Cotton GHB614 x LLCotton25 x MON15985

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others

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a. Assessment:
b. Food Safety Assessment:
Toxicology

Considerations from the EFSA: Quote: “Food and feed from cotton GHB614 × LLCotton25 × MON 15985 are expected to have the same nutritional impact as those derived from the non-GM comparator.”

“Are expected to have” is not science.

Has RIKILT actually taken food safety samples? We agree with the comment by Belgium and Germany that the herbicides glyphosate- and gluphosinate-ammonium, which are used in this genetically modified cotton, are toxic and that food safety is therefore compromised. Accordingly, we would ask you to carry out an internal review. We do not agree that the GMO panel is not authorised to carry out such a review, partly because of the following judgment of the ECJ General Court:

"85 " It is plain, as was stated in paragraphs 49 and 62 above, that the request for internal review is admissible, in this case, only to the extent that it claims that the authorisation decisions contravened provisions of environmental law within the meaning of Regulation No 1367/2006. Article 4(1)(a) and Article 16(1)(a) of Regulation No 1829/2003 provide that the food and feed concerned must not be placed on the market if they cause adverse effects on human health, animal health or the environment. The 305423, MON 87769 and MON 87705 soybeans constituted, when being cultivated, elements modified by human intervention that were in interaction with the natural environment. Accordingly, genetic modifications of those elements of the environment were liable to have consequences for their nutritional value or to represent a risk for food safety and constituted therefore matters within the scope of environmental law within the meaning of Regulation No 1367/2006."

Source: InfoCuria – Case-law of the Court of Justice, Judgment of the General Court (Seventh Chamber), 14 March 2018 (*) (Environment — Genetically modified products — Regulation (EC) No 1367/2006 — Regulation (EC) No 1829/2003 — Genetically modified soybeans MON 87769, MON 87705 and 305423 - Rejection of an application for internal review of market authorisation decisions - Concept of ‘environmental law’ - Article 10 of Regulation No 1367/2006)

In Case T‑33/16,

TestBioTech eV, applicant, established in Munich (Germany), represented by R. Stein, Solicitor, K. Smith QC, and J. Stevenson, Barrister, v European Commission, defendant, represented by J. Tomkin, L. Pignataro-Nolin and C. Valero, acting as Agents. Please regard the entire judgment as an integral part of the present document. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62016TJ0033&from=NL

More on the poisonous properties of glyphosate:

Global Glyphosate Study pilot phase shows adverse health effects at "safe" dose.

Effects on sexual development, genotoxicity, and the intestinal microbiome Glyphosate-based herbicide caused adverse health effects in rats at a dose claimed to be safe by regulators, according to a new study. Glyphosate herbicides are used on the vast majority of all GM crops worldwide. Meer: BRON: https://www.gmwatch.org/en/news/latest-news/18278

Global Glyphosate Study Pilot Phase The three peer-reviewed accepted manuscripts below will be published in the prestigious scientific journal Environmental Health later in May 2018: 1. Accepted Manuscript: The Need For Independent Research On The Health Effects Of Glyphosate-Based Herbicides. Environmental Health, 2018. Authors: Philip J Landrigan, Fiorella Belpoggi. https://glyphosatestudy.org/wp-content/uploads/2018/05/COMMENTARY-GLY-PILOT-IN-PRESS-Manuscript-8-5-1.pdf 2. Accepted Manuscript: The Ramazzini Institute 13-Week Study On Glyphosate-Based Herbicides At Human-Equivalent Dose In Sprague Dawley Rats: Study Design And First In-Life Endpoints Evaluation. Environmental Health, 2018. Authors: Simona Panzacchi, Daniele Mandrioli, Fabiana Manservisi, Luciano C Bua, Laura Falcioni, Marcella Spinaci, Giovanna Galeati, Giovanni Dinelli, Rossella Miglio, Alberto Mantovani, Stefano Lorenzetti, Jianzhong Hu, Jia Chen, Melissa Perry, Philip J Landrigan, Fiorella Belpoggi. https://glyphosatestudy.org/wp-content/uploads/2018/05/DESIGN-GLY-PILOT-IN-PRESS-Manuscript-8-5-1.pdf 3. Accepted Manuscript: The Ramazzini Institute 13-Week Pilot Study On Glyphosate And Roundup Administered At Human-Equivalent Dose To Sprague Dawley Rats: Effects On The Microbiome. Environmental Health, 2018. Authors: Qixing Mao, Fabiana Manservisi, Simona Panzacchi, Daniele Mandrioli, Ilaria Menghetti, Andrea Vornoli, Luciano C Bua, Laura Falcioni, Corina Lesseur, Jia Chen, Fiorella Belpoggi, Jianzhong Hu. https://glyphosatestudy.org/wp-content/uploads/2018/05/MICROBIOME-GLY-PILOT-IN-PRESS-8-5-1.pdf https://glyphosatestudy.org/global-glyphosate-study-pilot-phase/ The conclusions of Prof. Séralini about toxicity and carcinogenicity of glyphosate for rats at low dose are correct. His research has been put in bad light by an employee of Monsanto. See https://www.oneworld.nl/food/eten-bedrijf/monsanto-betrokken-bij-intrekkinggeruchtmakende-studie-over-roundup-tonennet?utm_content=bufferdba07&utm_medium=social&utm_source=twitter&utm_campaign=b uffer. Several court cases about glyphosate are ongoing. https://usrtk.org/wpcontent/uploads/2017/08/8-Monsanto-Scientist-Admits-to-Leveraging-Relationship-withFood-and-Chemical-Toxicology-Journal.pdf Allergenicity Monsanto pressured Wallace Hayes, Editor of Food and Chemical Toxicology Journal to retract the famous Séralini study, which discovered the damage caused by GM maize NK603. http://sustainablepulse.com/2017/08/01/monsanto-secret-documents-show-massive-attack-onseralini-study/#.WYnDNbpuKUl As the emails of Monsanto employees that appeared

during the court cases show that misleading activity is commonplace, and that prof. Séralini has it right with his research, we can only conclude these toxic GM maize should not enter the European market!! https://www.facebook.com/GmoSeralini/ Monsanto Secret Documents Show Massive Attack on Séralini Study . In secret internal Monsanto documents released on Tuesday 1st August 2017 by legal firms in the U.S. it was made clear how Monsanto successfully pressured Wallace Hayes, Editor of Food and Chemical Toxicology Journal to retract the famous Séralini study which discovered the damage caused by GM maize NK603 and low doses of Roundup herbicide. https://www.baumhedlundlaw.com/toxic-tort-law/monsantoroundup-lawsuit/monsanto-secret-documents/ http://sustainablepulse.com/2017/08/01/monsanto-secret-documents-show-massive-attack-onseralini-study/#.WYnDNbpuKUl

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4. Conclusions and recommendations

No authorisation! Rather, a re-evaluation, this time taking account of the toxicity of the herbicides used.

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5. Others

The Gentechvrije Burgers are supported by Stichting Natuurwetmoeders, Bussum and Stichting Ekopark, Lelystad.

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6. Labelling proposal

Not applicable until there has been a thorough examination of the food safety implications for humans and animals.

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
Molecular characterisation

The 2015 COGEM report states: “COGEM noted that the molecular characterisation of MON531, the GM cotton line that was used to produce MON15985, contained weaknesses. Consequently, also the molecular characterisation of MON15985 was flawed.7,8 Despite these weaknesses, COGEM concluded that import and processing of MON15985 poses a negligible risk to the environment because cotton cannot survive in the Netherlands and MON531 has a history of safe use”.
https://cogem.net/index.cfm/nl/publicaties/publicatie/import-van-gg-katoen-ghb614xllcotton25xmon15985-en-llcotton25xmon15985 Our comment: It is becoming increasingly hotter in the Netherlands and in the EU, and it is certainly possible in the very near future that genetically modified cotton will survive and grow in the Netherlands or another EU Member State (Spain* or Greece: Greece is the biggest European producer, accounting for 1.7 million bales***. Cotton is also grown in other EU Member States. “The EU is a cotton producer and has developed from being a net cotton importer up to 2008 to a net cotton exporter since 2009.**). It is inconceivable for COGEM to give authorisation, partly because: “COGEM noted that the molecular characterisation of MON531, the GM cotton line that was used to produce MON15985, contained weaknesses. Consequently, also the molecular characterisation of MON15985 was flawed.7,8”. This cannot be ignored. * “ALICANTE – The Ministry of the Environment has announced that it will subsidise 1 000 hectares of cotton plantations in la Vega Baja with money from the European Union.” https://inspanje.nl/algemeen/2377/medio-ambiente-subsidieert-katoenvelden-la-vega-baja/ **http://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:52016PC0712&from=NL ***Wikipedia states: “The introduction of genetically modified cotton in Australia in 1996 ended in commercial disaster. Revenue was much lower than predicted, and there was cross-pollination with other types of cotton plants, which could potentially cause numerous legal problems for unsuspecting farmers …. The original, genetically manipulated variety has since been banned.” https://nl.wikipedia.org/wiki/Katoen

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b. Food Safety Assessment:
Toxicology

See our comments of 20 May 2016. See also the article "Het kanamycine rapport, kritisch bekeken" (*"The Kanamycin Report": A Critical Examination"*).
https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/kanamycine-rapport-kritisch-bekeken/

Allergenicity

Fragment: "Below, I would like to set out a few conclusions, referred to in our letters of complaint and letters of appeal to the Ministry of Housing, Spatial Planning and the Environment (VROM) and the Council of State (73 items in all), in brief, omitting the names of the producers and the data set out in the pleadings! The tests failed to look at the effect of intestinal juice; only five- day feed tests with unsprayed rapeseed, no 90-day feed tests; a distinction can be made using different analytical methods, i.e. substantial equivalence; in our view, insufficiently precise registration methods; large-scale supply of plant parts containing this gene will lead to high levels of resistance in pathogens (in the intestines of humans and animals being treated for illness) (cotton seed in cattle feed)." BRON, L. Eijsten and J.

Vermeulen. https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/een-en-ander/

Others

Numerous cases of suicide in India, where poverty-stricken cotton farmers take their own lives out of desperation by drinking the herbicides intended for the BT Cotton: “But he had been tense for three months – the crop had not been good and the debts had mounted. The genetically modified BT seeds had added to the cost. There was crop-loss from flooding and from the ‘reddening disease’ that the farmers have come to associate with the new cotton strain.” https://newint.org/features/2007/04/01/farmersuicide/

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4. Conclusions and recommendations

As we have already said: No market authorisation before satisfactory food safety assessments (which also means satisfactory in terms of duration) have been carried out. The Gentechvrije Burgers wrote this comment dated 22 May 2018 and the one dated 20 May 2018 jointly on behalf of Stichting Ekopark, Donaustraat 152, Lelystad (Chamber of Commerce reg. no. 39080548).

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5. Others

We put the following question to COGEM: “The EFSA is talking about cotton, GHB614 × LLCotton25 × MON 15985, EFSA-GMO-NL-2011-94. In your 2015 report, you talk about genetically modified cotton cross-strains GHB614xLLCotton25xMON15985 and LLCotton25xMON15985 (EFSA/GMO/NL/2011/94). How can this difference be explained?” COGEM replied as follows: “The original application for authorisation, with respect to which COGEM gave its recommendation, concerned both cross-strains. Later in the process, the applicant, acting on a request from the EFSA, removed the cross-strain LLCotton25xMon15985 from the application on procedural grounds.” Our question to the EFSA now is: 'What were those "procedural grounds"?'

Because other bodies perform food safety assessment, COGEM did not assess the risks of occasional consumption when examining the application. RIKILT was supposed to do that. However, we can find no reference to such an assessment on the Internet: https://cogem.net/index.cfm/nl/publicaties/publicatie/import-van-gg-katoen-ghb614xllcotton25xmon15985-en-llcotton25xmon15985

Organisation: Testbiotech
Country: Germany

Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The assessment of the parental plants shows there are many open reading frames created by the insertion of the additional genes. These multiple new open reading frames were found in the parental plants and can give rise to RNA that is translated into DNA, or which might be involved in gene regulation without producing proteins (RNAi). However, EFSA only assessed the probability of unintended proteins being produced by the DNA sequences – other biologically active compounds, such as miRNA, were not assessed.

Data regarding the sites of insertion and open reading frames are highly relevant for risk assessment. The sequence data should be made public to allow independent experts to perform further assessments. Uncertainties regarding possible gene products should be fully identified.

Further, the way in which the expression data from the constructs were assessed is inconclusive. There is plenty of evidence that genetic background, soil and climate conditions substantially impact Bt expression in the plants (Adamczyk & Meredith, 2004; Adamczyk et al., 2008; Beura & Rakshit, 2013; Chen et al., 2005; Chen et al., 2012; Luo et al., 2008; Wang et al., 2015; Zhu et al., 2018). Therefore, the expression of the constructs in the stacked plants should have been assessed under a wide range of defined environmental conditions, taking into account potential extreme stress conditions such as those caused by ongoing climate change. In addition, more varieties should have been included in the field trials since it is known that the genetic background of the varieties can influence the level of gene expression.

Apart from this, the protocols used for measuring Bt content in the plants should have been evaluated to make sure a sufficiently robust method was used to generate the data. As Székács, et al., 2011 point out, without further evaluation, the Bt content in the plants cannot be reliably determined.

The Bt expression data are not only relevant for the agronomic performance of the Bt cotton in the fields, but also necessary for assessment of exposure in the food and feed chain. A lack of further data means that the genetic and biological stability of the plants as well as the content of Bt toxins cannot be determined.

Further investigations should include data on the effects of the additional DNA on the plants' genome, transcriptome, proteome and metabolome.

Adamczyk, J.J., Meredith, W.R. (2004) Genetic Basis for Variability of Cry1Ac Expression Among Commercial Transgenic Bacillus thuringiensis (Bt) Cotton Cultivars in the United States, The Journal of Cotton Science 8:17–23 (2004)

Adamczyk J.J., Perera O., Meredith W.R. (2008) Production of mRNA from the cry1Ac transgene differs among Bollgard lines which correlates to the level of subsequent protein , Transgenic Res , DOI 10.1007/s11248-008-9198-z

Beura K., Rakshit A. (2013) Bt cotton influencing enzymatic activities under varied soils , Open Journal of Ecology , Vol.3, No.8, 505-509, http://dx.doi.org/10.4236/oje.2013.38059

Chen D., Ye G., Yang C., Chen Y., Wu Y. (2005) The effect of high temperature on the insecticidal properties of Bt Cotton, environmental and experimental botany, Vol 53, 3: 333-342, https://doi.org/10.1016/j.envexpbot.2004.04.004

Chen Y., Wen Y-j., Chen Y., Cothren, J.T., Zhang, X., Wang Y-h., Payne W.A., Chen D-h. (2012) Effects of Extreme Air Temperature and Humidity on the Insecticidal Expression Level of Bt Cotton, Journal of Integrative Agriculture, Vol 11, 11: 1836-1844, https://doi.org/10.1016/S2095-3119(12)60188

Luo Z., Dong H., Li W., Ming Z., Zhu Y (2008) Individual and combined effects of salinity and waterlogging on Cry1Ac expression and insecticidal efficacy of Bt cotton, Crop Protection 27 1485–1490

Székács, A., Weiss, G., Quist, D., Takács, E., Darvas, B., Meier, M., Swain, T., Hilbeck, A., (2011) Interlaboratory comparison of Cry1Ab toxin quantification in MON 810 maize by enzyme-immunoassay. Food and Agricultural Immunology, 23(2): 99-121

Wang, J., Chen, Y., Yao M-h., Li Y., Wen, Y-j., Chen Y., Zhang X., Chan D-h. (2015) The effects of high temperature level on square Bt protein concentration of Bt cotton, Journal of Integrative Agriculture, Vol 14, 10: 1971-1979 https://doi.org/10.1016/S2095-3119(15)61049-8

Zhu X., Sun L., Kuppu S., Hu R., Mishra N., Smith J., Esmaeili N., Herath M., Gore M.A., Payton P., Shen G., Zhang H. (2018) The yield difference between wild-type cotton and transgenic cotton that expresses IPT depends on when water-deficit stress is applied, Scientific Reports 8:2538, DOI:10.1038/s41598-018-20944-7

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

Various significant findings in compositional analysis and agronomic performance were observed in the parental plant as well as in the stacked event, including, amongst others, a much higher content in gossypol, which is known to be highly toxic.

In assessing these data, EFSA completely overlooked the biological effects of the EPSPS enzyme as expressed in the stacked cotton. As evidenced by research undertaken by Fang et al., (2018), Wang et al. (2014) and Yang et al. (2017), the EPSPS enzyme can render higher fitness in the plants and their offspring. These effects are also dependent on environmental stressors (Fang et al., 2018; Luo et al., 2008). These observations are not only relevant for environmental risk assessment (below) but also for food safety.

As Fang et al (2018) show, the EPSPS enzyme is very likely to interfere with the auxin content in the plant. Auxin is known to be involved in many metabolic pathways in cotton (Xu et al., 2013). Further, there is evidence that enhanced content of auxin also causes higher

accumulation of gossypol in the cells (Baksha et al., 2006). Thus, the data provided by the applicant indicate some interference in the endogenous metabolism in the plants probably leading to changes in the auxin content and, therefore, resulting in changes in plant composition and a higher content of gossypol.

There are concerns over the enhanced content of gossypol that are increased due to the additional EPSPS enzymes. These concerns are additionally intensified by the fact that the stacked event GHB614 x LL25 also showed a higher content of gossypol, while MON15985 did not. Our hypothesis is further supported by a more detailed investigation of the data from field trials made available by German experts (EFSA 2018 b): "Those plants including the modified 2mEPSPS showed less phosphorus but more gossypol compared to those plants including the unmodified EPSPS and this result was continuous for all sites tested. (…) the results indicate potential difference in compositional and agro-phenotypic performance at events including the modified 2mEPSPS."

These findings make it necessary for EFSA to reassess the available data and, if needed, request further data to investigate the changes in plant composition and agronomic performance in order to determine food and environmental safety - thereby taking into account the effects of the EPSPS enzyme, the auxin content, the increase in phytoalexins, such as gossypol, and other relevant compounds. Investigation of these issues should also take into account a wide range of defined environmental stress conditions since the gossypol content will very likely be influenced by genome x environmental interactions.

Baksha, R., Mavlanov G.T., Nasirova G.B., Djataev S.A. (2006) Gossypol Accumulation and Morphogenesis in Cotton (G. hirsutum L.) Callus Culture, Journal of biological sciences, 6 (6): 1126-1129

EFSA (2018b) Comments from the experts of Member States to GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified cotton GHB614 9 LLCotton25 9 MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94), accessed via the register of EFSA http://registerofquestions.efsa.europa.eu/roqFrontend/login?1

Fang J., Nan P., Gu Z., Ge X., Feng Y-Q. Lu B-R. (2018) Overexpressing Exogenous 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS) Genes Increases Fecundity and Auxin Content of Transgenic Arabidopsis Plants., Front. Plant Sci. 9:233, doi: 10.3389/fpls.2018.00233

Luo Z., Dong H., Li W., Ming Z., Zhu Y (2008) Individual and combined effects of salinity and waterlogging on Cry1Ac expression and insecticidal efficacy of Bt cotton, Crop Protection 27 1485–1490

Wang, W., Xia, H., Yang, X., Xu, T., Si, H.J., Cai, X.X., Wang, F., Su, J., Snow, A.A., Lu, B.-R. (2014). A novel 5-enolpyruvoylshikimate-3-phosphate (EPSP) synthase transgene for glyphosate resistance stimulates growth and fecundity in weedy rice (Oryza sativa) without herbicide. New Phytol. 202, 679–688. doi:10.1111/nph.12428

Yang, X., Li, L., Jiang, X., Wang, W., Cai, X., Su, J., et al. (2017). Genetically engineered rice endogenous 5-enolpyruvoylshikimate-3-phosphate synthass (epsps) transgene alters

phenology and fitness of crop-wild hybrid offspring. Sci. Rep. 7:6834. doi: 10.1038/s41598-017-07089-9

Xu Z., Zhang C., Zhang X., Liu, C., Wu, Z., Yang, Z., Zhou, K., Yang X., Li F (2013) Transcriptome Profiling Reveals Auxin and Cytokinin Regulating Somatic Embryogenesis in Different Sister Lines of Cotton Cultivar CCRI24, Journal of Integrative Plant Biology 2013, 55 (7): 631–642

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b. Food Safety Assessment:
Toxicology

The toxicological risk assessment is based on assumptions and biased considerations but not on facts. There are strong indications that further toxicological studies are needed because changes in plant composition, the potential combinatorial and cumulative effects of new biologically active substances produced in the plants (such as Bt toxins) as well as residues from spraying with high dosages of the complementary herbicides and relevant herbicidal formulations are to be expected. For example, specific patterns of residues from spraying with the complementary herbicides and their impact on plant constituents and potential combinatorial effects require detailed risk assessment (see, for example, Then & Bauer Panskus, 2017). In addition, the possible interaction of the two Bt toxins and other substances require more detailed investigations (see, for example, Bøhn et al., 2016; Bøhn, 2018; and Hilbeck & Otto, 2015).

The overall combinatorial effects can only be assessed if the stacked event is subjected to an assessment of the whole food and feed. However, only one nutritional feeding study was performed with the whole food and feed and this was not accepted by EFSA (2018a) due to an overall high mortality of the animals. There were no studies carried out with the whole food and feed to investigate any potential health effects from the consumption of products derived from the stacked cotton.

Strong indications that the composition of the plants was unintentionally changed by biochemical mechanisms involving the auxin hormone and the gossypol content were ignored. Therefore, the risk assessment has to be rejected.

Bøhn, T., Rover, C.M., Semenchuk, P.R. (2016) Daphnia magna negatively affected by chronic exposure to purified Cry-toxins. Food Chem. Toxicol., 91: 130–140.

Bøhn, T. (2018) Criticism of EFSA's scientific opinion on combinatorial effects of ‘stacked’ GM plants. Food and Chemical Toxicology.
https://www.sciencedirect.com/science/article/pii/S0278691517306907

Hilbeck, A., Otto, M. (2015) Specificity and Combinatorial Effects of Bacillus Thuringiensis Cry Toxins in the Context of GMO Environmental Risk Assessment. Front. Environ. Sci. 3.
https://doi.org/10.3389/fenvs.2015.00071

Then, C., Bauer-Panskus, A. (2017) Possible health impacts of Bt toxins and residues from spraying with complementary herbicides in genetically engineered soybeans and risk

assessment as performed by the European Food Safety Authority EFSA. Environ. Sci. Eur. 29, 1. https://doi.org/10.1186/s12302-016-0099-0

Allergenicity

Based on the data provided, no conclusion can be drawn on the overall allergenicity of food and feed derived from the stacked cotton. Immune system responses must be investigated since the Bt proteins are known for adjuvant properties – something that the EFSA (2018b) has acknowledged and which is evidenced in several publications (see, for example, Rubio-Infante & Moreno-Fierros, 2016).

Rubio-Infante, N., Moreno-Fierros, L. (2016) An overview of the safety and biological effects of Bacillus thuringiensis Cry toxins in mammals. J. Appl. Toxicol. 36, 630–648. https://doi.org/10.1002/jat.3252

EFSA (2018b) Comments from the experts of Member States to GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified cotton GHB614 9 LLCotton25 9 MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94), accessed via the register of EFSA http://registerofquestions.efsa.europa.eu/roqFrontend/login?1

Others

The risk manager should take into consideration that this stacked event produces enzymes which render resistance to antibiotics. NptII provide resistance to neomycin and kanamycin. Both antibiotics are classified by the WHO as “highly important” (see EFSA 2018b). EFSA (2018 a) even considers there to be some likelihood that the DNA sequences for NptII will be transferred to microorganisms. The risk manager should answer the question of whether from a global human health perspective the cultivation and consumption of plants conferring resistance to antibiotics should still be encouraged (by allowing imports of products such as the stacked cotton), whilst, at the same time, EU regulation actually requires that this technology should have been phased out years ago.

EFSA (2018a) GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified cotton GHB614 9 LLCotton25 9 MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94). EFSA Journal 2018;16(4):5213, 27 pp. https://doi.org/10.2903/j.efsa.2018.5213

EFSA (2018b) Comments from the experts of Member States to GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified cotton GHB614 9 LLCotton25 9 MON 15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94), accessed via the register of EFSA http://registerofquestions.efsa.europa.eu/roqFrontend/login?1

3. Environmental risk assessment

It was not considered that the stacked cotton is very likely to show enhanced fitness (see Fang et al., 2018), therefore, the environmental risk assessment is inconclusive and has to be rejected.

Fang J., Nan P., Gu Z., Ge X., Feng Y-Q. Lu B-R. (2018) Overexpressing Exogenous 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS) Genes Increases Fecundity and Auxin Content of Transgenic Arabidopsis Plants., Front. Plant Sci. 9:233, doi: 10.3389/fpls.2018.00233

4. Conclusions and recommendations

The risk assessment is inconclusive and there are indications of substantial risks for animal and human health. Market authorisation for import and usage in food and feed cannot be given.

5. Others

General surveillance as well as monitoring requires specific methods to trace and detect this particular stacked event under practical conditions. But no such methods were made available. Thus, market authorisation cannot be issued.