



2020/2895(RSP)

24.11.2020

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D069149/02 – 2020/2895(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Tilly Metz,

Günther Sidl, Anja Hazekamp, Eleonora Evi, Sirpa Pietikäinen,

**European Parliament resolution on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D069149/02 – 2020/2895(RSP))**

The European Parliament,

- having regard to the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D069149/02),
- having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed¹, and in particular Articles 11(3) and 23(3) thereof,
- having regard to the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 26 October 2020, at which no opinion was delivered,
- having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers²,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 3 December 2008 and published on 18 December 2008³,
- having regard to the opinion adopted by EFSA on 25 September 2019, and published on 07 November 2019⁴,
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs')⁵,

¹ OJ L 268, 18.10.2003, p. 1.

² OJ L 55, 28.2.2011, p. 13.

³ Scientific opinion of the EFSA Panel on Genetically Modified Organism on the application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of the insect-resistant genetically modified maize MON89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto
<https://www.efsa.europa.eu/en/efsajournal/pub/909>

⁴ Scientific opinion of the EFSA Panel on Genetically Modified Organisms on the assessment of genetically modified maize MON 89034 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-015). EFSA Journal 2019;17(11):5845;
<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5845>

⁵ In its eighth term, the European Parliament adopted 36 resolutions objecting to the authorisation of genetically modified organisms. Furthermore, in its ninth term Parliament has adopted the following resolutions:

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- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0028).
 - European Parliament resolution of 10 October 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0029).
 - European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0030).
 - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0054).
 - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0055).
 - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0056).
 - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0057).
 - European Parliament resolution of 14 May 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0069).
 - European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0291).
 - European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0292).
 - European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603

- having regard to Rule 112(2) and (3) of its Rules of Procedure,
 - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas Commission Decision 2009/813/EC⁶ authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified ('GM') maize MON 89034; whereas the scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of genetically modified maize MON 89034 for the same uses as any other maize, with the exception of cultivation;
 - B. whereas on 3 August 2018, Monsanto Europe N.V. on behalf of Monsanto Company, United States, submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation;
 - C. whereas, on 3 December 2008, EFSA adopted a favourable opinion, which was published on 18 December 2008, in relation to the initial authorisation application;
 - D. whereas, on 25 September 2019, EFSA adopted a favourable opinion, which was published on 07 November 2019, in relation to the renewal application;
 - E. whereas GM maize MON 89034 has been engineered to produce Cry1A.105 and Cry2Ab2, synthetic insecticidal proteins (also known as Bt toxins) with enhanced toxicity, compared to the natural bacteria they are derived from, to protect against specific lepidopteran pests⁷;
 - F. whereas Regulation (EC) No 1829/2003 states that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision;

Member State concerns about EFSA opinions

- G. whereas, during the consultation period in relation to the initial authorisation application, Member States submitted many critical comments to EFSA's draft opinion⁸; whereas those critical comments include concerns that the feeding study with broilers is not appropriate for assessing toxicological safety since it does not consider toxicological endpoints, that the applicant's proposal for an environmental monitoring plan does not meet the objectives defined in Annex VII of Directive 2001/18/EC of the

and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0293).

⁶ Commission Decision 2009/813/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89034-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 21).

⁷ EFSA first opinion, p 21 <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5845>

⁸ Annex G, Member States' comments:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-042>

European Parliament and of the Council⁹, that the combinatorial effects of both toxins were not studied, that an increase in the allergenic activity due to Cry1A.105 and Cry2Ab2 proteins in food and feed from GM maize MON 89034 cannot be excluded and that the conclusion as to substantial equivalence of GM maize MON 89034 and conventional maize are premature;

- H. whereas, during the consultation period in relation to the renewal application, Member States again submitted many critical comments to EFSA's draft opinion¹⁰; whereas those critical comments include the observation that the latest annual monitoring reports make no mention of the fact that wild populations of teosinte plants able to cross with maize have recently been recorded in Europe (in France), and that the monitoring plan based on consent given by Commission Decision 2005/635/EC¹¹ and the monitoring reports (2010 to 2018) have many deficiencies and are neither in line with Directive 2001/18/EC and the corresponding guidelines nor with EFSA guidance on the post-market environmental monitoring; furthermore many Member States reiterated their concerns regarding EFSA's initial risk assessment¹²;

Invalid toxicity studies

- I. whereas safety studies to assess acute toxicity and degradation in digestive fluids were conducted with Cry1A.105 and Cry2Ab2 proteins produced in an *E. coli* strain; whereas a Member State competent authority raised concerns about the lack of equivalence between the proteins expressed in *E. coli* and in MON89034¹³, raising doubts about the validity of those toxicity studies;
- J. whereas, in general, little significance can be attributed to toxicological tests conducted with proteins in isolation, due to the fact that the effects of the protein in combination with the plant itself are not considered;
- K. whereas, for example, some plants, including maize, naturally produce proteinase inhibitors (PI) which have been shown to slow down the degradation of Bt toxins; whereas this results in much higher toxicity of the Bt toxin, if it is ingested together with the plant tissue, compared to the toxin in isolation; whereas a 1990 study, conducted by scientists at Monsanto, showed that even the presence of extremely low levels of PI enhanced the insecticidal activity of Bt toxins up to 20-fold¹⁴; whereas this interaction has never been assessed, or mentioned, by EFSA in its risk assessments of

⁹ 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 - Commission Declaration (*OJL 106, 17.4.2001, p. 1*).

¹⁰ Member States' comments:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00673>

¹¹ Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (*OJL 228, 3.9.2005, p. 11*).

¹² See recital G.

¹³ See p 7 of Member State comments: <https://doi.org/10.2903/j.efsa.2009.1193> and page 27 of MS comments here: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00673>

¹⁴ MacIntosh, S.C., Kishore, G.M., Perlak, F.J., Marrone, P.G., Stone, T.B., Sims, S.R., Fuchs, R.L. (1990) Potentiation of *Bacillus thuringiensis* insecticidal activity by serine protease inhibitors. *J Agric Food Chem*, 38: 1145-1152.

GM Bt plants;

- L. whereas it has been shown that factors which enhance the toxicity of the Bt toxins can also impact their selectivity¹⁵: if efficacy of the Bt toxin on target organisms is increased, its selectivity may also be decreased and a wider range of non-target organisms may become susceptible; whereas, whilst no systematic research has been undertaken to date, several studies indicate the effects of PI combined with Bt toxins on non-target insects¹⁶;
- M. whereas the risk of higher toxicity to humans and mammals, due to interaction between PI and Bt toxins in GM plants, is not known;

Questions of Bt adjuvanticity

- N. whereas a number of studies show that side effects have been observed that may affect the immune system following exposure to Bt toxins and that some Bt toxins may have adjuvant properties¹⁷, meaning that they can increase the allergenicity of other proteins with which they come into contact;
- O. whereas whilst EFSA recognises that Cry1Ac¹⁸ has been shown to act as an adjuvant, it concludes that, as maize is not a common allergenic food, the adjuvant effect of Cry proteins, observed after high dosage intragastric or intranasal administration, is unlikely to raise any concerns regarding allergenicity¹⁹; whereas, however, EFSA does not take into account the fact that maize produces PI²⁰ and therefore a much slower degradation of the Bt toxins has to be assumed if it is ingested with the plant material, compared to its isolated form; whereas this difference can also enhance its adjuvanticity and renders studies using isolated proteins invalid; whereas no empirical studies were performed to investigate the actual immunogenicity of the Bt toxin produced by the GM plant; whereas degradation of the proteins in digestive fluids, which is also relevant for the assessment of potential allergenicity, was tested by using proteins produced in *E.coli* in isolation;

Bt crops: effects on non-target organisms and increased resistance

- P. whereas, unlike the use of insecticides, where exposure is at the time of spraying and for a limited time afterwards, the use of Bt GM crops leads to continuous exposure of the

¹⁵ See, for example, Then, C. (2010) Risk assessment of toxins derived from *Bacillus thuringiensis*: synergism, efficacy, and selectivity. *Environ Sci Pollut Res Int*, 17: 791–797.

¹⁶ See, for example, Han P, Niu CY, Lei CL, Cui JJ, Desneux N. Quantification of toxins in a Cry1Ac + CpTI cotton cultivar and its potential effects on the honey bee *Apis mellifera* L. *Ecotoxicology*. 2010;19(8):1452-1459. <https://link.springer.com/article/10.1007/s10646-010-0530-z> Influence of Bt-transgenic pollen, Bt-toxin and protease inhibitor (SBTI) ingestion on development of the hypopharyngeal glands in honeybees, Dirk Babendreier, Nicole M. Kalberer, Jörg Romeis, Peter Fluri, Evan Mulligan and Franz Bigler, *Apidologie*, 36 4 (2005) 585-594, DOI: <https://doi.org/10.1051/apido:2005049>, and Liu, X.D., Zhai, B.P., Zhang, X.X., Zong, J.M. (2005b) Impact of transgenic cotton plants on a non-target pest, *Aphis gossypii* Glover. *Ecol Entomol*, 30: 307-315. <https://doi.org/10.1111/j.0307-6946.2005.00690.x>.

¹⁷ For a review, see Rubio-Infante, N., Moreno-Fierros, L., ‘An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals’, *Journal of Applied Toxicology*, May 2016, 36(5): pp. 630-648, <http://onlinelibrary.wiley.com/doi/10.1002/jat.3252/full>

¹⁸ Cry1Ac is one of only several Bt toxins which have been investigated in detail by EFSA.

¹⁹ EFSA 1st opinion, p 16 <https://www.efsa.europa.eu/en/efsajournal/pub/909>

²⁰ See recital K.

target and non-target organisms to Bt toxins;

- R. whereas the assumption that Bt toxins exhibit a single target-specific mode-of-action can no longer be considered correct and effects on non-target organisms cannot be excluded²¹; whereas an increasing number of non-target organisms are reported to be affected in many ways; whereas 39 peer-reviewed publications that report significant adverse effects of Bt toxins on many ‘out-of-range’ species are mentioned in a recent overview²²;
- S. whereas combinatorial effects such as combination with PI may significantly contribute to the toxicity of Bt toxins; whereas the question of selectivity is especially relevant for synthetic Bt toxins, such as Cry1A.105 and Cry2Ab2, which may show lower selectivity in combination with higher toxicity; whereas EFSA still considers that Bt toxins only affect a narrow range of non-target organisms, not taking into account any combinatorial effects; whereas a wider range of non-target organisms might be exposed to Bt toxins via spillage, waste and manure;
- T. whereas no effects on non-target organisms were evaluated in the risk assessment; whereas a Member State competent authority comments that ‘the studies are not sufficient to conclude that exposure of the environment and thus effects on non-target organisms will be negligible’ and ‘experimental evidence from the few studies available demonstrates that Bt toxins will be present in faeces of livestock fed with Bt crops. Consequently, for any market application of Bt crops, experiments should be presented in order to conclude on subsequent effects and risks for non-target organisms’²³;
- U. whereas the risk assessment did not consider the development of resistance in the target pests to Bt toxins, possibly resulting in the use of less environmentally safe pesticides or increased doses and the number of applications to the GM crop in the country of cultivation; whereas, the US Environmental Protection Agency is proposing to phase out many current Bt corn hybrids, as well as some Bt cotton varieties, in the next three to five years, due to the growth in insect resistance to such crops²⁴;
- V. whereas, whilst it has been claimed that the use of Bt crops leads to a decrease in the use of insecticides, a recent study published in the United States²⁵, finds that ‘several analyses on the influence of Bt crops on pesticide-use patterns do not seem to have considered seed treatments and so may have overstated reductions in insecticide use (especially “area treated”) associated with Bt crops’; whereas the same study finds that neonicotinoid seed treatments are often used in conjunction with Bt maize and soybean crops, that ‘[t]his pattern of use may have unintended consequences, namely resistance in target pests, outbreaks of non-target pests, and pollution with detrimental effects cascading to wildlife.’ and that ‘some of these effects have already emerged’; whereas

²¹ See, for example, Hilbeck, A. and M. Otto. 2015. Specificity and combinatorial effects of *Bacillus thuringiensis* Cry toxins in the context of GMO risk assessment. *Frontiers Environmental Science* 3:71.

²² RAGES (2020) Sub-report: Insecticidal Bt crops. EFSA's risk assessment approach for GM Bt plants fails by design, p 4 https://www.testbiotech.org/sites/default/files/RAGES_report-Insecticidal%20Bt%20plants.pdf

²³ Member States' comments, p 16:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00673>

²⁴ <https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/09/29/epa-proposes-phasing-dozens-bt-corn>

²⁵ Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops', Douglas, M.R., Tooker, J.F., *Environmental Science and Technology* 2015, 49, 8, 5088-5097, <https://pubs.acs.org/doi/10.1021/es506141g>

the Union has banned the outdoor use of three neonicotinoids, including as seed coatings, because of their impact on honeybees and other pollinators²⁶;

- W. whereas the Union is party to the UN Convention on Biological Diversity ('UN CBD'), which makes it clear that both exporting and importing countries have international responsibilities regarding biological diversity;

Literature review

- X. whereas Commission Implementing Regulation (EU) No 503/2013²⁷ requires the applicant to undertake a literature review for the renewal procedure; whereas a literature search identified 285 publications, yet the applicant only selected five publications, after applying its own eligibility/inclusion criteria, that it considered relevant for food and feed safety assessment or molecular characterisation; whereas one Member State competent authority commented that the literature search did not adequately address potential adverse effects on human and animal health, since the following search terms were not included in the search: 'toxicity', 'toxic', 'animal studies', 'toxic effects', 'adverse effects' and 'health effects'²⁸; whereas, in general, the literature reviews carried out by applicants for renewal of GMO authorisations are not of a high quality;

Undemocratic decision-making

- Y. whereas the vote on 26 October 2020 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States;
- Z. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but which has become the norm for decision-making on GM food and feed authorisations, is problematic;
- AA. whereas, in its eighth term, Parliament adopted a total of 36 resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (three resolutions); whereas, to date, Parliament has adopted eleven objections in its ninth term; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;

²⁶ Neonicotinoids,

https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

²⁷ 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).

²⁸ Member States' comments p 1:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00673>

- AB. whereas, under Regulation (EU) No 182/2011, the Commission may decide not to authorise a GMO when there is no qualified majority of Member States in favour in the Appeal Committee²⁹; whereas no change of law is required in this respect;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
 2. Considers that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim of Regulation (EC) No 1829/2003, which is, in accordance with the general principles laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council³⁰, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to GM food and feed, while ensuring the effective functioning of the internal market;
 3. Calls on the Commission to withdraw its draft implementing decision;
 4. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs³¹; expresses its strong disappointment, however, that, on 28 September 2020, the Commission authorised another GM soybean for import³² despite an objection by Parliament and a majority of Member States voting against;
 5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;
 6. Urges the Commission, again, to take into account the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN CBD and the UN Sustainable Development Goals, in the authorisation process;
 7. Reiterates its call on the Commission to stop authorising GMOs, whether for cultivation or for food and feed uses, when no opinion is delivered by Member States in the Appeal Committee, in accordance with Article 6(3) of Regulation (EU) No 182/2011;
 8. Calls on EFSA to finally accept the substantial differences between native Bt toxins and those expressed by synthetic transgenes in GM crop plants, and to widen its risk assessment in order to fully take into account all interactions and combinatorial effects between Bt-toxins, GM plants and their constituents, residues from spraying with the complementary herbicides, the environment as well as impacts on health and food safety;

²⁹ The Commission 'may, and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee, according to Article 6(3) of Regulation (EU) No 182/2011.

³⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

³¹ <https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf>

³² MON 87708 × MON 89788 × A5547-127,

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=100

9. Calls on EFSA to no longer accept toxicity studies based on isolated proteins which are likely to be different in structure and biological effects compared to those produced by the plant itself, and to require that all tests are carried out with tissue from the GM plant;
10. Calls on EFSA to make sure that data from field trials or green houses cover a sufficiently broad range of agronomic and environmental conditions to assess the impact of all stress factors which have to be expected during cultivation on gene expression and plant composition;
11. Calls on EFSA to make sure that the data from field trials or green houses cover a sufficiently broad range of different varieties to assess the impact of various genetic backgrounds on gene expression and plant composition;
12. Calls on EFSA to request data on the impact of the consumption of food and feed derived from GM plants on the intestinal microbiome;
13. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.