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## Assessment of genetically modified soybean 40-3-2 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-023)

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### Abstract

Following the submission of application EFSA-GMO-RX-023 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of 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 herbicide-tolerant genetically modified soybean 40-3-2, 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 sequence of the event in soybean 40-3-2 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2.

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## Summary

Following the submission of application EFSA-GMO-RX-023 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of 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 herbicide-tolerant genetically modified soybean 40-3-2. The scope of the renewal application EFSA-GMO-RX-023 is for the renewal of the placing on the market of products containing, consisting of, or produced from soybean 40-3-2, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-023, 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-023 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 event in soybean 40-3-2 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-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2 (EFSA GMO Panel, 2010).

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# 1. Introduction

## 1.1. Background

On 08 February 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-023 for the renewal of the authorisation of soybean 40-3-2 (Unique Identifier MON-04032-6), submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003<sup>1</sup>.

Following receipt of application EFSA-GMO-RX-023, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.<sup>2</sup>

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013<sup>3</sup> and, when needed, asked the applicant to supplement the initial application. On 17 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-RX-40-3-2 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2010), the placing on the market of soybean 40-3-2 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/82/EU<sup>4</sup> and Commission Implementing Decision (EU) 2019/1579 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union.<sup>5</sup> A copy of the original authorisation was provided by the applicant.<sup>6</sup>

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 six months to issue a scientific opinion on application EFSA-GMO-RX-023. 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.<sup>7</sup> The MS had three months to make their opinion known on application EFSA-GMO-RX-023 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 40-3-2 for the renewal of authorization

<sup>1</sup> 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.

<sup>2</sup> Available online: <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00077>

<sup>3</sup> 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.

<sup>4</sup> Commission Implementing Decision 2012/82/EU of 10 February 2012 authorising the continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-20 (MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 40/14, 14.2.2012.

<sup>5</sup> Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union. Official Journal of the European Union L 244/8, 24.9.2019.

<sup>6</sup> Dossier: Soybean 40-3-2 – Annex I.

<sup>7</sup> 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.

for placing on the market of products containing, consisting of, or produced from GM soybean 40-3-2 in the context of its scope as defined in application EFSA-GMO-RX-023.

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.<sup>8</sup>

In addition to the present scientific opinion on soybean 40-3-2, 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 Open EFSA portal,<sup>9</sup> including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a 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-023 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 contracts OC/EFSA/GMO/2021/06 and OC/EFSA/GMO/2018/04, contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing updated bioinformatic analyses and literature search, respectively.

#### 2.1.1. Post-market monitoring reports<sup>10</sup>

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 40-3-2, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of soybean 40-3-2 (EFSA GMO Panel, 2010), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 10 annual PMEM reports covering a reporting period from October 2012 to 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 managed by EuropaBio<sup>11</sup> for the collection of information recorded by various operators (federations involved in soybean grains import, storage and processing) on any observed adverse effect(s) on human health and the environment arising from handling of soybean possibly containing soybean 40-3-2; (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<sup>12</sup>

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 917 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, 98 peer-reviewed and non-peer reviewed publications were identified as relevant for food and feed safety assessment or molecular characterisation. The relevant publications are listed in Appendix A.

<sup>8</sup> 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.

<sup>9</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00077>

<sup>10</sup> Dossier: Soybean 40-3-2 – Annex II; additional information: 18/3/2022.

<sup>11</sup> 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.

<sup>12</sup> Dossier: Soybean 40-3-2 – Annex III; additional information: 18/3/2022, 15/7/2022.

### 2.1.3. Updated bioinformatic data<sup>13</sup>

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for soybean 40-3-2 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017a), and a safety assessment of the newly expressed protein CP4 EPSPS regarding its capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

### 2.1.4. Additional documents or studies provided by the applicant<sup>14</sup>

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019a), the applicant provided an overview on the worldwide approvals of soybean 40-3-2 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<sup>15</sup>

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of soybean 40-3-2 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2010).

### 2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation<sup>16</sup>

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 40-3-2 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 40-3-2, 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 40-3-2 and the newly expressed protein 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 40-3-2 (EFSA GMO Panel, 2010) have been identified by the applicant.

<sup>13</sup> Dossier: Soybean 40-3-2 – Annex III; additional information: 7/9/2021, 15/7/2022, 26/10/2022.

<sup>14</sup> Dossier: Soybean 40-3-2 – Annex III; additional information: 7/9/2021.

<sup>15</sup> Dossier: Soybean 40-3-2 – Annex III.

<sup>16</sup> Dossier: Soybean 40-3-2 – Part I – Request for renewal; additional information: 26/10/2022.

### 3.3. Evaluation of the updated bioinformatic data

The updated bioinformatic analyses to assess the interruption of soybean endogenous genes by the event 40-3-2 confirm the results previously assessed by the GMO Panel (EFSA GMO Panel, 2022).

Analyses of the amino acid sequence of the newly expressed protein CP4 EPSPS reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the insert do not indicate sequence similarities to toxins or allergens in soybean 40-3-2. 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 40-3-2 (EFSA GMO Panel, 2010; EFSA, 2017b).

The updated bioinformatic analyses for event 40-3-2 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, 2010; EFSA, 2017b). Given the results of this analysis and that the recombinant DNA in soybean 40-3-2 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). The applicant provided new information on the sequence of the event. However, the quality of the study could not be assessed since the sequencing data was not submitted. Therefore, the GMO Panel assessed this application under the assumption that the sequence of the event is identical to the sequence of the originally assessed event (EFSA GMO Panel, 2018).

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 40-3-2.

### 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-023 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on soybean 40-3-2.

### 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 40-3-2. This general surveillance is coordinated by CroPLife Europe and implemented by selected operators (federations involved in soybean grains import, storage 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-023, 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 event in soybean 40-3-2 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-023 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean 40-3-2 (EFSA GMO Panel, 2010).

## 5. Documentation as provided to EFSA

- Letter from the European Commission to EFSA received on 8 February 2021 for the continued marketing of genetically modified soybean 40-3-2 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BV on behalf of Bayer CropScience LP (EFSA-GMO-RX-023)



- The application was made valid on 17 May 2021
- Additional Information (Clock 1) was requested on 7 July 2021
- Additional Information (Clock 1) was received on 7 September 2021
- Additional Information (Clock 2) was requested on 21 October 2021
- Additional Information (Clock 2) was received on 18 March 2022
- Additional Information (Clock 3) was requested on 1 April 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, 2017a. 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), Papadopoulou, N, Ramon, M and Waigmann, E, 2017b. Statement on the risk assessment of new sequencing information on genetically modified soybean event 40-3-2. *EFSA Journal* 2017;15(8):4968, 6 pp. <https://doi.org/10.2903/j.efsa.2017.4968>
- EFSA (European Food Safety Authority), Devos, Y, Guajardo, IM, Álvarez, F and Glanville, J, 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. EFSA supporting publications 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), 2010. Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-RX-40-3-2) for the renewal of authorisation for the continued marketing of (1) food containing, consisting of, or produced from genetically modified soybean 40-3-2; (2) feed containing, consisting of, or produced from soybean 40-3-2; (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation, all under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2010;8(12):1908, 38 pp. <https://doi.org/10.2903/j.efsa.2010.1908>
- 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), Casacuberta J, Nogué F, Naegeli H, Birch AN, De Schrijver A, Gralak MA, Guerche P, Manachini B, Messéan A, Nielsen EE, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Moxon S, Schneeberger K, Federici S, Ramon M, Papadopoulou N and Jones H, 2018. Scientific Opinion on the technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants. *EFSA Journal* 2018;16(7):5345, 11 pp. <https://doi.org/10.2903/j.efsa.2018.5345>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E, Bresson, J-L, Dalmay, T, Dewhurst, IC, Epstein, MM, Firbank, LG, Guerche, P, Hejatko, J, Moreno, FJ, Naegeli, H, Nogue, F, Rostoks, N, Sanchez Serrano, JJ, Savoini, G, Veromann, E, Veronesi, F, Goumperis, T and Raffaello, T, 2022. Statement on the risk assessment of a new bioinformatics evaluation of the insertion sites of genetically modified soybean event 40-3-2. *EFSA Journal* 2022;20(7):7412, 10 pp. <https://doi.org/10.2903/j.efsa.2022.7412>

## Abbreviations

EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
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 2010–April 2022)

### References

- Agelet LE, Armstrong CL, Tallada JG and Hurburgh CR, 2013. Differences between conventional and glyphosate tolerant soybeans and moisture effect in their discrimination by near infrared spectroscopy. *Food Chemistry*, 141, 1895–1901.
- Arruda S, Barbosa H, Azevedo RA and Arruda M, 2013. Comparative studies focusing on transgenic through cp4 EPSPS gene and non-transgenic soybean plants: an analysis of protein species and enzymes. *Journal of Proteomics*, 93, 107–116.
- Azevedo L, Dragano NRV, Sabino APL, Resck MCC, Alves de Lima PL and Gouvêa CMCP, 2010. In vivo antimutagenic properties of transgenic and conventional soybeans. *Journal of Medicinal Food*, 13, 1402–1408.
- Babujia LC, Pereira Silva A, Batoqui França Biondo P, Garcia JC, Gontijo Mandarino JM and Visentainer JV, 2015. Chemical composition of grains from glyphosate-resistant soybean and its conventional parent under different edaphoclimatic conditions in Brazil. In: *Agronomy AS* (ed.). Brazil, Universidade Estadual de Maringá. pp. 463–471.
- Barbosa HS, Arruda SCC, Azevedo RA and Arruda MAZ, 2012. New insights on proteomics of transgenic soybean seeds: evaluation of differential expressions of enzymes and proteins. *Analytical and Bioanalytical Chemistry*, 402, 299–314.
- Bednarek D, Dudek K, Kwiatek K, Świątkiewicz M, Świątkiewicz S and Strzetelski J, 2013. Effect of a diet composed of genetically modified feed components on the selected immune parameters in pigs, cattle and poultry. *Bulletin of the Veterinary Institute in Pulawy*, 57, 209–217.
- Bervaldo CMP, Mendes CR, Timm FC, Moraes DM, Barros ACSA and Peske ST, 2010. Physiological performance of soybean seeds from conventional and transgenic cultivars treated with glyphosate. *Revista Brasileira de Sementes*, 32, 9–18.
- Biel W, 2011. Composition and quality of protein of conventional and genetically-modified soybean meal. *Skład chemiczny i jakość białka konwencjonalnej i genetycznie zmodyfikowanej poekstrakcyjnej śruty sojowej. Folia Pomeranae Universitatis Technologiae Stetinensis*, 290, 17–24.
- Bohn T, Cuhra M, Traavik T, Sanden M, Fagan J and Primicerio R, 2014. Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans. *Food Chemistry*, 153, 207–215.
- Bonini EA, da Costa Zonetti P, Ferro AP, Ferrarrese Filho O, de Lourdes M and Ferrarrese L, 2015. Lignin content in seed coats of glyphosate-resistant soybean and their respective parents. *African Journal of Agricultural Research*, 1–4.
- Brandão AR, Barbosa HS and Arruda MAZ, 2010. Image analysis of two-dimensional gel electrophoresis for comparative proteomics of transgenic and non-transgenic soybean seeds. *Journal of Proteome Research*, 73, 1433–1440.
- Carvalho ER, Oliveira JA and Caldeira CM, 2014. Physiological quality of seeds in conventional and glyphosate-resistant soybean produced by foliar application of manganese. *Bragantia*, 73, 219–228.
- Carvalho ER, Oliveira JA, Costa Neto J, da Silva CAT and Ferreira VF, 2015. Rates and stages of foliar Mn application in the conventional soybean crop and its genetically modified RR descendants. *Doses e épocas de aplicação de manganês via foliar no cultivo de soja convencional e em derivada transgênica RR. Bioscience Journal*, 31, 352–361.
- Carvalho TC, Grzybowski CRS, Ohlson OC and Panobianco M, 2012. Comparison of physiological quality of soybean seeds and their transgenic derivatives. *Revista Brasileira de Sementes*, 34, 164–170.
- Chen P, Shannon G, Ali M, Scaboo A, Crisel M, Smothers S, Clubb M, Selves S, Vieira C and Mitchum M, 2020. Registration of 'S14-9017GT' soybean cultivar with high yield, resistance to multiple diseases, and high seed oil content. *Journal of Plant Registrations*, 14, 347–356.
- Chen P, Shannon G, Scaboo A, Crisel M, Smothers S, Clubb M, Selves S, Canella Vieira C, Liakat Ali M, Goellner Mitchum M, Nguyen H, Li Z, Bond J, Meinhardt C, Klepadlo M, Li S, Mengistu A and Robbins RT, 2020. Registration of 'S14-15146GT' soybean, a high-yielding RR1 cultivar with high oil content and broad disease resistance and adaptation. *Journal of Plant Registrations*, 14, 35–42.
- Chorna IV, 2019. Structure and functions of kidneys of two generations of rats fed on glyphosate-resistant genetically modified soybean and Roundup. *ScienceRise: Biological Science*, 1, 25–29.
- Chorna IV, Dronik GB, Lukashiv TO and Yuzkova VD, 2019. Oxidatively modified proteins in kidneys of rats fed with glyphosate-resistant genetically modified soybean and the herbicide Roundup. *Regulatory Mechanisms in Biosystems*, 10, 319–325.

- Czerwiński J, Bogacki M, Jalali BM and Konieczka PSS, 2015a. The use of genetically modified Roundup Ready soyabean meal and genetically modified MON 810 maize in broiler chicken diets. Part 1. Effects on performance and blood lymphocyte subpopulations. *Journal of Animal and Feed Sciences*, 24, 134–143.
- Czerwiński J, Słupecka-Ziemilska M, Woliński J, Barszcz M, Konieczka P and Smulikowska S, 2015b. The use of genetically modified Roundup Ready soyabean meal and genetically modified MON 810 maize in broiler chicken diets. Part 2. Functional status of the small intestine. *Journal of Animal and Feed Sciences*, 24, 144–152.
- da Costa LF, Tormena CF and Arruda MAZ, 2021. Ionomics and lipidomics for evaluating the transgenic (cp4-EPSPS gene) and non-transgenic soybean seed generations. *Microchemical Journal*, 165, 106130.
- da Costa Zonetti P, Suzuki D'Oliveira LS, Bonini EA, Lúcio Ferrarese M and Ferrarese-Filho O, 2013. Root growth and lignification of glyphosate susceptible and resistant soybean at low temperatures. *Semina-Ciencias Agrarias*, 34, 509–516.
- de Andrade GJM and Rosolem CA, 2011. Absorcao de manganês em soja RR sob efeito do glifosato. Uptake of manganese in RR soybean under glifosato application. *Revista Brasileira de Ciência do Solo*, 35, 961–968.
- de Melo D, de Mendonça Brandão WT, Pereira Nóbrega LH and Werncke I, 2016. Seeds quality of conventional and Roundup Ready (RR) soybeans produced for own and commercial consumption. Qualidade de sementes de soja convencional e Roundup Ready (RR), produzida para consumo proprio e comercial. *Revista de Ciencias Agrarias*, 39, 300–309.
- de Sousa Leite W, Unêda-Trevisoli SH, Grolí EL, Giaretta Azevedo CV, Pedroso Val BH, Bizari EH, Mota da Silva F and Di Mauro AO, 2016. Agronomic performance and path analysis of Roundup Ready and conventional soybean from two-way crosses in the northwestern of Sao Paulo, Brazil. *African Journal of Agricultural Research*, 4584–4593.
- Dolaichuk OP, Fedoruk RS, Kovalchuk II and Khrabko MI, 2013. Physiological effects of native and transgenic soybeans on female rats of the third generation. *Biology of Animals*, 15, 22–28.
- Duke SO, Rimando AM, Reddy KN, Cizdziel JV, Bellaloui N, Shaw DR, Williams MM and Maul JE, 2018. Lack of transgene and glyphosate effects on yield, and mineral and amino acid content of glyphosate-resistant soybean. *Pest Management Science*, 74:1166–1173.
- Eissa MI, El-Sherbiny MA, Ibrahim AM, Abdelsadik A, Mohamed MM and El-Halawany MS, 2019. Biochemical and histopathological studies on female and male Wistar rats fed on genetically modified soybean meals (Roundup Ready). *The Journal of Basic and Applied Zoology*, 80, 54, 1–12.
- Fortes Gris C, de Resende Von Pinho EV, Andrade T, Baldoni A and de Moreira Carvalho ML, 2010. Physiological quality and lignin content in the seed coat of conventional and RR transgenic soybean submitted to different harvest periods. Qualidade fisiologica e teor de lignina no tegumento de sementes de soja convencional e transgenica RR submetidas a diferentes epocas de colheita. *Ciencia e Agrotecnologia*, 34, 374–381.
- Fuhrmann Wagner J and Merotto AJ, 2014. Parâmetros fisiológicos e nutricionais de cultivares de soja resistentes ao glifosato em comparação com cultivares isogênicas próximas. Physiological and nutritional evaluation of soybean resistant to glyphosate in comparison with near isogenic lines. *Ciencia Rural*, 44, 393–399.
- Furgał-Dierżuk I, Strzetelski J, Kwiatek K, Twardowska M, Mazur M, Sieradzki Z, Kozaczyński W, Bednarek D and Reichert M, 2013. Genetically modified maize MON 810 and Roundup Ready soybean meal in cattle feeding. Genetycznie modyfikowana kukurydza MON 810 i poekstrakcyjna śruta sojowa Roundup Ready w żywieniu byd.a. *Wiadomości Zootechniczne*, 2, 3–30.
- Furgał-Dierżuk I, Strzetelski J, Kwiatek K, Twardowska M, Mazur M, Sieradzki Z, Kozaczyński W and Reichert M, 2014. The effect of genetically modified maize (MON 810) and soyabean meal (Roundup Ready) on rearing performance and transfer of transgenic DNA to calf tissues. *Journal of Animal and Feed Sciences*, 23, 13–22.
- Furgał-Dierżuk I, Strzetelski J, Twardowska M, Kwiatek K and Mazur M, 2015. The effect of genetically modified feeds on productivity, milk composition, serum metabolite profiles and transfer of tDNA into milk of cows. *Journal of Animal and Feed Sciences*, 24, 19–30.
- Galão OF, Carrão-Panizzi MC, Gontijo Mandarino JM, Santos Júnior OO, Maruyama SA, Figueiredo LC, Bonafe EG and Visentainer JV, 2014. Differences of fatty acid composition in Brazilian genetic and conventional soybeans (*Glycine max* (L.) Merrill) grown in different regions. *Food Research International*, 62, 589–594.
- Galazzi RM, Lopes Júnior CA, De Lima TB, Gozzo FC and Zezzi Arruda MA, 2019. Evaluation of some effects on plant metabolism through proteins and enzymes in transgenic and non-transgenic soybeans after cultivation with silver nanoparticles. *Journal of Proteomics*, 191, 88–106.
- Galbas M, Borys K, Wozniak A and Selwet M, 2011. Impact of globulins derived from genetically modified and conventional soybean on swine lymphocyte proliferation in in vitro cultures. *Annals of Animal Science*, 11, 497–505.
- Gonçalves JM, Barboza de Souza ER, Fernandes EP and Leandro WM, 2014. Nutritional efficiency of glyphosate-resistant soybean without glyphosate. Eficiência nutricional da soja RR na ausência do glifosato. *Cientifica*, 42, 157–163.

- Gorbach TV, Gubina-Vakulik GI and Denisenko SA, 2016. Influence of genetically modified soya in the diet of white rats on the metabolism and histology of the liver and kidneys from parents and descendants. *Problems of Aging and Longevity*, 25, 80–86.
- Hanusova L, Rehout V and Citek J, 2011. Transgene Fragments in the Blood and Tissue of Chicken Fed with Genetically Modified Soy and Maize. *Animal Nutrition and Feed Technology*, 11, 249–256.
- Harrigan GC, Skogerson K, MacIsaac S, Bickel A, Perez T and Li X, 2015. Application of 1H NMR profiling to assess seed metabolomic diversity. A case study on a soybean era population. *Journal of Agricultural and Food Chemistry*, 63, 4690–4697.
- Harrigan GG, 2013. Investigation of biochemical diversity in a soybean lineage representing 35 years of breeding. *Journal of Agricultural and Food Chemistry*, 61, 10807–10815.
- Harrigan GG, Lundry D, Drury S, Berman K, Riordan SG, Nemeth MA, Ridley WP and Glenn KC, 2010. Natural variation in crop composition and the impact of transgenesis. *Nature Biotechnology*, 28, 402–404.
- Herrera-Agudelo M, Miró M and Arruda MAZ, 2017. In vitro oral bioaccessibility and total content of Cu, Fe, Mn and Zn from transgenic (through cp4 EPSPS gene) and nontransgenic precursor/successor soybean seeds. *Food Chemistry*, 225, 125–131.
- Hungria M, Carvalho Mendes I, Shigeyoshi Nakatani A, Bueno dos Reis-Junior F, Zucca Morais J, Neves de Oliveira MC and Ferreira Fernandes M, 2014. Effects of the glyphosate-resistance gene and herbicides on soybean: field trials monitoring biological nitrogen fixation and yield. *Field Crops Research*, 158, 43–54.
- Korwin-Kossakowska A, Sartowska K, Linkiewicz A, Tomczyk G, Prusak B and Sender G, 2013. Evaluation of the effect of genetically modified Roundup Ready soya bean and MON 810 maize in the diet of Japanese quail on chosen aspects of their productivity and retention of transgenic DNA in tissues. *Archiv für Tierzucht*, 56, 597–606.
- Korwin-Kossakowska A, Sartowska K, Tomczyk G, Prusak B and Sender G, 2016. Health status and potential uptake of transgenic DNA by Japanese quail fed diets containing genetically modified plant ingredients over 10 generations. *British Poultry Science*, 57, 415–423.
- Kubo A, Aono M, Nakajima N, Nishizawa T, Tamaoki M and Saji H, 2013. Characterization of hybrids between wild and genetically modified glyphosate-tolerant soybeans. *Plant Biotechnology*, 1–32. <https://doi.org/10.5511/plantbiotechnology.13.0314a>
- Kusano M, Baxter I, Fukushima A, Oikawa A, Okasaki Y, Nakabayashi R, Bouvrette DJ, Achard F, Jakubowski AR, Ballam JM, Phillips JR, Culler AH, Saito K and Harrigan GG, 2014. Assessing metabolomic and chemical diversity of a soybean lineage representing 35 years of breeding. *Metabolomics*, 11, 261–270.
- Kutateladze T, Bitskinashvili K, Sapojnikova N, Kartvelishvili T, Asatiani N, Vishnepolsky B and Datukishvili N, 2021. Development of multiplex PCR coupled DNA chip technology for assessment of endogenous and exogenous allergens in GM soybean. *Biosensors (Basel)*, 11.
- Li SX, Chen LH, Zheng FY and Li YC, 2013. Effect of the cp4-epsps gene on metal bioavailability in maize and soybean using bionic gastrointestinal tracts and ICP-MS determination. *Journal of Agricultural and Food Chemistry*, 61, 1579–1584.
- Li W, Lu P, Xie H, Li G, Wang J, Guo D and Liang X, 2019. Effects of glyphosate on soybean metabolism in strains bred for glyphosate-resistance. *Physiology and Molecular Biology of Plants*, 25, 523–532.
- Liu H, Liu X, Han D, Jin J, Zhu X, Yang Y and Xie S, 2019. Effects of genetically modified and non-genetically modified soybeans with different heat treatments on growth and health of Cyprinidae species with different feeding habits. *Aquaculture Research*, 1–12.
- Loecker JL, Nelson NO, Gordon WB, Maddux LD, Janssen KA and Schapaugh WT, 2010. Manganese Response in Conventional and Glyphosate Resistant Soybean. *Agronomy Journal*, 102, 606–611.
- Marrelli M, Tudisco R, Mastellone V and Conforti F, 2013. A comparative study of phytochemical composition of genetically and non-genetically modified soybean (*Glycine max* L.) and evaluation of antitumor activity. *Natural Product Research*, 27, 574–578.
- Mataveli LRV, Fioramonte M, Gozzo FC and Arruda MAZ, 2012. Improving metallomics information related to transgenic and non-transgenic soybean seeds using 2D-HPLC- ICP-MS and ESI-MS/MS. *Metallomics*, 4, 373–378.
- Mataveli LRV, Pohl P, Mounicou S, Zezzi Arruda MA and Szpunar J, 2010. A comparative study of element concentrations and binding in transgenic and non-transgenic soybean seeds. *Metallomics*, 2, 800–805.
- Moldes CA, Camiña JM, Medici LO, Tsai TM and Azevedo RA, 2012. Physiological effects of glyphosate over amino acid profile in conventional and transgenic soybean (*Glycine max*). *Pesticide Biochemistry and Physiology*, 102, 134–141.
- Moldes CA, Cantarelli MA, Camina JM, Tsai SM and Azevedo RA, 2017. Changes in Amino Acid Profile in Roots of Glyphosate Resistant and Susceptible Soybean (*Glycine max*) Induced by Foliar Glyphosate Application. *Journal of Agricultural and Food Chemistry*, 65, 8823–8828.

- Morera P, Basicó L, Ronchi B and Bernabucci U, 2016. Fate of transgenic deoxyribonucleic acid fragments in digesta and tissues of rabbits fed genetically modified soybean meal. *Journal of Animal Science*, 94, 1287–1295.
- Oliveira SR, Menegário AA and Arruda MAZ, 2014. Evaluation of Fe uptake and translocation in transgenic and non-transgenic soybean plants using enriched stable  $^{57}\text{Fe}$  as a tracer. *Metallomics*, 6, 1832–1840.
- Ortez OA, Tamagno S, Salvagiotti F, Prasad PVV and Ciampitti IA, 2019. Soybean nitrogen sources and demand during the seed-filling period. *Agronomy Journal*, 3, 1–9.
- Petineli R, Moraes LA, Heinrichs R, Moretti LG and Moreira A, 2020. Conventional and transgenic soybeans: physiological and nutritional differences in productivity under sulfur fertilization. *Communications in Soil Science and Plant Analysis*, 51, 2045–2053.
- Petter FA, Zuffo AM, de Alcântara Neto F, Pereira Pacheco L, de Almeida FA, Ribeiro Andrade F and Zuffo Júnior JM, 2016. Effect of glyphosate and water stress on plant morphology and nutrient accumulation in soybean. *Australian Journal of Crop Science*, 251–257.
- Qian B, Huang L, Zhao J and Zhu J, 2021. Analysis of physiochemical composition and antioxidant properties between hulls of the genetically modified glyphosate-tolerant soybean and northeast soybean. *Food Science and Biotechnology*, 30, 505–512.
- Reichert M, Kozaczyński W, Karpinska TA, Bocian L, Jasik A, Kycko A, Świątkiewicz M, Świątkiewicz S, Furgal-Dierzuk I, Arczewska-Włosek A, Strzetelski J and Kwiatek K, 2012. Histopathology of internal organs of farm animals fed genetically modified corn and soybean meal. *Bulletin of the Veterinary Institute in Pulawy*, 56, 617–622. <https://doi.org/10.2478/v10213-012-0109-y>
- Rosolem CA, Andrade GJM, Lisboa IP and Zoca SM, 2010. Manganese uptake and redistribution in soybeans as affected by glyphosate. *Revista Brasileira de Ciência do Solo*, 34, 1915–1922.
- Sanden M, Johannessen LE, Berdal KG, Sissener N and Hemre GI, 2011. Uptake and clearance of dietary DNA in the intestine of Atlantic salmon (*Salmo salar* L.) fed conventional or genetically modified soybeans. *Aquaculture Nutrition*, 17, E750–E759.
- Sartowska K, Korwin-Kossakowska A, Sender G, Jozwik A and Prokopiuk M, 2012. The impact of genetically modified plants in the diet of Japanese quails on performance traits and the nutritional value of meat and eggs – preliminary results. *Archiv für Geflügelkunde*, 76, 140–144.
- Sartowska KE, Korwin-Kossakowska A and Sender G, 2015. Genetically modified crops in a 10-generation feeding trial on Japanese quails. Evaluation of its influence on birds' performance and body composition. *Poultry Science*, 00:1–8:1–8.
- Sbruzzi F, Venancio V, Costa Resck M, Pereira Lima Brigagao M and Azevedo L, 2013. Transgenic and conventional Brazilian soybeans don't cause or prevent preneoplastic colon lesions or oxidative stress in a 90-day in vivo study. *Revista De Nutricao-Brazilian Journal of Nutrition*, 26, 443–453.
- Shi Z, Zou S, Lu C, Wu B, Huang K, Zhao C and He X, 2019. Evaluation of the effects of feeding glyphosate-tolerant soybeans (CP4 EPSPS) on the testis of male Sprague–Dawley rats. *GM Crops & Food*, 10, 181–190.
- Shim SM, Choi MH, Park SH, Gu YU, Oh JM, Kim S, Kim HY, Kim GH and Lee Y, 2010. Assessing the digestibility of genetically modified soybean: Physiologically based in vitro digestion and fermentation model. *Food Research International*, 43, 40–45. <https://doi.org/10.1016/j.foodres.2009.08.011>
- Sissener NH, Johannessen LE, Hevry EM, Wiik-Nielsen CR, Berdal KG, Nordgreen A and Hemre GI, 2010a. Zebrafish (*Danio rerio*) as a model for investigating the safety of GM feed ingredients (soya and maize); performance, stress response and uptake of dietary DNA sequences. *British Journal of Nutrition*, 103, 3–15.
- Sissener NH, Martin SAM, Cash P, Hevroy EM, Sanden M and Hemre GI, 2010b. Proteomic profiling of liver from Atlantic Salmon (*Salmo salar*) fed genetically modified soy compared to the near-isogenic non-GM Line. *Marine Biotechnology*, 12, 273–281.
- Stadnik J, Karwowska M, Dolatowski Z, Świątkiewicz M and Kwiatek K, 2011a. Effect of genetically modified feeds on physico-chemical properties of pork. *Annals of Animal Science*, 4, 597–606.
- Stadnik J, Karwowska M, Dolatowski ZJ, Świątkiewicz S and Kwiatek K, 2011b. Effect of genetically modified, insect resistant corn (MON810) and glyphosate tolerant soybean meal (Roundup Ready) on physico-chemical properties of broilers' breast and thigh muscles. *Bulletin of the Veterinary Institute in Pulawy*, 55, 541–546.
- Świątkiewicz M, Bednarek D, Markowski J, Hanczakowska E and Kwiatek K, 2013a. Effect of feeding genetically modified maize and soybean meal to sows on their reproductive traits, haematological indices and offspring performance. *Bulletin of the Veterinary Institute in Pulawy*, 57, 413–418. <https://doi.org/10.2478/bvip-2013-0071>
- Świątkiewicz M, Bednarek D, Twardowska M, Markowski J, Mazur M, Sieradzki Z, Hanczakowska E and Kwiatek K, 2013b. Genetically modified HT soybean meal and Bt maize in pig feeding. Genetycznie modyfikowana poekstrakcyjna sruta sojowa HT i ziarno kukurydzy Bt w żywieniu swin. *Wiadomości Zootechniczne*, 2, 31–47.

- Świątkiewicz M, Hanczakowska E, Twardowska M, Mazur M, Kwiatek K, Kozaczyński W, Świątkiewicz S and Sieradzki Z, 2011a. Effect of genetically modified feeds on fattening results and transfer of transgenic DNA to swine tissues. *Bulletin of the Veterinary Institute in Pulawy*, 55, 121–125.
- Świątkiewicz S, Arczewska-Włosek A, Twardowska M, Markowski J, Mazur M, Sieradzki Z, Tomczyk G, Minta Z, Bednarek D, Kozaczyński W, Reichert M and Kwiatek K, 2013c. Extracted soybean meal and GM maize grain in poultry nutrition. *Poekstrakcyjna sruta sojowa i ziarno kukurydzy GMO w żywieniu drobiu. Wiadomości Zootechniczne*, 2, 49–64.
- Świątkiewicz S, Koreleski J, Arczewska A, Twardowska M, Kwiatek K, Tomczyk G, Kozaczyński W, Mazur M and Bednarek D, 2010a. Safety of transgenic feed materials in poultry nutrition - results of Polish study. *Bezpieczeństwo transgenicznych materiaoów paszowych w żywieniu drobiu - wyniki doswiadczeń krajowych. Życie Weterynaryjne*, 85, 161–165.
- Świątkiewicz S, Koreleski J, Arczewska-Włosek A and Twardowska M, 2010d. Soybean meal and maize grain from genetically modified plants in laying hens nutrition. *Zeszyty Problemowe Postępów Nauk Rolniczych*, 544, 45–52.
- Świątkiewicz S, Koreleski J, Arczewska-Włosek A, Świątkiewicz M, Twardowska M, Markowski J, Mazur M, Sieradzki Z and Kwiatek K, 2011b. Detection of transgenic DNA from Bt maize and herbicide tolerant soybean meal in tissues, eggs and digestive tract content of laying hens fed diets containing genetically modified plants. *Food Research International*, 11, 413–424.
- Świątkiewicz S, Świątkiewicz M, Koreleski J and Kwiatek K, 2010b. Nutritional efficiency of genetically-modified insect resistant corn (MON 810) and glyphosate-tolerant soybean meal (Roundup Ready) for broilers. *Bulletin of the Veterinary Institute in Pulawy*, 54, 43–48.
- Świątkiewicz S, Twardowska M, Markowski J, Mazur M, Sieradzki Z and Kwiatek K, 2010c. Fate of transgenic DNA from Bt corn and Roundup Ready soybean meal in broilers fed GMO feed. *Bulletin of the Veterinary Institute in Pulawy*, 54:237–242.
- Tan J, Liu S, Sun Z, Zhang H, Y W and Liu D, 2012. Comparison of broiler performance, carcass yields and intestinal microflora when fed diets containing transgenic (MON-40-3-2) and conventional soybean meal. *African Journal of Biotechnology*, 11, 12371–12378.
- Thompson MM, Niemuth A, Sabbatini J, Levin D, Breeze ML, Li X, Preez T, Taylor M and Harrigan GG, 2016. Analysis of Vitamin K1 in Soybean Seed: Assessing Levels in a Lineage Representing Over 35 Years of Breeding. *Journal of the American Oil Chemists' Society*, 93, 587–594.
- Tudisco R, Calabró S, Cutrignelli MI, Grossi M, Piccolo V and Infascelli F, 2012. Influence of Sample Storage on the Quality of DNA Extracted from Milk of Goats Fed Conventional or Transgenic Soybean. *Veterinary Science*, 199–203.
- Tudisco R, Calabró S, Cutrignelli MI, Moniello G, Grossi M, Mastellone V, Lombardi P, Pero ME and Infascelli F, 2015. Genetically modified soybean in a goat diet: Influence on kid performance. *Elsevier B.V.*, 26, 67–74
- Tudisco R, Mastellone V, Cutrignelli MI, Lombardi P, Bovera F, Mirabella N, Piccolo G, Calabro S, Avallone L and Infascelli F, 2010. Fate of transgenic DNA and evaluation of metabolic effects in goats fed genetically modified soybean and in their offsprings - RETRACTED. *Animal*, 4, 1662–1671. <https://doi.org/10.1017/s1751731110000728>
- Xia Y, Chen F, Liu K, Zhang L, Duan X, Zhang X and Zhu Z, 2019. Compositional differences between conventional Chinese and genetically modified Roundup Ready soybeans. *Crop & Pasture Science*, 70, 526–534.
- Yuan J, Zhongwei T, Zhao J, Shi Z and Wang J, 2017. Toxicologic evaluation of chronic feeding of glyphosate-resistant transgenic soybean GTS40-3-2 meal to rats. *Emirates Journal of Food and Agriculture*, 29, 856–862.
- Zanatta TSC, Manica-Berto R, Dietrich Ferreira C, Crizel Cardozo MM, Rombaldi CV, Zambiasi RC and Guerra Dias AR, 2017. Phosphate fertilizer and growing environment change the phytochemicals, oil quality, and nutritional composition of roundup ready genetically modified and conventional soybean. *Journal of Agricultural and Food Chemistry*, 65, 2661–2669.
- Zhou J, Harrigan GG, Berman KH, Webb EG, Klusmeyer TH and Nemeth MA, 2011. Stability in the composition equivalence of grain from insect-protected maize and seed from glyphosate-tolerant soybean to conventional counterparts over multiple seasons, locations, and breeding germplasms. *Journal of Agricultural and Food Chemistry*, 59, 8822–8828.
- Zinoviev SG, 2014. Some biochemical parameters of blood of pigs using GM-soya in their diets. *The Animal Biology*, 16, 76–80.
- Zobiole LHS, Oliveira RS, Huber DM, Constantin J, Castro C, Oliveira FA and Oliveira A, 2010a. Glyphosate reduces shoot concentrations of mineral nutrients in glyphosateresistant soybeans. *Plant Soil*, 328, 57–69.
- Zobiole LHS, Oliveira RS, Kremer RJ, Constantin J, Yamada T, Castro C, De Oliveira FA and Junior AO, 2010b. Effect of glyphosate on symbiotic N<sub>2</sub> fixation and nickel concentration in glyphosate-resistant soybeans. *Applied Soil Ecology*, 44, 176–180.
- Zobiole LHS, Oliveira RS, Visentainer JV, Kremer RJ, Bellaloui N and Yamada T, 2010c. Glyphosate affects seed composition in glyphosate-resistant soybean. *Journal of Agriculture and Food Chemistry*, 58, 4517–4522.

## 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 40-3-2

Study identification	Title
RAR-10-346	Meta-Analysis of Grain from Commercial Roundup Ready® and Conventional Soybean Varieties Grown in the United States and Canada from 2000 to 2009
REG-10-518/ MSL0023409	Compositional Analyses of Commercial Roundup Ready® and Conventional Soybean Varieties Grown in the United States in 2010
REG-2018-0744/ MSL0030112	Sequence Analysis of the 40-3-2 Inserts in the Single Trait Product 40-3-2
SCR-2016-0535	Additional Assessment of the in vitro Digestibility of CP4 EPSPS Protein by Pepsin and Pancreatin