soybean DAS-81419-2 x DAS-44406-6

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

Herbicides glyphosate and glufosinate ammonium negatively affect human sperm mitochondria respiration efficiency.

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Fragment A B S T R A C T

. Glyphosate GLY and glufosinate ammonium GA the active principles of the main formulations have been investigated for their effects on human health mainly cancer and reproductive toxicity. However little is known about their effects on the molecular mechanisms related to sperm quality. https//doi.org/10.1016/j.reprotox.2020.11.011

US EPA finds glyphosate is likely to injure or kill 93 of endangered species Details Published 03 December 2020 Twitter “The hideous impacts of glyphosate on the nation’s most endangered species are impossible to ignore now” – Center for Biological Diversity The Environmental Protection Agency has released a draft biological evaluation finding that glyphosate is likely to injure or kill 93 of the plants and animals protected under the Endangered Species Act. US EPA finds glyphosate is likely to injure or kill 93 of endangered species gmwatch.org

Draft National Level Listed Species Biological Evaluation for Glyphosate Protecting Endangered Species from Pesticides US EPA

Others

20 years later and still a hot potato

A CRITICAL EXAMINATION OF THE ARGUMENTS USED BY PROPONENTS OF THE GENETIC MODIFICATION OF FOOD CROPS. The following letter was sent to the Agrarisch Dagblad (a Dutch newspaper targeted primarily at the farming community) for publication.

Amsterdam, 7 March 2000

Never-Never-Land! Numerous media articles and letters have recently been published on genetic modification, especially of food crops. Supporters such as the US Ambassador and opponents like Greenpeace have all had their say. Claims of facts being 'twisted' are freely bandied about. But we never hear what those facts are. This takes the place of any explanation of the advantages or analysis of the criticisms of the advantages claimed, or any critical appreciation of the drawbacks. The public relations industry has an adage which says: "... if the importance and thus the available PR budget is big enough, any desired untruth can ultimately gain acceptance." Writing in the Chemisch Weekblad (a weekly magazine published by the Royal Netherlands Chemical Association/KNCV) of 26 February, Dr Paul E. Metz asks if the authorities and other interested parties are sufficiently aware of this repetitive aspect of paid advertisements. GM advocates endlessly repeat certain 'arguments', and we would like to subject a few of them to critical scrutiny.

One such 'argument' is that genetic modification can make a valuable contribution to easing the global food problem. Our first critical remark: How this is supposed to happen is never explained. The people who peddle this claim are speculating that the public will accept it as gospel truth. They don't want you to take a closer look and see how higher yields for herbicide- and insect-resistant crops have been promised but never demonstrated with hard data. In March 1999, marketing boards worldwide reported that the corn borer had caused a 4% decrease in crops: not something to shout from the rooftops. Herbicide-resistant crops are just another way of keeping weeds at bay. Compared with the alternatives, their ability to increase yields is illusory. Those alternatives are perhaps more expensive in terms of money and manpower, but that is not the issue. The issue is crop yields. And in the meantime, the herbicide residues end up on our plates. Alternatives, such as releasing ichneumon wasps or sterile males, are also used for insect control. We really are not waiting with bated breath for herbicide-resistant or insect-resistant crops. The fact that agricultural land in the Netherlands is to be rewilded and that sugar cane is used in Brazil for alcohol rather than motor vehicle fuel does not mean that genetic modification could be a solution to the global food problem. Specifically, the efforts are not aimed at increasing production, but at changing production and increasing the incomes of seed traders and chemical giants, possibly at the cost of a real fall in production. Moreover, a huge increase in food production can be achieved by growing existing varieties with a high edible content, such as cabbages, potatoes or edible seeds, rather than short-straw wheat. This can also be done in the traditional manner. In the meantime, the world market is being flooded with a growing supply of food at increasingly low prices, in addition to premiums for abandoning agricultural land in America. We have been scouring the recognised scientific journals for serious articles on these topics (the growing world population and production growth), but have found nothing relevant.

Another claim we often hear is that genetic modification is very precise and predictable, in the sense that there are only effects on the gene introduced. Experience does not confirm this. Avebe's amylopectin potato provides a clear example. Here, a gene was inserted into the potato as an antisense with the aid of a gene construct, together with numerous other genes (the gene construct). The belief that the genetic modification only affects a single, well-

defined characteristic imparted by a single gene is another misunderstanding. Avebe's work gave rise to a number of transformations, all of them different. Two of them, which are visible to the naked eye and involve differences in inflorescence and leaf shape, were the varieties Apriori and Apropos. Was the different inflorescence compared with the parent line predicted? It is an unsettling fact that highly sought-after amylopectin is obtained from waxy maize. We never wanted GM potatoes. Another unsettling detail is that there is already a mutant potato with the desired property. It would certainly have been possible to breed in that characteristic through traditional cultivation. We weren't waiting for genetic modification to save the day. In conclusion, we can say that little consideration was given to human health. But human health cannot be left to market forces. Generous subsidies from the Ministry of Economic Affairs make the government party to all of this. We see it everywhere. For example, the text of the motion by Ms Van Ardenne , in which she speaks of the broad public debate on GMOs and food … the creation of a wide-ranging Biotechnology Committee to report in due course on desired and acceptable uses ... the need for broad public support ... dispelling uncertainties about the risks … taking stock of the benefits of GM foods could help to boost confidence in this type of food, blah, blah, blah. In other words, remove the uncertainties and accentuate the benefits. Never-Never-Land! How do you dispel uncertainties? Not by trying to downplay the health risks. However, consumers can see that the balance is shifting in favour of producers. Consumers also want to have as much information on GMOs as possible. This information is kept to a minimum and the media devote no attention to it at all (for example, they ignore pronouncements by the Council of State). The dangers are lying in wait. As regards the genes of the construct introduced into plants, scientists report that we should be WORRIED: worried, for example, about the toxic gene of Bacillus thuringiensis (Bt) entering other bacteria and having unforeseen effects on the balance of the soil fauna. Let's hope that Ms Van Ardenne has ready answers to some difficult questions.
J. van der Meulen L. Eijsten. TSS Archive, TSS complaints and commentaries by Lily Eijsten.

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4. Conclusions and recommendations

We The European GMO-free- Citizens do not want it on our plates and do not want it as feed for the animals.

Why is our comment only translated in English and not in all other languages of the EU countries

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5. Others

Resistance

Through resistance the herbicide accumulates in plants in the form of an acetylated product from which the herbicide is subsequently released into the gastrointestinal tract of warm-blooded animals. This has been demonstrated in the case of rats chickens and goats used as

test animals by M.N. Huang et al Metabolism of 14 C Glufosinate and in 14 C—N-Acetyl Glufosinate in lactating goats and laying hens – Agrevo Frankfurt whereby the herbicide also enters the human food chain – with all the consequences that that entails. Source Eijsten and Van der Meulen also see page 15 20 21 26 30 and 31 in this book https//www.gentechvrij.nl/2020/11/27/book-eijsten/ . This must be assessed with certainty in your EFSA comment. For the EFSA to write that it is not its job to assess this is fallacious we are dealing here with processes taking place within plants. Glyphosate residue is also present in this glyphosate-resistant genetically modified Soybean DAS–81419–2 x DAS–44406–6 as a protein adduct. Here too the herbicide is released in the intestinal tract. We are not talking in general about herbicide residues but highly specifically about the residues of herbicides to which crops have been made resistant and highly specifically about the properties of the particular residues and highly specifically about the mechanisms that enable these herbicide residues to enter the food chain. And hence we find the proposal inconceivable.

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6. Labelling proposal

This genetically modified Soybean DAS–81419–2 x DAS–44406–6 must not placed on the EU market

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Organisation: Testbiotech e.V. - Institute for Independent Impact Assessment of Biotechnology
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

It is known that environmental stress can cause unexpected patterns of expression in newly introduced DNA see for example Trtikova et al. 2015. More specifically Fang et al. 2018 show that stress responses can lead to unexpected changes in plant metabolism inheriting additional EPSPS enzymes. However the expression of the additional enzymes was only measured under field conditions in the US for one year. Further according to Member States' experts the genetic stability of the insert was only shown in a very low number of plants 3 single individual plants which is insufficient for reliable results EFSA 2020b.

The plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability. Whatever the case they should also have been tested in the largest soybean producing countries in South America.

A high number of open reading frames ORFs is reported in Member States comments see EFSA 2020b. Uncertainties remain about biologically active substances arising from the method of genetic engineering and newly introduced gene constructs such as non-coding small RNAs.

Therefore EFSA should have requested a much more detailed investigation into potential biologically active gene products as well as changes in metabolic pathways and gene expression.

In regard to expression of the additionally inserted genes Implementing Regulation 503/2013 requests “Protein expression data including the raw data obtained from field trials and related to the conditions in which the crop is grown in regard to the newly expressed proteins.”

However the data presented do not represent the conditions in which the plants will be grown as the field trials were not conducted in all the relevant regions and no extreme weather conditions were taken into account. Furthermore it is not clear from the EFSA opinion whether the field trials actually represent current agricultural management practices.

It is known that the genomic background of the variety can influence the expression of the inserted genes see for example Trtikova et al. 2015 Lohn et. al. 2020 de Campos et al. 2020.

Therefore EFSA should have requested additional data from several varieties including those cultivated in South America.

The material derived from the plants should have been assessed by using omics techniques to investigate changes in the gene activity of the transgene and the plant genome as well as changes in metabolic pathways and the emergence of unintended biological active gene products. Such in-depth investigations should not depend on findings indicating potential adverse effects they should always be necessary to come to sufficiently robust conclusions to inform the next steps in risk assessment.

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

Implementing Regulation 503/2013 requests "In the case of herbicide tolerant genetically modified plants and in order to assess whether the expected agricultural practices influence the expression of the studied endpoints three test materials shall be compared the genetically modified plant exposed to the intended herbicide the conventional counterpart treated with conventional herbicide management regimes and the genetically modified plant treated with the same conventional herbicide management regimes." "The different sites selected for the field trials shall reflect the different meteorological and agronomic conditions under which the crop is to be grown the choice shall be explicitly justified. The choice of non-genetically modified reference varieties shall be appropriate for the chosen sites and shall be justified explicitly."

Field trials for the compositional and agronomic assessment of the stacked soybeans were only conducted in the US for one year but not in other relevant soybean production areas such as Brazil Argentina Paraguay or Uruguay - and even for the US it is disputed if the field trial locations are representative. According to Member States' experts EFSA 2020b "Soybean is for example also grown in the South and South East of the US and not only in Midwest and East of the US where the trial sites were located. Therefore the presented data are considered insufficient to establish that the trials are representative for the whole range of possible agronomic and environmental conditions under which soybean is produced in North America."

It is not acceptable that EFSA failed to require further studies e.g. field trials lasting for more than one season. Thus based on current data it is hardly possible to assess site-specific effects. Further no data were generated representing more extreme environmental conditions such as those caused by climate change. Nevertheless regarding agronomic parameters multiple significant differences were detected in GE soybean plants whether or not they were treated with the intended herbicides EFSA 2020a

• "For soybean DAS-81419–2 x DAS-44406-6 not treated with the intended herbicides the test of difference identified statistically significant differences with the conventional counterpart for early stand count days to maturity plant height 100-seed weight yield and lodging. Of those endpoints 100-seed weight fell under equivalence category IV while the other endpoints fell under equivalence category I or II. • For soybean DAS-81419-2 x DAS-44406-6 treated with the intended herbicides the test of difference identified statistically

significant differences with the conventional counterpart for days to 50 flowering days to maturity plant height 100-seed weight and lodging. Of those endpoints 100-seed weight fell under equivalence category IV while the other endpoints fell under equivalence category I."

Further the compositional analysis also showed statistically significant differences to the conventional counterpart in many analysed compounds treated and not treated with glyphosate 24-D and glufosinate ammonium EFSA 2020a.

• "For soybean DAS–81419–2 x DAS–44406–6 not treated with the intended herbicides statistically significant differences with the conventional counterpart were identified for 32 endpoints all in seeds. For two of them acid detergent fibre ADF and phosphatidylinositol the test of equivalence was not applied because the variability among the reference varieties was estimated to be zero while lectin activity fell under equivalence category IV Table 6. The other 29 endpoints fell under equivalence category I or II. • For soybean DAS–81419–2 x DAS–44406–6 treated with the intended herbicides statistically significant differences with the conventional counterpart were identified for 39 endpoints 34 in seeds and 5 in forage. The test of equivalence was not applied to four of the forage endpoints while lectin activity and glutamic acid levels in seed fell under equivalence category III and IV respectively Table 6. The other 33 endpoints fell under equivalence category I or II."

There are several cases where genetically engineered plants show for example unintentionally enhanced fitness which can be influenced by environmental factors for overview see Bauer-Panskus et al. 2020. More specifically Fang et al. 2018 showed that stress responses can lead to unexpected changes in plant metabolism inheriting additional EPSPS enzymes.

Stress tests under a broad range of defined environmental conditions should have been carried out including taking pollen viability and seed dormancy into account.

Whatever the case much more data would be needed to develop a sufficiently defined hypothesis for risk assessment in regard to phenotypical characteristics and compositional analysis of the soybeans. This is especially relevant in this case because of the extremely high expression levels of the additionally produced proteins compared to wild-type cereals EFSA 2020a.

It is known that soybeans contain many biologically active substances e.g. estrogens allergens and anti-nutritional compounds which may interact with trait-related characteristics and act as stressors. Changes in the composition of these components may not only be triggered by the process of genetic engineering but also by interactions with the complementary herbicides see Miyazaki et al. 2019.

Therefore EFSA should have requested further tests to be carried out under exposure to a wider range of environmental conditions which should also have taken all relevant agronomic practices into account. The plant material should in addition have been assessed in more detail by using omics techniques to investigate changes in plant composition and agronomic characteristics.

Compositional analysis should also include measuring the herbicide residues and metabolite levels. This is requested by several Competent Authorities. For example according to Austrian experts EFSA 2020b "We consider that the scope of the comparative analysis concerning food and feed risk assessment is too narrow with a view to the characteristics of GM soybean

DAS-81419-2 x DAS-44406-6 and that the presence of residual levels of herbicides as well as residual metabolites of the complementary herbicides in GM soybean seed material should be determined."

However instead of assessing the overall patterns of change in plant components in greater detail as well as their causes and possible impacts EFSA only assessed the observed changes in isolation. This approach turns the comparative approach into a trivial concept of assessing bits and pieces and ignores questions on the overall safety of the whole food and feed.

Consequently based on the available data no final conclusions can be drawn on the safety of the plants.

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b. Food Safety Assessment:
Toxicology

Implementing Regulation 503/2013 requests "Toxicological assessment shall be performed in order to a demonstrate that the intended effects of the genetic modification has no adverse effects on human and animal health b demonstrate that unintended effects of the genetic modifications identified or assumed to have occurred based on the preceding comparative molecular compositional or phenotypic analyses have no adverse effects on human and animal health"

“In accordance with the requirements of Articles 4 and 16 of Regulation EC No 1829/2003 the applicant shall ensure that the final risk characterisation clearly demonstrates that a the genetically modified food and feed has no adverse effects on human and animal health”

Feeding studies Significant changes in plant composition were identified in many parameters these should have triggered a request for a 90-day subchronic study in rats. However according to EFSA this was not considered necessary.

Instead of testing the stacked soybean EFSA asked the applicant to provide a study in which groups of rats were given diets containing DAS-81419-2 or DAS-44406-6 soybean. According to EFSA this study found “that no treatment-related adverse effects were observed in rats after feeding diets including soybean DAS-81419-2 or soybean DAS-44406-6 up to 30 defatted toasted meal 2 hulls and 2.7 oil for 90 days.”

Interestingly the applicant even conducted a study with the stacked soybean for the authorisation process. However this study was not accepted by EFSA mainly because the percentage of GE soybean in the diet in the high dose group was considered too low. Nevertheless this study yielded interesting results which should have been scrutinised in a second better planned study. Whereas the outcome of this study is not reported in the EFSA opinion comments from Member States point to the fact that many significant effects were found when feeding rats with the stacked soybean. One Competent Authority lists these significant effects EFSA 2020b which should have prompted more detailed investigations

“- Kidney weight males Dunnett’s Test - Relative kidney weights males - Albumin males Dunnett’s Test - Glucose males Dunnett’s Test - Potassium males Dunnett’s Test - Red Blood cell Count males Dunnett’s Test - Haemoglobin males Dunnett’s Test - Haematocrit males Dunnett’s Test - Relative heart weight females Dunnett’s Test - Relative liver weight females - Relative spleen weight females Dunnett’s Test - Urea nitrogen females Dunnett’s Test - Glucose females Dunnett’s Test - Relative adrenal weight sexdose Dunnett’s Test - Relative kidney weight sexdose Dunnett’s Test - Relative kidney weight males - Relative liver weight sexdose Dunnett’s Test - Relative liver weight females - Reticulocytes sexdose Dunnett’s Test”

Herbicides Furthermore there are specific health risks resulting from the intended use of the GE soybeans engineered to be resistant to herbicides such as glyphosate glufosinate or 24-D.

The residues from spraying were considered to be outside the remit of the GMO Panel. However without a detailed assessment of these residues no conclusion can be drawn on the safety of the imported products due to specific agricultural practices in the cultivation of the herbicide-resistant plants there are e.g. specific patterns of application exposure occurrence of specific metabolites and emergence of combinatorial effects that require special attention see also Kleter et al. 2011.

More detailed assessment is also in accordance with pesticide regulation that requires specific risk assessment of imported plants if pesticide usage in the exporting countries differs compared to EU usage. In this regard it should be taken into account that EFSA 2018 explicitly stated that no conclusion can be drawn on the safety of residues from spraying with glyphosate in genetically engineered plants resistant to this herbicide. Further a recent review comes to the conclusion that “literature on the potential effects of glyphosate on livestock is very scarce and mainly reporting in vitro studies hence a solid basis of in vivo studies with

livestock in physiological and productive phases particularly sensitive to disorders in mineral status and in the gut microbiota is needed" Sørensen et al. 2020.

In addition glufosinate is classified as showing reproductive toxicity and there are indications of additive or synergistic effects of the residues from spraying http//ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/eventhomepagelanguageEN. Further recent research regarding 24-D seems to indicate that health risks may be underestimated de Azevedo Mello et al. 2020.

Mixtures In summary the GE soybeans intended for import are not unlikely to contain a toxic mix of chemicals without any testing of combinatorial effects at the stage of consumption being requested. In addition it is known that soybeans contain many biologically active substances e.g. estrogens allergens and anti-nutritional compounds which may interact with trait-related characteristics and act as stressors. Changes in the composition of these components can be triggered by the process of genetic engineering as well as by interactions with the complementary herbicides.

Therefore as shown in a recent report Then et al. 2020 a far more detailed assessment is needed of combinatorial effects or potential mixed toxicity arising from simultaneous exposure to a fixed combination of potential stressors from GE plants at the stage of consumption. Consequently the GE soybeans should be tested following the 'whole mixture' approach which considers them to be "insufficiently chemically defined to apply a component-based approach" EFSA 2019.

Currently the most appropriate method to test these substances are life-time feeding studies with whole plant materials. To generate reliable data for products that are used daily in the food chain the feeding studies will need to be long-term and include several generations.

In addition in vitro testing systems and testing systems using non-vertebrates might also be applied to reduce the overall number of animals needed for feeding studies.

The material derived from the plants should be assessed in regard to organ toxicity immune system responses and reproductive toxicity also taking combinatorial effects with other plant components into account.

Bt toxins and protease inhibitors Selectivity and efficacy of Bt toxins as produced in GE plants can be influenced by many co-factors see for example Then 2010 Hilbeck Otto 2015. One crucial impact factor are protease inhibitors PI which delay the degradation of Bt proteins and thereby enhance their toxicity see Pardo-López et al. 2009.

Already in 1990 Monsanto showed that maize cotton and soybeans produce protease inhibitors PI which considerably enhance the toxicity of Bt proteins in plants. In the presence of PIs Bt toxin will degrade much more slowly than in isolation. This results in a much higher toxicity of the Bt toxin if it is taken up together with the plant tissue compared to the isolated toxin MacIntosh et al. 1990 Zhao et al. 1999 Zhang et al. 2000 Gujar et al. 2004 Zhu et al. 2007 Pardo-López et al. 2009 Ma et al. 2013 Mesén-Porras et al. 2020. The effects described indicate for example a 20-fold higher toxicity of Bt proteins if produced in the plants and taken up with PIs MacIntosh et al. 1990.

Therefore any risk assessment which does not take a combination of plant material with the Bt toxin into account is not reliable and systematically underestimates the risks.

It is known from scientific publications that co-factors which enhance the toxicity of the Bt proteins can also impact their selectivity for overview see Then 2010 if synergistic or additive effects occur that increase efficacy of the Bt toxin its selectivity may be decreased and a wider range of non-target organisms may become susceptible. In addition there has never been any systematic research into these combinatorial effects. There are just a few publications available which indicate the effects of protease inhibitors combined with Bt toxins on non-target insects Babendreier et al. 2005 Liu et al. 2005a Liu et al. 2005b Han et al. 2010.

The synergistic effects described by MacIntosh et al. 1990 Zhao et al. 1999 Zhang et al. 2000 Gujar et al. 2004 Zhu et al. 2007 Pardo-López et al. 2009 Ma et al. 2013 Mesén-Porras et al. 2020 causing higher toxicity of the Bt toxins are also relevant to the risk assessment of food and feed safety the combination with protease inhibitors is likely to be associated with a delay in the degradation of the Bt toxins after consumption. This delay in degradation extends the exposure of the intestinal immune system to Bt toxins and may trigger or enhance health impacts such as chronic inflammation and allergies.

Overall the toxicological assessment carried out by EFSA is not acceptable.

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Allergenicity

The synergistic effects described by MacIntosh et al. 1990 Zhao et al. 1999 Zhang et al. 2000 Gujar et al. 2004 Zhu et al. 2007 Pardo-López et al. 2009 Ma et al. 2013 Mesén-Porras et al. 2020 causing higher toxicity of the Bt toxins are also relevant to risk assessment in regard to the immune system the combination with protease inhibitors is likely to be associated with a delay in the degradation of the Bt toxins after consumption. This delay in degradation extends the exposure of the intestinal immune system to Bt toxins and may trigger or enhance health impacts such as chronic inflammation and allergies see also Then Bauer-Panskus 2017

EFSA does not mention that Cry1Ac is thought to be allergenic Santos-Vigil et al. 2018 see also www.testbiotech.org/en/press-release/can-bt-toxins-cause-allergies. In the published reports and also in references made by EFSA 2020a there is a general lack of empirical data. Consequently EFSA can only conclude on an absence of evidence but not on evidence of safety for the immune system.

None of the reports mention discuss or assess the potential enhancement of toxic or immunogenic effects caused by interaction with plant components such as PI. Furthermore EFSA 2020a does not address non IGE-immune reactions.

Although lectins are known immunogens Parenti et al. 2019 the highly significant increase in the concentration of lectins was not investigated as a risk for the immune system if taken up together with higher concentration of Cry toxins present in the stacked event.

Furthermore Parenti et al. 2019 state that “one of the most important drivers of immune response is the gut microbiota and other microbial constituent of the human body which are able to regulate host-pathogen balance and to produce systemic pro-inflammatory stimuli. The lifelong antigenic load represented by foods and bacteria/bacterial products leads to a profound remodeling of the gut microbiota and these changes are emerging as a driving force of the functional homeostasis of the immune system. As a matter of fact a perturbation of the gut microbiota homeostasis due to irregular lifestyles stress and age may lead to gut microbiota dysbiosis. This condition may predispose the host to metabolic disorders and inflammation.”

However potential changes in the microbiota were not taken into account by EFSA 2020a even though this was also mentioned by experts of Member States EFSA 2020b.

In conclusion the safety of the GE soybeans in regard to potential impacts on the immune system was not demonstrated.

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4. Conclusions and recommendations

Regulation 1829/2003 Recital 9 states that "…any risks which they present for human and animal health and as the case may be for the environment…" have to be avoided. Our analysis shows that the safety of the products derived from the GE soybeans could not be demonstrated. There are however substantial indications that the consumption of the soybeans may provoke adverse health effects. Therefore the risk assessment is not conclusive and approval for the EU market cannot be granted.

5. Others

For monitoring and methods to identify the specific event Implementing Regulation 503/2013 requests "The methods shall be specific to the transformation event hereafter referred to as 'event-specific' and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorised otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised transformation events and conventional counterparts. This testing shall include closely related transformation events."

However no such method for identification was made available. Based on the information that is available it will not be possible to distinguish the stacked event from a mixture of single parental events or stacked events that overlap with the actual stack.

If approval for import is given the applicant has to ensure that post-market monitoring PMM is developed to collect reliable information on the detection of indications showing whether

any adverse effects on health may be related to GM food or feed consumption. Thus the monitoring report should at very least contain detailed information on • i actual volumes of the GE products imported into the EU • ii the ports and silos where shipments of the GE products were unloaded • iii the processing plants where the GE products was transferred to • iv the amount of the GE products used on farms for feed • v transport routes of the GE products.

Environmental monitoring should be run in regions where viable material from GE products such as kernels are transported stored packaged processed or used for food/feed. In case of losses and spread of viable material such as kernels all receiving environments need to be monitored. Furthermore the impact on the environment from organic waste material by-products sewage or faeces containing GE products during or after the production process should be part of the monitoring process both during and after human or animal consumption.

Finally in regard to the literature research we do not agree with the way it was carried out. The review should take into account all publications on the parental plants and provide all relevant information regarding gene expression findings from field trials and feeding studies. However the applicant only presents four studies from the past 14 years deemed to be important for risk assessment of the stacked soybean all of them conducted by Dow. Clearly this form of literature review cannot be taken seriously and should have been rejected by EFSA. Further monitoring data should be provided on imports of parental plants into the EU.