soybean 305423

Organisation: individual
Country: Romania
Type: Consultant

a. Assessment:
Molecular characterisation

Molecular characterisation has similar description with the agronomic traits. Practically no diference between varieties and GM traits.

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

Improved composition within oil content of GM trait with beneficial omega component.

b. Food Safety Assessment:
Toxicology

No toxicological negative effects.

Allergenicity

No allergenic simptoms.

Nutritional assessment

Higher nutritional value.

Others

Improved diet

---

3. Environmental risk assessment

No environmental risk

---

4. Conclusions and recommendations

This GM trait should be registerred as soon as possible

---

5. Others

Socio-economic important benefits

---

6. Labelling proposal

According to EU regulations

Organisation: myself
Country: Belgium
Type: Others...

---

a. Assessment:
Molecular characterisation

I can't speak very well English but I can say that in french ; un jour vos enfants vous maudiront. Vous décidez de laisser faire l'agro alimentaire qui vous mène par le bout du nez pour les pesticides et les OGM, c'est mauvais pour la santé un point c'est tout et il faut les supprimer très vite car notre nature n'a pas à être modifiée elle s'est faite toute seule et elle était tellement bien organisée avant que l'agro alimentaire ces mafieux du fric et rien d'autre

y mettent leurs mains. On devrait les condamner pour crime contre l'humanité. Sommes nous tellement si nombreux sur cette terre que vous n'ayez aucun scrupule à ce que nos enfants meurent de cancer ? Voilà ce que j'avais à vous dire, vous crier ma révolte de mère qui a empoisonné sans le savoir pendant des années ses enfants par les pesticides qui continuent à nous tuer avec les OGM maintenant le wifi et les téléphones portables. Quand réagirez vous avec votre conscience et votre cœur plutôt qu'avec votre portefeuille et vos intérêts politiques et économiques.

Merci

Organisation: Private
Country: Sweden
Type: Individual

---

a. Assessment:
4. Conclusions and recommendations

This product has a clear consumer benefit profile. EFSA has concluded seven times (!) that it is safe for human health and the environment. The food labelling legislation ensures that those consumers that do not want this product can choose other alternatives. I fully support the approval of this dossier.

Organisation: Leibniz-Universität Hannover
Country: Germany
Type: Scientific Institution

---

a. Assessment:
Molecular characterisation

The molecular characterisation is sound and scientific

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

The GM soybean 305423 provides substantial benefits to consumers as the enhanced unsaturated fatty acids are definitely healthier than saturated ones

---

b. Food Safety Assessment:
Toxicology

As the unsaturated fatty acids have less deleterious effects than the oils from nonGM-soybean, no negative toxicoligic effects are expectable

---

Allergenicity

As the fatty acid composition is affected, no new allergenicity risks can be expected

---

Nutritional assessment

Positive

---

3. Environmental risk assessment

No novel risks expectable

---

4. Conclusions and recommendations

I agree with EFSA´s conclusions

---

6. Labelling proposal

Adequate

Organisation: AGROBIOTECHROM
Country: Romania

Type: Association

---

a. Assessment:
Molecular characterisation

High oleic soybean with less unstable fatty acids. Molecular structure is similar to conventional soybean.

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

Higher content in unstable acids for agronomic traits and better Plenish high oleic soybeans.

---

b. Food Safety Assessment:
Toxicology

Safe from toxicological point of view with higher value for omega 3 and 6.

Allergenicity

No allergenic symptoms

Nutritional assessment

Increased nutritional value due to high oleic content and stable fatty acids. Better nutrition with improved taste, zero trans fat, less saturated fat.

Others

Farmers high yielding plants, higher value beans. HIGHER VALUE OIL OFFERING. No hydrogenation needed. Improved flavor and better shelf life. High in mono unsaturated fat.

---

3. Environmental risk assessment

No environmental risk. Beneficial for nitrogen fixation in soil.

---

4. Conclusions and recommendations

Plenish soybean is a BENEFIT for food companies due to high stable fatty acids oil content. Also it is important for EU livestock.

---

5. Others

Socio-economic favourable impact.

---

6. Labelling proposal

No need for special label.

Organisation: Insitute of Agricultural Economics, Romanian Academy
Country: Romania
Type: Scientific Institution

---

a. Assessment:
Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

Weed pressure in Romania: weeds are the main problem farmers are facing for all the arable crops in Romania. They significantly contribute to the diminution of average yields per hectare and to product quality deterioration, to their underrating, and to poor commercialization as a result of the presence of weed traces in the final grain product for sale. The research on the damages produced by weeds in Romania reveal that the harvest losses in corn grain induced by the weeds range from 40 to 84% (N. Sarpe 1977). In Romania, the glyphosate tolerant corn is in the testing stage. Glyphosate tolerant corn was cultivated in the year 2010 on one of the 22 interviewed farms on an area of 0.3 ha. This farm is in a very low zone, with high weed infestation; the ground water is found at small depth; the migratory birds come here in spring and in autumn, and the surplus of water from rainfall

flows directly into the Danube, directly affecting the water fauna. The farm has experience in RR soybean cultivation. In the years when RR soybean was cultivated as well as glyphosate tolerant corn, no incidents were signaled out with regard to water fauna and flora and to migratory birds. Another data set on glyphosate tolerant corn cultivation comes from the testing plots organized in 5 different locations: Calaraşi, Braila, Galati, Teleorman and Buzău.

Only here we can find some results!!! In the table below we summarized the data referring to the production costs related to conventional corn cultivation, on the 22 interviewed farms. A wide range of costs per hectare can be noticed, as well as by different items. We must specify that the obtained average yield is much over the national average (see Figure 2). The gross margin can increase up to three times in the conditions when: (1) the production costs increase more than twice; (2) the costs of planting seeds increase 1.5 times; (3) and the crop herbicides costs increase 3 times.

Tab. 3 Structure of costs related to conventional corn in the year 2010, (euro/ha)

Structure of costs Minimum Average Maximum Cultivated area – hectares 150 427 2200 Average yield – kg/hectare 5 8 11 Total costs per hectare 455 562 806 - Mechanical works 107 201 309 - Manual labor 1 9 48 - Seeds 71 92 107 - Herbicides 36 63 108 - Irrigation of crop 71 87 129 - Crop insurance 4 13 71 Total incomes per hectare 660 1056 1452 Gross margin euro/ha 205 494 646 Source: Data obtained on the interviews conducted in the period November 2010 -April 2011; the prices in euro were calculated on the basis of the average exchange rate published by the Central Bank of Romania for the year 2010; €1 = 4.2099 RON The results regarding conventional corn cultivation versus glyphosate tolerant corn show that an additional profit of 48 euro/ha can be obtained, in the conditions in which the seed costs increased by 14 euro/ha, while the herbicide costs decreased by 110 euro/ha. It must be specified that the farm on which glyphosate tolerant corn was tested uses glyphosate as post-emergent herbicide under the yearly crop herbicide application scheme. The yield increased by 4%.

Tab. 4 Structure of costs of conventional corn and glyphosate tolerant corn corn cultivation in one location Braila, in the year 2010, euro/ha

Structure of costs Conventional corn Glyphosate tolerant corn Differences +/- glyphosate tolerant corn/conventional corn Cultivated area – hectares 331 0.3 Average yield - kg/hectare 8.0 8.3 4 % Total costs per hectare 874 779 -95 - Mechanical works 80 75 -5 - Manual labor 9 7 -2 - Seeds 86 101 14 - Herbicides 125 15 -110 - Irrigation of crop 32 32 0 - Crop insurance 4 4 0 Total incomes per hectare 1056 1096 40 Gross margin per hectare 182 317 135 Source: Data obtained on the interviews conducted in the period November 2010 - April 2011, the prices in euro were calculated on the basis of the average exchange rate published by the Central Bank of Romania for the year 2010; €1 = 4.2099 RON

The glyphosate tolerant corn tests conducted by State Institute for Variety Testing and Registration carried out in 5 different locations in the period 2008-2010 revealed that yields increased by 3 - 34%. As control, different hybrids from the same precocity group (300/400 FAO), and the same technology were used. Tab.5 Average yields – 5 different locations - glyphosate tolerant corn in the year 2010, tons/ha

Structure of costs Location 1 Galati County Location 2 Calarasi County Location 3 Buzau County Location 4 Braila County Location 5 Teleorman County Conventional corn 8.338

7.257 8.281 7.777 8.074 Glyphosate tolerant corn 9.005 8.515 8.515 10.392 9.527 Yield gain % 8 17 3 34 18 Source: data from The State Institute for Variety Testing and Registration

The herbicides used for glyphosate tolerant corn were based on glyphosate solo concept: 2 applications of glyphosate (2 + 3 liters) in the 1-3 leaves stage and the second in the stage up to 8 leaves. In the case of conventional corn, 29 herbicide application schemes were used, with a total number of 56 active substances. The main active substances were the following: nicosulfuron (used in 8 cases), isoxaflutole + terbuthylazine (used in 7 cases), acetochlor (used in 7 cases), 2,4 D (used in 6 cases). The herbicide costs on the farm rather reveal the farm financial power than the weed infestation of crop. The better the financial situation of farms, the stronger the tendency to use herbicides based on 2 or even 3 active substances in a single application to fight against a wide range of weeds, and in this case the herbicide costs are higher as last generation herbicides are used. We can notice that a different number of herbicides are used, a different number of applications, as well as different costs associated to them. From the financial point of view, all interviewed farmers had profit at the end of the year, being included in the category of solvent customers. Most of them take credit from banks for funding their production costs. There are also a few cases when farmers use only their own resources and do not take credit to fund their production costs. Following the processing of questionnaires and the analysis of the results (the coefficients obtain by using probit model) we can draw the following conclusions: with a mean of 0.55 and a standard deviation of 0.51, the farmers answered that.

Tab. 8 Willingness to adopt

Items Mean Standard Deviation It’s very unlikely I would change to glyphosate tolerant corn 0.00 0.00 It’s somewhat unlikely I would change to glyphosate tolerant corn 0.00 0.00 It’s uncertain I would change to glyphosate tolerant corn 0.00 0.00 It’s likely I would change to glyphosate tolerant corn 0.55 0.51 It’s very likely I would change to glyphosate tolerant corn 0.45 0.51 Source : data collected on interviews

All farmers believe that they will have economic advantages if they cultivate glyphosate tolerant corn because: they are guaranteed a better profit per hectare; they reduce the cost regarding combating weeds while cultivating glyphosate tolerant corn but also the cultures that may follow, and they are also guaranteed cutting the losses that survey from the growth of weeds that affect the corn.

Tab. 9 Economic reasons

Items Mean Standard Deviation ,It guarantees the reduction of losses caused by weed growth’ 0.68 0.48 ,It guarantees higher income’ 0.86 0.35 ,It reduces weed control costs’ 0.82 0.39 Source : data collected on interviews

In the case of glyphosate tolerant corn cultivation farmers use fewer types of herbicides and in smaller guantities and as a result the technology is more eco friendly. All farmers think that using glyphosate tolerant corn is going to make their work easier because the process of combating weeds is less invasive both in the case of NK corn but also for the cultures that will follow.

Tab.10 Environmental impact reduction, and facilitation of work

Items Mean Standard Deviation ,the environmental impact on farm is reduced because it involves a cut down in herbicides' 0.86 0.35 Facilitation of work , It facilitates my work being a technology that makes cultivation easier' 0.59 0.5 Source : data collected on interviews

Talking from an administrative point of view, the farmers will have to inform their neighbours about the plots of land where they plan to cultivate geneticaly modified corn and also they will have to identify their plot in a public register. However they do not consider this as an impediment in the cultivation of glyphosate tolerant corn.

Tab. 11 Administrative measures

Items Mean Standard Deviation 'the plot must be identified in a public register' 0.45 0.51 'the neighboring farmers must be notified' 0.36 0.42 'if the land is rented, the owner has to be notified' 0.45 0.51 'it must under public registration for 5 years' 0.32 0.48 Source : data collected on interviews

Although the farmers who have been interviewed believe that they will face difficulties when they will have to make the compulsory separation between harvesting and transportation, they consider that they will be able to do a thourough cleaning of the combine after and before harvesting glyphosate tolerant corn.

Tab. 12 Technical reasons

Items Mean Standard Deviation 'the combine harvester must be thoroughly cleaned both before and after harvesting' 0.55 0.51 'the compulsory of separate harvesting and transportation' 0.18 0.39 Source : data collected on interviews

The farmers that have answered this interview don't seem to be discouraged by the new insurance policy; the distance (coexistence)they have to keep between the geneticaly modified cultures and the other corn production systems; the new technology they will have to start using. This things do not represent a problem since they have wide areas, so they are able to separate de cultures; they afford to pay a bigger insurance and almost all of them have the experience of cultivating glyphosat tolerant soybeans.

Tab. 13 Insurance policy

Items Mean Standard Deviation 'an insurance policy to cover claims for neighbors' 0.36 0.49 Source : data collected on interviews

The crop isolation distance is established by each Member State of the European Union. In Romania, the Ministry of Agriculture and Rural Development took over the isolation distance of genetically modified crops from the commercial crops as being the same as in the case of certified seed production, this being 200 meters in the case of corn. Afterwards, MARD made studies in this respect and reached the conclusion that an isolation distance of 50 metrrs is sufficient in order to avoid the infestation of the commercial corn fields. We expect that in the year 2012 the isolation distancxe will be modified to 50 m, which will also permit the small farms to cultivate genetically modified corn. Tab.14 Separation distance

Items Mean Standard Deviation 'The distance over which I would stop growing glyphosate tolerant corn is..'' 0.05 0.21 Source : data collected on interviews

Tab.15 Disbelief in GM technology

Items Mean Standard Deviation ‘I do not think there would be an improvement in yield’ 0.36 0.49 ‘I do not think there would be an improvement in financial returns’ 0.00 0.00 ‘I do not belief in these new products’ 0.00 0.00 ‘I prefer not to change the type of crop. I do not really like change’ 0.00 0.00 ‘I have been advised not to use this type of corn’ 0.00 0.00 ‘I think it would be difficult to market the grain’ 0.23 0.43 “it will not be well received by society in general’ 0.23 0.43 Source : data collected on interviews

Glyphosate a necessary herbicide in Romania ? Since 1978 until 1985 Romania has used glyphosate in agriculture, according with Fundulea Institute of Crop Research. First time the glyphosate was used to control the wide range emerged weeds in Danube Delta and Big Island of Braila were the weeds have been exceeding 1200 plants/square meter. There, glyphosate was used to spray more than 76 thousand hectares. Also glyphosate was used as desiccant for wheat, corn and sunflower at that time. It was the most efficient herbicide used in Romania at the time. It was used as well with good results in vineyards and orchards. In the period 1985-1990, the decision taken by the state was to give up the imports of herbicides, while the foreign currency obtained from exports should be used only for foreign debt payment; in conclusion glyphosate was neither imported nor used in this period. After 1990 the glyphosate started being used again in Romanian agriculture, industrial and urban areas. In Romania the weeds have been expanding in number and diversity per square meter, due to the land abandonment or absence of herbicide usage to control weeds. As a consequence, for an efficient control of the weeds it is necessary to use a non-selective herbicide or a large number of selective herbicides. From an economic point of view it is more convenient to use a non-selective herbicide once per year. Commercial farms used the glyphosate as part of a yearly weeds control systems. Usually farmer used glyphosate as a post-harvest herbicide to destroy the weeds seed stock. In the wet years it could be used as a pre-harvest herbicide or as harvest desiccant. For example: in 2010, farmers needed to spray the rapeseed crop to avoid increase costs (with fuel, drying, buy new harvest combine parts) or to loose yield due to delayed harvest time. Due to the lack of data regarding glyphosate quantities used and in stock in the Romanian market we make estimations based on available data and stories collected during the farms interviews. According to the input from the company data, 89% of the produced glyphosate is used in the agriculture. Tab.16 Estimation of used glyphosate in Romania cropping area

Items 2010 Comercial farms area1 ha. 3,646,586 Total area with herbicides2 ha 3,142,770 Glyphosate quantities used3 litre 1,300,000 Area sprayed with glyphosate4 3 litre/ha hectars 433,333 Of wich comercial farms that used glyphosate4 ha 386,000 Source : 1 eligible farms for payments according to the National Agency for Payments in Agriculture; 2National Institute for Statistics; 3 base of input company data; 4own estimation;

Calculation of losses by not using glyphosate usually glyphosate it sprayed as a post-harvest herbicide, applied after rapeseed and wheat to reduce the level of seed stock in soil. The first impact is visible on the crop that follows, but after several years of application it reduces a number of weed per square meter. More visible results were pointed out by farmers in a rapeseed and wheat field. Based on 2010 prices we estimate that Romanian agriculture would lose annually 42 million euro if the glyphosate was not used. To cover the reduction in yield it is necessary to increase the area cultivated under rapeseed and wheat by 152,778 hectares, and to increase the herbicide quantities and number used per hectare.

Around 10% of rapeseed and 7% of wheat are estimated to be treated with glyphosate as a pre planting spraying. The drought years are exception. The reduction in yield would impact on national crop production with 12% for wheat and 13% for rapeseed. It is necessary to cultivate additional land to ensure that the rapeseed and wheat production will remain at the level reached in 2010.

Tab.17 Estimation of losses and increasing area plantind for wheat and rapeseeds

Items rapeseed wheat total Estimated losses to industry due loss of glyphosate euro 34,962,677 93,733,046 128,695,723 Estimated increase of area to maintain production at curent level in the absence of glyphosate ha 124,605 249,097 373,702 Source: own calculation

Not using glyphosate would require farmers to increase cultivation and herbicide application to try to maintain the weed control at the same level. Socio-economic impact Glyphosate has a beneficial financial impact at farmer level, as well as upon the quality of farmers' lives. Glyphosate enables the use of fast and easy cultivation technologies, which supports the use of minimum tillage technology. The farmers prefer to use glyphosate due to the low exposure risks, compared to other herbicides. The climate changes determined part of the commercial farms to invest in minimum tillage technology. Significant investments were made starting with the year 2000, with the introduction of glyphosate tolerant soybean. Even after banning the cultivation of glyphosate tolerant soybean, farmers continued to use minimum tillage as a post-harvest technology. The obtained results, even under drought conditions, determined them to increase their areas under minimum tillage around to 600 – 900 thou.ha, according to specialist opinion. The introduction of glyphosate tolerant corn into cultivation would facilitate a much more efficient weed control, and the minimum tillage technology might be extended in direct proportion with the area cultivated with glyphosate tolerant corn.

---

4. Conclusions and recommendations

- Romania is situated on the first place concerning the surface on which corn is cultivated, but as for the production of corn Romania is situated only on the 7th place in UE 27. - The coexistence of modern farming with subsistence farms has generated quite a big problem concerning the high weeds density hard to handle. - The method of using herbicides for combating weeds is used on almost 3 million hectares, and if we take into consideration that the big farms apply this method 2-3 times a year we can see that on at least 1/3 of the arable area herbicides are used. Romanian farmers averagely use pesticides worth 15 euro per hectare, while in Hungary; the average cost per hectare is 32 euro. This happens due to a tight budget. - Romanian farmers already have an experience with the cultivation on genetically modified soy and together with the economic performances they have obtained they are eager to try this kind of technology. - The glyphosate tolerant corn is still in a testing stage in Romania. - The results obtained from the cultivation of glyphosate tolerant corn show us that we can get a supplementary 40 euro/ha, gross margin goes up to 135 euro/ha, and the expenses with the seed go up only by 14 euro/ha. - The average yield in the case of glyphosate tolerant corn is with 3-34% higher than in the case of conventional corn. - We

conclude that the farmers seem to be eager to try the glyphosate tolerant corn in favor of the conventional corn. - The public opinion in Romania generally agrees that the products should be labeled as genetically modified, but the same thing must also happen for the products that are imported, as at present the cultivation of glyphosate tolerant corn is banned, but at the same time this crop enters the country through imports, and it can be consumed without the consumers being informed on this. - Not using glyphosate will result in severe losses for commercial farms and for Romania's agriculture and environment.

Organisation: CESFAC
Country: Spain
Type: Association

---

a. Assessment:
4. Conclusions and recommendations

Our members/we are concerned that EU approvals of GM products often lag behind those in other parts of the world, contributing to the potential for significant disruption in trade flows of essential agricultural commodities and processed products . We believe that GM events that have received a favorable opinion from EFSA should be approved as quickly as possible in order to avoid potential trade disruption and to demonstrate that the EU regulatory system is based on objective scientific criteria. In light of this, we believe that GM soybean 305423 from Pioneer should be approved for food, feed, import and processing in the EU as soon as possible.

Organisation: AFOEX
Country: Spain
Type: Association

---

a. Assessment:
5. Others

Our members/we are concerned that EU approvals of GM products often lag behind those in other parts of the world, contributing to the potential for significant disruption in trade flows of essential agricultural commodities and processed products . We believe that GM events

that have received a favorable opinion from EFSA should be approved as quickly as possible in order to avoid potential trade disruption and to demonstrate that the EU regulatory system is based on objective scientific criteria. In light of this, we believe that GM soybean 305423 from Pioneer should be approved for food, feed, import and processing in the EU as soon as possible.

Organisation: GeneWatch UK
Country: United Kingdom
Type: Non Profit Organisation

---

a. Assessment:
Molecular characterisation

The molecular characterisation is acknowledged to be unusually complex, including complete and/or partial copies of the cassettes in 4 different insertion arrangements plus an unintended fragment (claimed to be non-functional). The applicant has also demonstrated instability in the genome of soybean 305423 as a single plant has been found to be GM-HRA negative. Further, the use of RNA interference can give rise to unintended off-target effects (Heinemann JA, Agapito-Tenfen SZ, Carman JA. A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environment International. 2013;55:43–55; 1. Lundgren JG, Duan JJ. RNAi-Based Insecticidal Crops: Potential Effects on Nontarget Species. BioScience. 2013;63(8):657–665. doi:10.1525/bio.2013.63.8.8). Especially given the unexpected and unintended alterations in compositional analysis (e.g. altered calcium, zinc, glycitin, trypsin inhibitor and forage fibre fractions, as well as complex and unexpected effects on fatty acid profile), a full proteomic analysis should be requested from the applicant. Such an analysis would be able to better characterise these unintended effects (Zolla L, Rinalducci S, Antonioli P, Righetti PG. Proteomics as a complementary tool for identifying unintended side effects occurring in transgenic maize seeds as a result of genetic modifications. J Proteome Res. 2008;7(5):1850–1861).

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

A single field trial (at 10 US sites only in a single year) is insufficient to provide the necessary data, particularly for nutritional analysis. Environment and gene-environment interactions (GxE) are known to have important effects on nutrient (including fatty acid) composition of soybeans (Whent M, Hao J, Slavin M, et al. Effect of Genotype, Environment, and Their Interaction on Chemical Composition and Antioxidant Properties of Low-Linolenic Soybeans Grown in Maryland. J Agric Food Chem. 2009;57(21):10163–10174)and such effects can vary

at different developmental stages (Han Y, Xie D, Teng W, Zhang S, Chang W, Li W. Dynamic QTL analysis of linolenic acid content in different developmental stages of soybean seed. Theor Appl Genet. 2011;122(8):1481–1488). It is therefore essential that data is obtained from a wide variety of agronomic conditions, representative of expected growing conditions. In the interests of achieving a level regulatory playing field it is also worth noting that Monsanto included data from the US and Chile in its MON87705 (Vistive Gold) application (EFSA, 2012). Whilst the MON87705 data is arguably also insufficient, Pioneer's soybean 305423 application contains worrying signs of unintended effects on nutrient composition (as noted above) which should warrant more data being supplied not less. Statistically significant differences in 51 parameters, including fibre, minerals and phytoestrogens not intended to be altered by the modification, merit considerably more detailed investigations. Further data from other sites (including South America) and different years should be requested from the applicant.

---

b. Food Safety Assessment:
Toxicology

There is an extremely worry and puzzling lack of data provided here on the effects of processing on the nutrient profile (especially the fatty acid profile) of the soybeans. Processing is known to significantly alter nutrient levels and some such data was required for the MON87705 application (EFSA,2012) it is therefore hard to understand why it was not requested here. This data is essential before any meaningful nutritional assessment can be conducted. It must include information on nutrient and anti-nutrient levels and on bioavailability and bioefficacy taking onto account the potential influences of transport, storage and expected treatments of the food.

The applicant has applied for an authorisation which covers the GMO and foods containing it. Although information on the nutritional composition has been supplied for the GMO, it has not been supplied for the foods containing it. This means that no assessment can be conducted for such foods and no authorisation can be granted. Data on the nutrient (and anti-nutrient) composition of all the foods within the scope of the application (salad dressings, margarines, cooking oils, salty snacks, tofu, soymilk etc.) must be provided by the applicant as well as for secondary products such as soy lecithin.

Nutrient (and anti-nutrient) composition is also required for meat, milk and eggs from animals fed on soybean 305423. The scientific assessment incorrectly implies that the soybean oil will be largely for human consumption, whilst defatted soybean meal will be fed to animals. Whilst this is indeed normal practice in the industry, the addition of GM soybean oil or seeds to animal feed is an active topic of research, with the aim of altering milk fat composition (Bernal-Santos G, O'Donnell AM, Vicini JL, Hartnell GF, Bauman DE. Hot topic: Enhancing omega-3 fatty acids in milk fat of dairy cows by using stearidonic acid-enriched soybean oil from genetically modified soybeans. J Dairy Sci. 2010;93(1):32–37. doi:10.3168/jds.2009-2711) as has already been attempted using supplements (e.g. Glasser F, Ferlay A, Chilliard Y. Oilseed lipid supplements and fatty acid composition of cow milk: a meta-analysis. J Dairy Sci. 2008;91(12):4687–4703). Since potential food and feed applications have not been restricted, this application should fall within the scope of the

assessment. Further, it is likely that a similar approach could be applied to meat and eggs where diet is known to affect fat composition (e.g. Berthelot V, Bas P, Schmidely P. Utilization of extruded linseed to modify fatty composition of intensively-reared lamb meat: effect of associated cereals (wheat vs. corn) and linoleic acid content of the diet. Meat Sci. 2010;84(1):114–124.; Oliveira DM, Ladeira MM, Chizzotti ML, et al. Fatty acid profile and qualitative characteristics of meat from zebu steers fed with different oilseeds. J Anim Sci. 2011;89(8):2546–2555). Additional data should be requested from the application to cover these scenarios, to underpin a revised nutritional assessment.

The animal studies provided are inadequate to cover the required assessments. For example, in the rat studies reported, soybean 305423 was not treated with the intended herbicide. GeneWatch UK is not aware of any studies regarding nutrient composition and ALS-inhibiting herbicides, however it is well established in the case of the more commonly grown glyphosate-resistant GM crops that application of glyphosate alters the nutrient profile as well as leaving pesticide residues on the soybeans (Bellaloui N, Abbas HK, Gillen AM, Abel CA. Effect of glyphosate-boron application on seed composition and nitrogen metabolism in glyphosate-resistant soybean. J Agric Food Chem. 2009;57(19):9050–9056.; Bøhn T, Cuhra M, Traavik T, Sanden M, Fagan J, Primicerio R. Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans. Food Chemistry. 2014;153:207–215). It is therefore essential to include a study of the actual product as it is intended to be produced, with the intended herbicide. This is particularly important for the soybean oil as this is the product intended to be fed to humans.

The feeding studies also omit any study of the effect of the altered nutrient profile on health: this is important because the purpose of the toxicological assessment is to demonstrate that the intended and unintended effects of the genetic modification have no adverse effects on human or animal health. Relevant questions and endpoints might be, for example, whether the altered fatty acid composition (increased omega-3 PUFAs and MUFAs) might increase the risk of breast or prostate cancer (see comments on nutritional assessment below). The applicant should be required to submit a detailed risk assessment on these aspects.

Although a limited quantity of oil was included in the chicken feeding study (0.5%) this is insufficient to explore the possible deliberate application of a greater quantity of oil with the intention of altering the fatty acid profile of the eggs (so that they can potentially be marketed as premium products like “omega-3 eggs”). Further, no data on the nutrient profiles of the eggs has been reported. This is necessary for the nutritional assessment. As noted above, nutrient profiles for meat and milk should also be provided.

Nutritional assessment

There is no nutritional assessment as such included in the scientific assessment and the EFSA GM Panel appears to be relying solely on The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)’s 2010 report on Dietary Reference Values for fatty acids. This serious omission has perhaps occurred because there are no nutritionists on the GMO Panel

(although one expert from the NDA has acted as a hearing expert) which means the panel lacks the relevant expertise to conduct a nutritional assessment.

GeneWatch UK considers the lack of any proper nutritional assessment to be the most serious omission from the scientific assessment. Combined with the lack of adequate labelling (see below) it means that in practice, consumers will have no idea about the nutrient content of the foods they are consuming. Potentially serious safety issues could be missed and there is no clear mechanism for recall of products if (as is common in the nutrition literature) new studies identify unexpected adverse effects or confirm adverse effects that are currently uncertain, some of which may impact the health of specific subpopulations.

Serious limitations on compositional information (nutrient profiles) have been noted above. In addition, no data has been provided for the 97.5th percentile intakes, needed to assess risk to more highly exposed consumers. Some such information was provided in the EFSA's statement complimenting its scientific opinion for MON87705, again raising questions about the lack of a level playing field.

Use of the NDA Dietary Reference Values (DRVs) is inadequate for a number of reasons including: (i) the report is out of date and more recent studies must be included in the scientific assessment of soybean 305423; (ii) it does not consider population subgroups who may be particularly affected by changes in the fatty acid profile of their food; (iii) it is not applicable to GMO foods which require a safety assessment under Regulation (EC) No. 1829/2003. This requires a scientific evaluation of the highest possible standard (conducted by EFSA) followed by a risk management decision by the Community.

The introduction of GM soybean oil with altered nutritional properties onto the EU market is a decision which is the responsibility of EU institutions, not merely a recommendation (as DRVs are) to individuals about what foods to consume. GM foods placed on the market in the EU must not have adverse effects on human health or be nutritionally disadvantageous for the consumer (EC 1829/2003 Article 4(1)) and no authorisation can be granted unless the applicant has adequately and sufficiently demonstrated this. A full nutritional assessment is therefore required by EFSA. This should not have been omitted.

It is startling that there are no references to any of the extensive literature on nutrition in the scientific assessment. The starting point of any nutritional assessment must be a comprehensive literature review. Since nutrition studies rarely provide definitive conclusions, there is a need to weigh up the evidence taking into account the need for a precautionary approach. This is because new studies can support or reverse previously held views and the ability of consumers to avoid products based on new evidence (or retailers to withdraw them or manufacturers to change formulations) is much lower in the case of an oil likely to be used in multiple products than it is for supplements (which people can simply choose not to buy). The applicant should be required to provide a systematic review of studies published in the scientific literature and to submit new studies without delay should they arise during the course of consideration of the application. Without such a review hazard identification and hazard characterisation are likely to be incomplete and risk characterisation cannot be completed.

It is impossible to fill the important gap left by the lack of nutritional assessment in these short comments, but examples of studies that should be considered include: • Studies

suggesting a link between omega-3 fatty acids and prostrate cancer (Brasky TM, Darke AK, Song X, et al. Plasma phospholipid fatty acids and prostate cancer risk in the SELECT trial. J Natl Cancer Inst. 2013;105(15):1132–1141; Brasky TM, Till C, White E, et al. Serum Phospholipid Fatty Acids and Prostate Cancer Risk: Results From the Prostate Cancer Prevention Trial. Am J Epidemiol. 2011;173(12):1429–1439; Chua ME, Sio MCD, Sorongon MC, Morales ML Jr. The relevance of serum levels of long chain omega-3 polyunsaturated fatty acids and prostate cancer risk: A meta-analysis. Can Urol Assoc J. 2013;7(5-6):E333–343). • Studies suggesting a link between oleic acid/MUFAs and breast cancer (Chajès V, Thiébaut ACM, Rotival M, et al. Association between Serum trans-Monounsaturated Fatty Acids and Breast Cancer Risk in the E3N-EPIC Study. Am J Epidemiol. 2008;167(11):1312–1320; Saadatian-Elahi M, Norat T, Goudable J, Riboli E. Biomarkers of dietary fatty acid intake and the risk of breast cancer: A meta-analysis. International Journal of Cancer. 2004;111(4):584–591). • Studies suggesting a link between MUFAs and poor memory function (Gibson EL, Barr S, Jeanes YM. Habitual fat intake predicts memory function in younger women. Front Hum Neurosci. 2013;7:838). • Studies suggesting beneficial effects from high intake of linolenic acid (which is reduced in soybean 305423) (e.g. Djoussé L, Hunt SC, Arnett DK, Province MA, Eckfeldt JH, Ellison RC. Dietary linolenic acid is inversely associated with plasma triacylglycerol: the National Heart, Lung, and Blood Institute Family Heart Study. Am J Clin Nutr. 2003;78(6):1098–1102).

The nutritional assessment must also consider the outcomes of animal feeding studies but this is impossible without further information from the applicant because: (i) (as noted above) the rat feeding study supplied did not include soybean oil from soybean305423 treated with the intended herbicide (and this is important because it is likely to change nutrient levels); (ii) foods utilising the GMO (as opposed to the GMO itself) were not included in any animal feeding study so no data of relevance to human consumption of these foods was obtained; (iii) appropriate endpoints were not considered. Further feeding studies are therefore necessary to consider the nutritional impacts of all the food products intended for human consumption that are included within the scope of the application.

Although animal feeding studies are required as a first step, credible evidence of relative benefits and harms associated with the substantially altered fatty acid profile and other nutrient changes in soybean 305423 in terms of endpoints such as cardiovascular or cancer risk may only be obtained by conducting large-scale long-term clinical trials in humans. Relevant studies of this type should therefore also be provided.

These studies should be considered in the context of the latest evidence which suggests no consensus on the benefits of MUFAs for cardiovascular disease (Schwingshackl L, Hoffmann G. Monounsaturated Fatty Acids and Risk of Cardiovascular Disease: Synopsis of the Evidence Available from Systematic Reviews and Meta-Analyses. Nutrients. 2012;4(12):1989–2007) and a Cochrane Review which identifies possible benefits of dietary fat modification in terms of cardiovascular events but no overall confirmed effect on mortality (Hooper L, Summerbell CD, Thompson R, et al. Reduced or modified dietary fat for preventing cardiovascular disease. In: The Cochrane Collaboration, Hooper L, eds. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2011. Available at: http://doi.wiley.com/10.1002/14651858.CD002137.pub2. Accessed January 15, 2014). Further, it should be borne in mind that any benefits that might exist could be achieved my

means other than introducing soybean oil with a substantially altered and untested fatty acid profile into the food chain.

There are many gaps in the literature, leading to a lack of understanding, for example, of the implications of altering fatty acid profiles in foods for babies and young children. Although data has been supplied on estimated daily intakes for toddlers, children, teenagers, adults and the elderly, it is unclear how this relates to the (missing) compositional analysis of different foodstuffs such as margerines and snacks and no data on bioavailability or the nutritional status of different subgroups likely to consume the food has been provided. This data should be requested from the applicant.

EFSA Guidance and Codex Guidelines require population subgroups to be considered in the nutritional assessment. As well as categories by age, this should include other subgroups whose nutrient requirements may be different from the general population. Again, this work has been totally omitted. It is impossible to completely fill this gap in these short comments, however there are a number of monogenic disorders, for example in the category of Fatty Acid Metabolism Disorders (MCAD, LCAD and SCAD deficiencies) in which medium-chain triglycerides (MCTs) can't be broken down and linoleic acid deficiency may occur (Acosta PB: http://www.fodsupport.org/pdf/Nutrition_and_Fatty_Oxidation_Defects.pdf) and others, such as Waldmann's disease, which require MCT supplementation (Vignes S, Bellanger J. Primary intestinal lymphangiectasia (Waldmann's disease). Orphanet Journal of Rare Diseases. 2008;3(1):5. doi:10.1186/1750-1172-3-5). Patients with Refsum's Disease are advised to eat soya products based on the level of phytanic acid they contain (http://www.refsumdisease.org/patients/dietwhichfoods.shtml) and patients with propionic academia are also unable to process certain lipids (http://ghr.nlm.nih.gov/condition/propionic-acidemia). The implications of altering fatty acid profiles in soybean oil should have been considered for such groups.

Finally, as noted above, the potential for soybean 305423 to be fed to animals as a supplement (i.e. as oil or seeds, not solely as defatted meal) and alter the nutrient profiles of meat, milk or eggs has yet to be considered. Additional data is required from the applicant to consider this scenario.

In GeneWatch's view the existing literature suggests that it is extremely questionable whether soybean 305423 should be allowed on the market, particularly when the options for recall or consumer avoidance may be difficult (see comments on labelling below).

Others

Since the application covers the authorisation of the GMO and its use in assorted foods, consumption of all of these foods must be monitored as part of the post-market monitoring. Effects on health should also be monitored but it is impossible to specify monitoring requirements in the absence of a nutritional assessment (as noted above).

---

4. Conclusions and recommendations

The risk assessment is incomplete and inadequate to support approval of the product.

---

6. Labelling proposal

The labelling proposal "genetically modified soybean with altered fatty acid profile" is inadequate. Numerous GM soybeans with altered fatty acid profiles are in the GM industry pipeline with a wide variety of properties (http://www.soyconnection.com/sites/default/files/Biotech_PipelineCharts.pdf and Wilson RF. The role of genomics and biotechnology in achieving global food security for high-oleic vegetable oil. J Oleo Sci. 2012;61(7):357–367). These products all have different fatty acid profiles and molecular characterisations (see for example the EFSA Scientific Opinion on MON88705). It is essential that consumers and medical professionals are provided with more information on the label (i.e. a list of all fatty acids and other nutrients that are significantly increased or decreased) and the means to find more detailed information should this become necessary (i.e. the Unique Identifier DP-305423-1). This is essential because: 1. New information may become available in future about unexpected harms associated with the particular method of genetic modification or molecular characterisation (e.g. stability of a particular construct or off-target effects) which is only traceable via the Unique Identifier. 2. New information may become available regarding specific harms associated with specific types of fatty acid (e.g. confirming the reported association between omega-3 fatty acids and prostate cancer) which may lead to (some or all) consumers wishing to avoid some altered oil products but not others and/or retailers/manufacturers to withdraw some products. This can only be done if the fatty acid profile of each product is known and its source is traceable. 3. Small subgroups of consumers (e.g. suffering from a particular metabolic disorder) may find health problems are caused by some fatty acid profiles but not others. They may therefore wish (or need) to avoid specific fatty acids or groups of fatty acids. Any of these situations may necessitate withdrawal of products and/or consumer information to be issued regarding specific products (allowing specific subgroups of persons to avoid them). This can only be done if the fatty acid profile and its source is known to the consumer (and in some cases can be discussed with a medical professional) via information on its label.

Regulation (EC) 1829/2003 Preamble (22) states: "In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns".

The proposed labelling does not conform to these requirements. A new proposal is therefore needed.

Although not currently provided for in the legislation, labelling of meat, milk and dairy products from animals fed on soybean 305423 as feed is also necessary, because the use the

potential use of whole soybeans or soybean oil as dietary supplements can significantly alter the fatty acid profile of these products.

Organisation: Agricultural University of Plovdiv
Country: Bulgaria
Type: Scientific Institution

---

a. Assessment:
Molecular characterisation

The introduction of a fragment of the endogenous FAD2-1 gene, which suppresses production of the soybean's own omega-6-desaturase, has no effect on other traits or properties of the plant, except for the intended ones.

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

An accumulation of oleic acid in the oil is combined with significant decrease in palmitic acid (a saturated one) and several-fold decrease in the polyunsaturated acids (linoleic and linoleniuc acids). While improving the composition of soybean oil this could have no conceivable effect on agronomic traits.

---

b. Food Safety Assessment:
Toxicology

Plenish High Oleic soybeans has as only known change the reduction of saturated and polyunsaturated fatty acids in the oil. Thus any increase in toxicity as compared to conventional counterpart should not be expected from the use of this product. Furthermore, in an attempt to comply with the unscientific requirement of the EU legislation the product was developed without the use of antibiotic marker resistance gene(s), although no harmful effects from the use of such genes has ever been demonstrated.

Allergenicity

I am not aware of any possibility that the induced change can result in production of more allergenic products than the ones, contained in the conventional counterpart.

Nutritional assessment

Changes in oil composition are intended to improve the nutritional quality of the soybean oil. Therefore numerous benefits from the use of the product are expected for the consumer. For example, trans fats in the processed oil, which can impact on cholesterol levels and increase the risk of heart disease, will be eliminated while the amount of some saturated fats will be greatly reduced.

---

3. Environmental risk assessment

No conceivable increase in the risk levels as compared to the use of the conventional counterpart for the plants, animals and microorganisms in the environment from the use of soybeans with increased oleic acid levels in the oil can be identified.

---

4. Conclusions and recommendations

Plenish high oleic acid soy should be approved for use without further delays.

Organisation: FGC CONSULT
Country: Poland
Type: Others...

---

a. Assessment:
Nutritional assessment

Nutritional advantages of this soy event are wonderful since the oil crushed out ot them has fatty acid profile so beneficial to human and animal body - the quality is so similar to olive

oil, which is obviously available on the market but is a few times more expensive and thus available to small percentage of consumers around the world, and cost-prohibitive to animals.

---

3. Environmental risk assessment

A wide selection of research data collected by the seed developer and made available to EFSA and the public shows almost zero environmental risk that is actually same as conventional soybean varieties! Especially in most parts of Europe the variety has little a chance to pose any risk to agricultural and/or wild nvironment.

---

4. Conclusions and recommendations

European livestock and feed and food industry has long awaited registration of this soy event as clearly offering numerous benefits to people and animals by providing a more healthy market products that could be used by feed and food processors and nutritionists. I strongly support registration of this event as Pioneer / DuPont requested it.

---

6. Labelling proposal

Labeling as "beneficial to human and animal cardio-vascuar health" is recommended. Labeling as "contains GMO" or so would be missleading to the users and consumers bringing negative images rather than providing any valuable knowledge.

Organisation: Irish Grain & Feed Assocation
Country: Ireland
Type: Association

---

a. Assessment:
5. Others

The Irish Grain and Feed Association (IGFA) is the representative body of the grain and feed industry in Ireland and is recognised by Government as the official voice of the feed industry. As a highly regulated industry, we are dependent on predictable, timely and reliable

functioning of regulatory procedures. We believe that EU approvals for GM products which have been positively assessed for safety by the European Food Safety Authority should not be delayed, since experience has shown that such delays can lead to severe shortages of animal feed due to the potential for traces of the GM product in imported commodities. In light of the overall positive EFSA assessment of GM soybean 305423, IGFA urges a rapid EU approval of this product.

Organisation: InnoPlanta e.V.
Country: Germany
Type: Non Profit Organisation

---

a. Assessment:
Molecular characterisation

-

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

-

---

b. Food Safety Assessment:
Toxicology

-

Allergenicity

-

Nutritional assessment

Bei der hochölsäurehaltigen Sojabohne 305423 handelt es sich um ein

ernährungsphysiologisch sehr hochwertiges Produkt, welches einen hohen Verbrauchernutzen hinsichtlich Ernährung und Gesundheit ausweist.

Others

Die GM Sojabohne 305423 wurde hinsichtlich Ernährungssicherheit, Allergenität und Toxikologie umfassend geprüft ist.

3. Environmental risk assessment

Es sind bei diesem Produkt keine anderen Wirkungen auf die Umwelt zu erwarten, als bei herkömmlichen (konventionellen) Sojabohnen.

4. Conclusions and recommendations

Bei der GM Sojabohne 305423 handelt es sich um die erste gentechnisch verbesserte Sojabohne mit einem direkten Verbrauchernutzen. Eine Zulassung ist nach 12 Jahren Verfahrensdauer und umfassender Prüfung überfällig. Die Zulassung wird von uns nachdrücklich unterstützt und gefordert!

Es ist nicht länger vermittelbar, dass innovative Produkte mit einem hohen Verbrauchernutzen nur deshalb nicht zugelassen werden, weil sie mittels Gentechnik hergestellt werden. Das Produkt mit seinen Eigenschaften muss im Genehmigungs-Focus stehen, nicht die Technologie mit der es hergestellt wurde. Hier ist dringlich ein Systemwechsel erforderlich.

5. Others

-

6. Labelling proposal

-

Organisation: Českomoravské sdružení organizací ZZN
Country: Czech Republic
Type: Association

---

a. Assessment:
Others

Abychom se vyhnuly s problémy s příměsi GM surovin v konvenčních komoditách při jejich dovozu do EU, navrhujeme co nejrychleji schválit sóju 305423 pro dovoz do EU.

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

---

a. Assessment:
Molecular characterisation

Soybean 305423 was produced by particle bombardment. This method is known to have a major impact on plant DNA (see for example Makarevitch et al., 2003). Molecular characterisation revealed multiple rearrangements and several complete and truncated copies of gene constructs were detected. These truncated DNAs and rearrangements can interfere with gene regulation in the plants and may cause unintended effects. Metabolic and genomic screening would be required to investigate such effects whereby environmental stress factors would also need to be taken into account. There have so far been no such investigations. Molecular characterisation has, however, revealed that one of the investigated plants showed signs of genetic instability.

The genetic modification to change the fatty acid composition in the soybeans is based on an inhibition of the expression of endogenous plants genes by RNAi interference (RNAi), resulting in reduced levels of the corresponding plant enzymes. The underlying molecular process is complex and encompasses the degradation of endogenous mRNAs. In this process, small interference RNA molecules might be produced, such as secondary (double stranded) dsRNAs, which can be biologically relevant to human health and the environment. (Short inhibitory) siRNA molecules may cause intended gene silencing and have off-target effects, i.e. may silence genes other than those intended (Senthil-Kumar et al., 2011). These effects can be passed from the plant to humans or animals at the consumption stage. Potential biological effects will depend on similarities between the cell regulation in mammals and plants. Zhang et al. (2011) show such biological effects based on these similarities. Thus, for the risk assessment of plants that produce new dsRNA it is necessary to

conduct bioinformatics studies to identify any likely unintended targets of the intended siRNAs in humans or animals.

For example, Heinemann et al. (2013) recommend the following process for a proper assessment of genetically engineered plants involving RNA interference: „(1) bioinformatics to identify any likely, unintended targets of the dsRNA in humans and other key organisms; (2) experimental procedures that would identify all new intended and unintended dsRNA molecules in the GM product; (3) testing animal and human cells in tissue culture for a response to intended and unintended dsRNAs from the product; (4) long-term testing on animals; and possibly (5) clinical trials on human volunteers."

But no such studies were conducted.

References: Heinemann, J. A., Agapito-Tenfen, S. Z., & Carman, J. A. (2013). A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environment international, 55, 43-55. http://www.sciencedirect.com/science/article/pii/S0160412013000494

Makarevitch, I., Svitashev, S.K., Somers, D.A. (2003) Complete sequence analysis of transgene loci from plants transformed via microprojectile bombardment. Plant Molecular Biology, 52(2): 421-432.

Senthil-Kumar, M., & Mysore, K.S. (2011) Caveat of RNAi in plants: the off-target effect. In RNAi and Plant Gene Function Analysis, Methods inMolecular Biology. 744: 13-25. Humana Press.

Zhang, L., Hou, D., Chen, X., Li, D., Zhu, L., Zhang, Y., Li, J., Bian, Z., Liang, X., Cai, X., Yin, Y., Wang, C., Zhang, T., Zhu, D., Zhang, D., Xu, J., Chen, Qu., Ba, Y., Liu, J., Wang, Q., Chen, J., Wang, J., Wang, M., Zhang, Q., Zhang, J., Zen, K., Zhang, C.Y. (2011) Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. Cell Research, 22(1): 107-126.

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

The results of just one field trial (conducted in the US in 2011) were the basis for the comparative assessment. Given the complex nature of the genetic modification in soybean 305423, this is inadequate. Field trials should have been conducted in different climatic regions to investigate any possible genome x environment interactions. Further, there should have been systematic testing of the various groups of herbicides applied to the plants.

As experts from European Member States stated, field trials with soybean 305423 which were part of the original Pioneer dossier and which were not assessed by EFSA due to severe flaws in study design (a null segregant was used as control instead of the isogenic variety), had shown great differences in composition of soybean 305423 in different climatic regions.

The US field trial also showed significant differences in several compounds between soybean 305423, its isogenic counterpart and several other soybean varieties. There was no

equivalence in 16 of 51 parameters in soybean 305423 not sprayed with ALS-inhibiting herbicides. Further, there was no equivalence in 16 of the 53 parameters in seeds from plants treated with ALS inhibitors.

Several significant differences can be attributed to the intended modifications in the fatty acid profile. However, apart from that, there were also changes in the levels of odd chain fatty acids. According to EFSA and Pioneer, the ALS enzyme may cause this unintended effect.

There were also significant differences (non-equivalence) in parameters such as calcium, zinc and glycitin and related total glycitein equivalents as well as in the trypsin inhibitor. According to EFSA, the variation for glycitin in soybean even exceeded „the lower and upper limits established by the non-GM reference varieties growing in the same field trial". Further, there are some significant differences in the trypsin inhibitor, which might be caused by gene silencing. In addition, there were some significant differences in agronomic parameters. Industry scientists in a recent study also confirmed some significant differences in yield. According to Spear et al. (2013), there was a significant yield drag in soybean 305423 when the construct was crossed in different genetic backgrounds: „The results indicated that the negative impact of the transgene on seed yield was consistent across multiple genetic backgrounds, ..."

However, EFSA saw no reason to ask for more data that might shed light onto the underlying mechanisms of the agronomic performance of soybean 305423.

Overall, soybean 305423 cannot be regarded as substantially equivalent. EFSA should have requested much more information on unintended genetic effects and possible metabolic changes. For example, a transcriptome and proteome analysis should have been performed to investigate unintended effects.

References: Spear, J. D., Fehr, W. R., & Schnebly, S. R. (2013). Agronomic and seed traits of soybean lines containing the high-oleate transgene DP-305423-1. Crop Science, 53(3), 906-912. https://dl.sciencesocieties.org/publications/cs/abstracts/53/3/906

---

b. Food Safety Assessment:
Toxicology

The applicant performed several nutritional studies with pigs, laying hens and broilers as well as a sub-chronic 90-day study with rats. Most of these studies are flawed and should have been excluded from the assessment: In the sub-chronic study with rats (Delaney et al., 2008) a negative segregant from soybean 305423 was used as control instead of the conventional counterpart; soybean 305423 in the feed was not treated with ALS-inhibitors; In the chicken study (McNaughton et al., 2008) the feeds were contaminated with another GM glyphosate-resistant soybean (a fact not mentioned by EFSA); soybean 305423 was not treated with ALS-inhibitors.

In general, nutritional studies on farm animals are of little value for the risk assessment. They are not sufficient to investigate the more subtle effects on human health that might be

caused by the intended or unintended changes in the composition of the soybeans. In conclusion, there is practically no reliable data on possible toxicity and the effects on health from soybean 3054233.

Further, there is no information on residues from ALS-inhibiting pesticides or the metabolism of the various complementary pesticides and mixtures that can be applied to soybean 305423. According to Kleter et al. (2011), no herbicide metabolites could be detected in ALS-inhibitor-resistant soybeans. Kleter (2011) also states that there is only very limited knowledge on this subject (i.e. no studies on residues as established by the JMPR).

References: Delaney, B., Appenzeller, L.M., Munley, S.M., Hoban, D., Sykes, G.P., Malley, L.A., & Sanders, C. (2008) Subchronic feeding study of high oleic acid soybeans (event DP-3Ø5423-1) in Sprague–Dawley rats. Food and Chemical Toxicology, 46(12): 3808-3817. http://www.sciencedirect.com/science/article/pii/S027869150800567X

Kleter, G.A., Unsworth, J.B., Harris, C.A. (2011) The impact of altered herbicide residues in transgenic herbicide-resistant crops on standard setting for herbicide residues. 67(10): 1193-1210.

McNaughton, J., Roberts, M., Smith, B., Rice, D., Hinds, M., Sanders, C., ... & Delaney, B. (2008) Comparison of broiler performance when fed diets containing event DP-3Ø5423-1, nontransgenic near-isoline control, or commercial reference soybean meal, hulls, and oil. Poultry science, 87(12): 2549-2561. http://ps.fass.org/content/87/12/2549.short

---

Allergenicity

EFSA (2010) speaks about the need for detailed investigations into allergenic risks for infants and individuals with impaired digestive functions. “The specific risk of potential allergenicity of GM products in infants as well as individuals with impaired digestive functions (e.g. elderly people, or individuals on antacid medications) should be considered, taking into account the different digestive physiology and sensitivity towards allergens in this subpopulation.” However, these specific risks were left aside during EFSA risk assessment.

Further, the soybeans were tested with sera from small groups of individuals known to react to allergens from soybeans. Several differences were observed but not deemed relevant. Instead, EFSA should have requested more detailed investigations. As the minutes of a meeting of the working group (WG) “Self Task on Allergenicity” of 24 September 2007 shows, EFSA has serious doubts about the reliability of the investigations with such a small number of patients conducted in this case. “More sera from patients are needed but they also need to be well characterised. Statistical calculations have been done showing that 60-70 well characterised sera are needed based on variability. Since this might not be feasible, the WG has to consider the reliability of studies with a lower number of sera.” Therefore,, the assessment conducted by EFSA is inadequate.

References:

EFSA (2010) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed. EFSA Journal 2010; 8(7):1700. [168 pp.] doi:10.2903/j.efsa.2010.1700. Available online: www.efsa.europa.eu

EFSA (2007), Minutes of the meeting of the EFSA working group (WG) “Self Task on Allergenicity” of 24 September 2007

Nutritional assessment

There are no data on the equivalence and quality of the products that are processed such as soybean sprouts, milk and baby food, or for products undergoing fermentation and heat treatment. Without such data, no conclusion can be drawn upon equivalence and food safety.

It is astonishing that there are no data on the effects of processing on compounds of soybean 305423. This is an obvious gap in risk assessment, which was also noted by the EU Commission in a different case (soybean MON87705). In the case of soybean MON87705, the Commission at least requested EFSA to conduct a separate assessment of the oil in this soybean event used for commercial frying (http://www.efsa.europa.eu/en/efsajournal/pub/3507.htm). It is hard to understand why EFSA once more omitted the assessment of the possible effects of processing.

Others

The assessment suffers from the fact that there is no independent data on soybean 305423. Even the studies that were published in peer-reviewed journals (such as the feeding studies) have Pioneer scientists among their authors. Therefore, industry influence on data cannot be excluded. Furthermore, much more data would be needed to assess true impact of these soybeans on human health. Conclusions cannot be made without detailed studies with human volunteers from various subgroups of consumers and all relevant processed food ingredients. This means that many more investigations are needed before these products could be marketed.

As a recent legal dossier compiled by Professor Ludwig Kraemer shows, the decision not to monitor effects on health at the stage when genetically engineered food is consumed, violates the requirements of EU regulations. Directive 2001/18 and Regulation 1829/2003 both require that potential adverse effects on human health from genetically modified plants are monitored during the use and consumption stage, including in those cases where such effects are unlikely to occur. Monitoring also has to include residues from spraying with the complementary herbicide. Thus, the EFSA opinion that monitoring of effects on health is unnecessary is wrong and contradicts current EU regulations.

References

Kraemer, L. (2012) The consumption of genetically modified plants and the potential presence of herbicide residues, legal dossier compiled on behalf of Testbiotech, http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

---

4. Conclusions and recommendations

On the basis of current risk assessment, no conclusion can be reached upon safety. In EU, soybean 305423 can not be allowed to be used in food & feed.

Organisation: BIOLOGICAL RESEARCH CENTRE OF THE HUNGARIAN ACADEMY OF SCIENCES
Country: Hungary
Type: Scientific Institution

---

a. Assessment:
Molecular characterisation

The plenish high oleic soybean is characterized in deep details, especially the fatty acid composition. It meets the scientific standard.

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

The comparison of novel traits of plenish GM soybean to traditional cultivars reveals benefits especially for the consumer. The higher levels of heart-healthy mono-unsaturated fatty acids can have a similar effect as olive oil.

---

b. Food Safety Assessment:
Toxicology

Accepting the results of the EFSA evaluation, we cannot see any problem with toxicology.

Allergenicity

Accepting the results of the EFSA evaluation we cannot see any problem with allergenicity.

Nutritional assessment

Based on the tests carried out by food companies we can accept the positive results indicating stability, improved flavour and nutrition qualities.

---

3. Environmental risk assessment

There is no reason to expect any environmental influence of these type of GM plants.

---

4. Conclusions and recommendations

Considering the significant improvement of this new GM cultivar it would be logical to introduce the cultivation of these variants also in Europe.

---

6. Labelling proposal

From the labelling point of view the focus should be on the high oleic content and not on the breeding technique using gene technology.

Organisation: Consultant
Country: Romania
Type: Consultant

---

a. Assessment:
Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

If the product allow to obtain oil similar as quality to olive oil I think this is a future valuable resource for food industry! a good alternative for health nutrition

---

b. Food Safety Assessment:
Toxicology

If ESFA study proves is safe I cannot see any inconvenient to utilise this.

Allergenicity

If ESFA study proves is safe I cannot see any inconvenient to utilise this.

Nutritional assessment

The high quality oil will ensure a huge market

---

3. Environmental risk assessment

If will be cultivated according to EU rules on safety I think will not be an environmental danger!

---

4. Conclusions and recommendations

Tacking into account the benefits which can be provides for a lot of disesses (cardio-vascular diseases especially) and the positive results of EFSA studies regarding this product, I think would be good to speed up the approval for cultivation. A lot of farms will benefit on this since innovation, and of cause a lot of consumers

---

5. Others

An knowledge campaign will be necessary

---

6. Labelling proposal

The label should be very clear , the consumers should take the decision to buy or not!

Organisation: Biological Research Center, Hungarian Academy of Sciences, Institute of Plant Biology
Country: Hungary
Type: Scientific Institution

---

a. Assessment:
Molecular characterisation

Detailed enough, no further characterization is needed.

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

The analysis is clear, the advantages of Plenish soybean are well documented.

---

b. Food Safety Assessment:
Toxicology

I do not see any scientifically sound reason for further assessment.

Allergenicity

The altered oil composition does not raise any reasonable suspect of increased allergenicity.

Nutritional assessment

The high oleic content provides clear advantages as food component and as cooking material.

4. Conclusions and recommendations

I strongly support to give permission for the placing on the market of food, feed and other products containing or consisting of genetically modified 305423 soybean.

6. Labelling proposal

A general labeling that this soybean (and the food/feed derived from it) is genetically modified, does not allow consumers to make objective and rational decision. Informative labeling which allows the consumer to understand the exact features of the current modifications in Plenish soybean would allow consumers to make their free choice whether they prefer the advantages derived from the clear, scientifically well documented new properties of this particular GMO; or they are willing to avoid this product because of the general, emotional fear against GMOs.

Organisation: ASSALZOO
Country: Italy
Type: Association

a. Assessment:
Molecular characterisation

//

b. Food Safety Assessment:
Toxicology

//

Allergenicity

//

5. Others

Assalzoo is of the opinion that approvals of GM events for import should be based on scientific evidences. Therefore a GM events, which has received a favorable opinion by EFSA, should be approved without any delay due to political interferences. the Italian Feed industries are concerned about "asynchronous approvals", that could lead to significant trade disruption. Expecially on soybean import Italy, and Euroope as well, cannot afford to have any kind of import interruption.