2003 for the assessment of the effects on health due to the consumption of the GM food and feed.

It must therefore be stressed that the protection of human health mentioned in Annex II of the Directive, is to be interpreted as covering health issues related to the release of GMOs in the environment, and not as covering the health effects of the consumption of the GM food and feed, which is regulated by Regulation (EC) 1829/2003.

In view of the above, we cannot agree with your conclusion that the environmental risk assessment to be performed under Article 5(5) and 17(5) of Regulation (EC) No 1829/2003 must cover all effects on human or animal health. In particular, the Commission considers that health effects, such as allergies, due to the consumption of genetically modified plants which are herbicide-resistant, are not part of the environmental risk assessment.

---

7 Page 8 of the Technical background of the request for internal review, emphasis added.
8 Point 6 of Points D.1 and D.2 of Annex II of Directive 2001/18/EC.
9 Page 7 of the Technical background of the request for internal review, last paragraph.
10 Page 11 of the Technical background of the request for internal review.
2.2. **On the claim related to the potential effects of the use of herbicides on human health, including possible cumulative effects**

The Commission cannot agree with your allegations that Annex II to Directive 2001/18/EC requires the assessment of the potential effects of the use of herbicides on human health, including possible cumulative effects.

Indeed, the assessment of the effects on human health of plant protection products is not regulated by the GMO legislation, but under two specific EU legislative acts:


As its title indicates, Regulation (EC) No 1107/2009 concerns the placing on the EU market of plant protection products. Given that the products covered under Decision 2012/347/EU do not correspond to the products enlisted in Article 2 "scope" of Regulation (EC) No 1107/2009, this Regulation is not applicable to the products covered by Decision 2015/687/EU.

However, Regulation (EC) No 396/2005 is fully applicable to the control of pesticides residues on food and feed imported from third country, including food and feed derived from GM plants. This Regulation provides for the risk assessment of pesticide residues in food and feed and sets maximum residue levels (MRL) applicable to all food and feed placed on the market, including GMOs. The MRL takes into account cumulative effects of regular consumption of food containing such residues.

In view of the aforesaid, the Commission concludes that the assessment of the effects on health of pesticide residues is not a condition for the authorisation of GM food and feed under Regulation (EC) No 1829/2003, and rejects your allegation on this regard.

3. **Monitoring: you allege that the Commission failed to impose appropriate monitoring obligations**

3.1 **On the monitoring of potential effects of the GMO on human health during the use and consumption stages**

You claim that the Commission has failed to impose a post-market monitoring plan and that the environmental monitoring plan as provided in Annex VII to Directive 2001/18/EC should address the potential effects of the GMO on human health during the use and consumption stages, including the cumulative effects of herbicide residues and genetically modified plants.

Such a conclusion is however not substantiated in law. Indeed, it must be recalled that the post-market monitoring plan and the post-market environmental monitoring plan are distinct

---

and serve two different purposes, which are clearly specified in Articles 5 and 17 of Regulation (EC) 1829/2003:

- According to Articles 5(3)(k) and 17(3)(k) of Regulation (EC) 1829/2003, "Where appropriate, a proposal for post-market monitoring regarding the use of the food/feed for human consumption" should be submitted in the application.

  This means that a post-market monitoring regarding the use of the food for human consumption and feed for animal consumption should be envisaged, only where necessary, on a case by case basis. The words "where appropriate" in this Article are mirrored by the words "where applicable" in Articles 6(5)(e) and 18 (5) (e).

- According to Articles 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003, in case of GM food and feed containing or consisting of GMOs, "a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for a duration for the monitoring plan (…)" shall be submitted by the applicant.

The Commission would like to underline in this context that Articles 5(5)(b) and 17(5)(b) relating to the post-market environmental monitoring plan only refer to "environmental effects", which includes the monitoring of the effects on the health workers which could be exposed to potentially harmful effects during the transport, or handling of the product (taking into account the fact that cultivation is excluded from the scope of the Decision) or to other persons which have been in contact or in the vicinity of GMOs.

According to Annex VII, Point A of Directive 2001/18/EC, the objectives of the monitoring plan are the following: i) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the environmental risk assessment are correct and; ii) to identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment that were not anticipated in the environmental risk assessment.

It results that the effects of the consumption by humans of the GMO are not covered by the environmental monitoring plan set out in accordance with Annex VII of Directive 2001/18/EC.

In the case of the GM oilseed rape MON 88302, EFSA considered that there was no need for post-market monitoring as referred to in Articles 5(3)(k) and 17 (3) (k) of Regulation (EC) 1829/2003 of GM food and feed products derived from oilseed rape MON88302, in line with its guidelines on the risk assessment of the food and food products derived from GM plants (EFSA, 2011).

The Commission considers therefore that your allegation that a post-market plan should have been imposed regarding the use of the food for human consumption and feed for animal consumption is not pertinent and should be refuted.

Regarding the post-market environmental monitoring plan referred to in Articles 5(5)(b) and 17(5)(b), EFSA considered that the scope of the post-market environmental monitoring plan provided by the applicant is in line with the intended uses of oilseed rape MON 88302, which exclude cultivation.

The Commission requested additional measures to be included in the draft monitoring plan, that shall be taken by operators on the premises, in order to avoid spillage during loading and
unloading of viable grains for any purposes, including transportation (see further explanations under E.6.3 of Annex II).

On the basis of the above, the Commission refutes your allegation that the environmental monitoring plan required by Commission Decision 2015/687/EU should address the potential effects of the GMO on human health during the use and consumption stages, including the cumulative effects of herbicide residues and genetically modified plants.

3.2 On the need to impose a case-specific monitoring

You allege that the monitoring plan should not consist of general surveillance only, but include a case-specific monitoring. Contrary to your claim, the Commission considers that the monitoring obligations provided in the monitoring plan for the oilseed rape MON 88302\textsuperscript{13} in accordance with Article 4 of Decision 2015/687/EU complies with Regulation (EC) 1829/2003 in light of the nature of the product and of the uses covered in the application for authorisation, and taking into account the outcome of the EFSA opinion following which no monitoring for the use of GM food/feed was deemed appropriate, and in so far that:

- Its objective is to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not anticipated in the environmental risk assessment (point 2.1. of the environmental monitoring plan);

- It is adapted to the authorised uses (import, processing and food and feed uses, and not cultivation) and proportionate to the extent of imports of MON 88302 oilseed rape and use in Member States;

- General surveillance of MON 88302 oilseed rape must be undertaken for the duration of the authorisation period (point 2.3. of the environmental monitoring plan). Since EFSA did not identify any potential adverse environmental effects, there was no need to extend the duration of the monitoring plan beyond the period of the consent for this specific application\textsuperscript{14};

- As the authorisation holder cannot control the entire food and feed chains, it involves operators involved in the import, handing and processing of viable 88302 oilseed rape. The most important operators in this area are associated to the monitoring obligations. As indicated in point 2.5 of the monitoring plan, "they are exposed to the imported viable MON 88302 oilseed rape and therefore the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles";

- It obliges the authorisation holder to actively screen relevant reports and peer-reviewed publications on the use of MON 88302, in order to identify potential unforeseen adverse effects related to MON 88302 oilseed rape;

\textsuperscript{13} Available at [http://ec.europa.eu/food/dyna/gm_register/MonitoringplanMON88302.pdf](http://ec.europa.eu/food/dyna/gm_register/MonitoringplanMON88302.pdf)

\textsuperscript{14} Section 1.5 of Council Decision 2002/811/EC of 3 October 2002 on time-period specifies that "It should also be considered whether it is necessary to extend the monitoring plan beyond the period of the consent".
- The authorisation holder shall immediately investigate and inform the European Commission of any potential unanticipated adverse effects, as required by Article 21 of the Regulation (point 3 of the environmental monitoring plan).

Section 1.3.1 of Council Decision 2002/811/EC of 3 October 2002\(^\text{15}\), to which you refer in your request\(^\text{16}\), states that that "case-specific monitoring serves to confirm that scientifically sound assumptions, in the environmental risk assessment, regarding potential adverse effects arising from a GMO and its use are correct" and adds that "Where the conclusions of the risk assessment identify an absence of risk or negligible risk, (...) case-specific monitoring may not be required".

In the case of MON 88302, EFSA considered that there is no need for a case-specific monitoring as the environmental risk assessment does not cover cultivation and identified no potential adverse environmental effects (as further explained in part E.6.1 of Annex II). On this basis, the Commission concluded that the environmental monitoring plan consisting of a general surveillance is in line with the intended uses for the GM oilseed rape MON 88302 and complies with Regulation (EC) 1829/2003.

In view of the above, the Commission rejects your allegation that a case-specific monitoring should be imposed by Commission Decision 2015/687/EU.


\(^{16}\) Page 10 of the Technical Background document of the request for internal review.