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Assessment of genetically modified soybean MON 87701 × MON 89788 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-022)

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Abstract

Following the submission of application EFSA-GMO-RX-022 under Regulation (EC) No 1829/2003 from Bayer CropScience LP, the Panel on Genetically Modified Organisms of the European Food Safety Authority was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide-tolerant genetically modified soybean MON 87701 × MON 89788, for food and feed uses, excluding cultivation within the European Union. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequences of the events in soybean MON 87701 × MON 89788 considered for renewal are identical to the sequences of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-022 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87701 × MON 89788.

Keywords: soybean, MON 87701 × MON 89788, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission

Question number: EFSA-Q-2021-00062

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Summary

Following the submission of application EFSA-GMO-RX-022 under Regulation (EC) No 1829/2003 from Bayer CropScience LP, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide-tolerant genetically modified soybean MON 87701 × MON 89788. The scope of the renewal application EFSA-GMO-RX-022 is for the renewal of the placing on the market of products containing, consisting of, or produced from soybean MON 87701 × MON 89788, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-022, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-022 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant and updated bioinformatic analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the events in soybean MON 87701 × MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-022 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87701 × MON 89788 (EFSA GMO Panel, 2012).

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1. Introduction

1.1. Background

On 1 February 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-022 for the renewal of the authorisation of soybean MON 87701 × MON 89788 (Unique Identifier MON-877Ø1-2 × MON-89788-1), submitted by Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1]

Following receipt of application EFSA-GMO-RX-022, EFSA informed the Member States (MS) and made the summary of the application available to the public on the Open EFSA portal.[2]

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013[3] and, when needed, asked the applicant to supplement the initial application. On 4 May 2021, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-BE-2009-73 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2012), the placing on the market of soybean MON 87701 × MON 89788 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/347/EU.[4] A copy of this authorisation was provided by the applicant.[5]

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of 6 months to issue a scientific opinion on application EFSA-GMO-RX-022. This time limit was extended whenever EFSA and/or its GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the MS and EC (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC.[6] The MS had 3 months to make their opinion known on application EFSA-GMO-RX-022 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of soybean MON 87701 × MON 89788 for the renewal of authorization for placing on the market of products containing, consisting of, or produced from GM soybean MON 87701 × MON 89788 in the context of its scope as defined in application EFSA-GMO-RX-022.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation including the opinions of the nominated risk assessment bodies of the MS.[7]

In addition to the present scientific opinion on soybean MON 87701 × MON 89788, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in the OpenEFSA portal,[8] including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a

[1] 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, pp. 1–23.
[2] Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00062.
[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 L157, 8.6.2013, pp. 1–48.
[4] Commission Implementing Decision of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-877Ø1-2 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C (2012) 4312). Official Journal of the European Union L 171/13, 30.6.2012.
[5] Dossier: Soybean MON 87701 × MON 89788 – Annex I
[6] 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, 12.3.2001, pp. 1–38.
[7] Opinions of the nominated risk assessment bodies of EU Member States can be found at the Open EFSA Portal https://open.efsa.europa.eu/questions, querying the assigned Question Number.
[8] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00062.

post-market environmental monitoring (PMEM) plan as provided by the applicant; the method(s), validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-022 submitted according to EFSA requirements (EFSA GMO Panel, 2015; EFSA, 2019a) and provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the frame of the contract OC/EFSA/GMO/2018/04 and OC/EFSA/GMO/2021/06, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing literature search and updated bioinformatic analyses, respectively.

2.1.1. Post-market monitoring reports[9]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from soybean MON 87701 × MON 89788, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean MON 87701 × MON 89788 (EFSA GMO Panel, 2012), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 10 annual PMEM reports covering a reporting period from July 2011 till June 2021. The annual PMEM plans submitted by the applicant included (1) commodity crop (GM and non GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio[10] for the collection of information recorded by various operators (federations involved in soybean grains import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean possibly containing soybean MON 87701 × MON 89788; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[11]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed systematic literature searches covering the period from January 2010 until April 2022, in accordance with the recommendations on literature search outlined in EFSA (2010, 2019b).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 2,163 publications (including the updated search) were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, nine publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

2.1.3. Updated bioinformatic data[12]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for soybean MON 87701 × MON 89788 including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed proteins Cry1Ac and CP4 EPSPS regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

[9] Dossier: Soybean MON 87701 × MON 89788 – Annex II.
[10] The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops were taken over by CropLife Europe as of 1 January 2021.
[11] Dossier: Soybean MON 87701 × MON 89788 – Annex III; additional information: 15/2/2022, 15/7/2022.
[12] Dossier: Soybean MON 87701 × MON 89788 – Annex III; additional information: 3/9/2021, 15/7/2022, 26/10/2022.

2.1.4. Additional documents or studies provided by the applicant[13]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019a), the applicant provided an overview on the worldwide approvals of soybean MON 87701 × MON 89788 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU (Appendix B).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant.

2.1.5. Overall assessment as provided by the applicant[13]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean MON 87701 × MON 89788 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2012).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[14]

The applicant indicated in the dossier that the environmental post-market monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the application for renewal of the authorisation of soybean MON 87701 × MON 89788 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015). The comments raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of soybean MON 87701 × MON 89788, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on soybean MON 87701 × MON 89788 and the newly expressed proteins Cry1Ac and CP4 EPSPS. The overall quality of the performed literature searches is acceptable.

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on soybean MON 87701 × MON 89788 (EFSA, 2012) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses to assess the interruption of soybean endogenous genes confirm previous results indicating that no endogenous genes have been interrupted by the events MON 87701 and MON 89788 (EFSA GMO Panel, 2012, 2019).

Analyses of the amino acid sequence of the newly expressed Cry1Ac and CP4 EPSPS proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the inserts do not indicate sequence similarities to toxins or allergens in soybean MON 87701 × MON 89788. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate sequence similarities to toxins or allergens in soybean MON 87701 × MON 89788 (EFSA GMO Panel, 2012, 2019).

[13] Dossier: Soybean MON 87701 × MON 89788 – Annex III.
[14] Dossier: Soybean MON 87701 × MON 89788 – Part I – Request for renewal; additional information: 26/10/2022.

The updated bioinformatic analyses for events MON 87701 and MON 89788 did not reveal any DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination, confirming previous conclusions (EFSA GMO Panel, 2012, 2019). Given the results of this analysis and that the recombinant DNA in soybean MON 87701 × MON 89788 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the reports of the additional studies provided (Appendix B). Overall, the new additional documents or studies provided by the applicant do not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on soybean MON 87701 × MON 89788.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA-GMO-RX-022 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean MON 87701 × MON 89788.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM plant material, including soybean MON 87701 × MON 89788. This general surveillance is coordinated by CropLife and implemented by selected operators (federations involved in soybean grains import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-022, but reminds that monitoring is related to risk management, and thus the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

Under the assumption that the DNA sequence of the events in soybean MON 87701 × MON 89788 considered for renewal is identical to the sequence of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-022 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87701 × MON 89788 (EFSA GMO Panel, 2012).

5. Documentation as provided to EFSA

- Letter from the European Commission to EFSA received on 1 February 2021 for the continued marketing of genetically modified soybean MON 87701 × MON 89788 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 Bayer CropScience LP (EFSA-GMO-RX-021)
- The application was made valid on 4 May 2021
- Additional Information (Clock 1) was requested on 2 July 2021
- Additional Information (Clock 1) was received on 3 September 2021
- Additional Information (Clock 2) was requested on 14 October 2021
- Additional Information (Clock 2) was received on 15 February 2022
- Additional Information (Clock 3) was requested on 24 February 2022
- Additional Information (Clock 3) was received on 15 July 2022
- Additional Information (Clock 4) was requested on 14 September 2022
- Additional Information (Clock 4) was received on 26 October 2022

References

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogué F, Papadopoulou N and Tebbe C, 2017. Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA supporting publication 2017:EN-1273, 11 pp. https://doi.org/10.2903/sp.efsa.2017.EN-1273

EFSA (European Food Safety Authority), 2019a. Administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003. EFSA supporting publication 2019:EN-1668, 19 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1668

EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Álvarez F and Glanville J, 2019b. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market – note on literature searching to GMO risk assessment guidance. EFSA Journal 2019;16(4):EN-1614, 62 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1614

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2012. Scientific Opinion on application (EFSA-GMO-NL-2009-73) for the placing on the market of insect resistant and herbicide tolerant genetically modified soybean MON 87701 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012;10(2):2560, 34 pp. https://doi.org/10.2903/j.efsa.2012.2560

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. https://doi.org/10.2903/j.efsa.2015.4129

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Eigenmann P, Epstein M, Hoffmann- Sommergruber K, Koning F, Lovik M, Mills C, Moreno FJ, van Loveren H, Selb R and Fernandez Dumont A, 2017. Guidance on allergenicity assessment of genetically modified plants. EFSA Journal 2017;15(5):4862, 49 pp. https://doi.org/10.2903/j.efsa.2017.4862

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay J-L, 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, Devos Y, Dumont AF, Gennaro A, Gómez Ruiz JÁ, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K and Raffaello T, 2019. Scientific Opinion on the assessment of genetically modified soybean MON 87751 x MON 87701 x MON 87708 x MON 89788 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-128). EFSA Journal 2019;17(11):5847, 31 pp. https://doi.org/10.2903/j.efsa.2019.5847

Abbreviations

GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PMEM	post-market environmental monitoring

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2009–April 2022)

Reference
Baranov EA, Shestakova S, Sadykova E and Tyshko N, 2019. GM stack soybean MON87701xMON89788 reproduction toxicity investigation. Toxicology Letters, 1–2.
Benevenuto RF, Zanatta CB, Guerra MP, Nodari RO and Agapito-Tenfen SZ, 2021. Proteomic profile of glyphosate-resistant soybean under combined herbicide and drought stress conditions. Plants (Basel), 10.
Berman KH, Harrigan GG, Riordan SG, Nemeth MA, Oliveira W, Tagliaferro F and Berger GU, 2011. Compositional equivalence of insect-protected glyphosate-tolerant soybean, MON 87701 × MON 89788, to conventional soybean extends across different world regions and multiple growing seasons. Journal of Agricultural and Food Chemistry, 59, 11643–11651.
Ferreira R and de Carvalho TC, 2019. Transgenic impact: analysis of the effect of storage on the physiological attribute of soybean seeds.Impacto dos transgenicos: analise do efeito do armazenamento no atributo fisiologico de sementes de soja. Brazilian Journal of Applied Technology for Agricultural Science, 12, 7–15.
Jose M, Vertuan H, Soares D, Sordi D, Bellini LF, Kotsubo R and Berger GU, 2020. Comparing agronomic and phenotypic plant characteristics between single and stacked events in soybean, maize, and cotton. *PLoS One*, 1–13.
Liu W, Xu W, Li L, Dong M, Wan Y, He X, Huang K and Jin W, 2018. iTRAQ-based quantitative tissue proteomic analysis of differentially expressed proteins (DEPs) in nontransgenic and transgenic soybean seeds. Scientific Reports, 8:17681, 1–10.
Liu W, Zhang Z, Liu H and Jin W, 2020. iTRAQ-based quantitative proteomic analysis of two transgenic soybean lines and the corresponding non-genetically modified isogenic variety. The Journal of Biochemistry, 167(1), 67–78.
Nikitin NS, 2019. 180-day toxicological research of GM soybean line MON87701xMON89788: the results of morphological examination. *Toxicology Letters*, 1–1.
Randhawa G, Singh M and Grover M, 2011. Bioinformatic analysis for allergenicity assessment of Bacillus thuringiensis Cry proteins expressed in insect-resistant food crops. Food and Chemical Toxicology, 49, 356–362.

Appendix B – List of additional studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU with regard to the evaluation of the safety of the food and feed for humans, animal or the environment from soybean MON 87701 × MON 89788

Study identification	Title
MSL0023109	Amended Report for MSL0022441: Compositional Analyses of Soybean Forage and Seed Collected from MON 87701, MON 89788, and MON 87701 × MON 89788 Grown in Brazil During 2008/2009
MSL0023051	Assessment of the Cry1Ac and CP4 EPSPS Protein Levels in Soybean Leaf Collected from MON 87701 and MON 87701 × MON 89788 Produced in Brazilian Field Trials during 2009–2010
MSL0024363	Comparison of endogenous allergens from MON 87701 × MON 89788 and conventional control soybeans
MSL0023845	Amended Report for MSL0023718: Western Blot Analysis of Cry1Ac and CP4 EPSPS Proteins in Leaf Tissue of MON 87701 × MON 89788, MON 87701, and MON 89788