MON87708

Organisation: Nature & Progrés
Country: France
Type: Association

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a. Assessment:
4. Conclusions and recommendations

The precautionary principle must be applied: no GMOs should be authorised because of uncertainties concerning their propagation and their impact on health.

Organisation: None
Country: Germany
Type: Individual

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a. Assessment:
Others

I object to yet another GMO to be approved, as long as there is conflicting research on the safety of those modified plants. Much more data on spillage, persistence and invasiveness are needed before any decision can be taken on risks for the environment. The decision not to monitor Effects on health at the stage of consumption of genetically engineered food, violates the requirements of EU regulations. Directive 2001/18 and Regulation 1829/2003 both require that potential adverse effects on human health of genetically modified plants are controlled during the use and consumption stage, including those cases where such effects are unlikely to occur. Thus, the EFSA opinion that monitoring of health effects is unnecessary, is wrong and contradicts current EU regulations.

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4. Conclusions and recommendations

there are other soybean varieties available, derived from conventional breeding that are

climatized. There is no identifiable reason why this specific soybean should be imported or cultivated.

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

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a. Assessment:
Molecular characterisation

No data on the impacts of the genetic modification on gene expression and plant metabolic pathways appears to have been provided. The potential production of novel dsRNA should have been investigated.

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

Several of the endpoints measured were significantly different. It is unclear why these differences were assumed to have no relevance to food safety. Gene-environment interactions can affect food safety but the crops studied were grown only in the US, not in other export markets i.e. South America, so the analysis is incomplete.

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b. Food Safety Assessment:
Toxicology

A number of changes were identified in the 90-day feeding study, which merit further investigation.

Allergenicity

The number of blood samples tested was very low and does not include any samples from potentially vulnerable persons with compromised immune systems. The digestion test is inadequate to predict outcomes in real human and animal digestive systems.

Others

The product is tolerant to the herbicide dicamba (3,6-dichloro-methoxy-benzoic acid). A major area of public interest will be the presence of residues of dicamba and its metabolites on the crop entering the food chain, due to blanket spraying of the plants. Impacts on human and animal health due to these changes in management must be considered in the risk assessment according to Directive 2001/18/EC. Dicamba-tolerance is achieved by the expression of dicamba mono-oxygenase (DMO) proteins, which demethylates dicamba, producing 3,6-dichlorosalicylic acid and formaldehyde. However, information about the impacts of formaldehyde have been omitted, although it is a known carcinogen, implicated in some food safety alerts (e.g. http://www.foodsafetynews.com/2013/09/formaldehyde-detected-in-supermarket-fish-imported-from-asia/#.Unu3I-K7R0M). For 3,6-dichlorosalicylic acid and dicamba residues, EFSA refers to the expertise of the EFSA Pesticides Unit in setting acceptable daily intakes (ADIs)and Maximum Residue Levels (MRLs). The Pesticides Unit has published a "Reasoned opinion on the modification of the MRL for dicamba in genetically modified soybean" (EFSA Journal 2013;11(10):3440) which states that "since the relevant component of the residues in dicamba-tolerant soybean was identified as the metabolite 3,6-dichlorosalicylic acid (DCSA) while dicamba was not detected at harvest, EFSA proposed to set a specific import tolerance of 0.4 mg/kg for the metabolite DCSA in soybean, and not to change the current MRL of 0.05* mg/kg set for dicamba". However, there are numerous gaps in information and thus little data to support the ADIs or how the relationship between the ADIs and MRLs has been set, especially as the metabolism pattern of the active substance in genetically modified plants was shown to be different and the available data did not allow EFSA to conclude whether dicamba and DCSA act through the same toxicological mode of action. Another metabolite, DCGA, was identified but there was insufficient toxicological data to set a specific ADI. A total of 22 supervised residue trials conducted in the USA were supplied by the applicants, which claimed to detect no residues of dicamba and only metabolites DCSA (up to 0.410 mg/kg) and DCGA (up to 0.132 mg/kg) were detected. The residue trials were performed on soybean varieties that contain the dmo expression cassette conferring tolerance against dicamba, stacked with a cp4 epsps cassette conferring tolerance against glyphosate, i.e. NOT on the actual product. This is a major limitation since management of this product in the field is likely to differ significantly from the product in the application, which is not tolerant to glyposate and therefore more likely to be blanket sprayed with dicamba. The testing product confers dicamba tolerance only as a secondary trait, to deal with the existence of glyposate tolerant weeds: its management is therefore likely to use less dicamba than the product in the application. It is difficult to understand why no data whatsoever was submitted or required for the product currently under consideration: this is essential before approval of the product. In addition, no data was provided for crops grown in South America (where gene-environment interactions will differ) and no information has been provided on how compliance with MRLs can be maintained over time as weeds will inevitably develop resistance to dicamba. In addition, no data has been provided regarding the potential use of other herbicides (especially as resistance develops) or the effects of consuming mixtures of the product with other products (such as RoundUp Ready soybeans). The EFSA Pesticides Unit reports only one metabolism study conducted on dicamba-tolerant soybean containing the dmo expression cassette: this means there is inadequate information regarding interactions between the residues from spraying and plant

biochemistry and metabolism. No information was provided in the framework of this application on the effect of processing on the nature of dicamba residues.

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4. Conclusions and recommendations

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

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5. Others

If the product were to be approved, extensive monitoring of herbicide residues (including metabolites) would be needed. However, it is unclear how this would be done in practice.

Organisation: Food & Water Europe
Country: United Kingdom
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

In July 2013 our parent organisation Food & Water Watch submitted a detailed critique of dicamba crops to USDA Aphis. As those comments are directly applicable to this consultation we are submitting them here (see section "5. Others" below).

As this form does not permit proper referencing I have copied the references below the text. However this is unsatisfactory as the locations of the references in the text cannot be seen. I would be happy to provide a properly formatted version of this submission on request to the email above.

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

See section "5. Others"

b. Food Safety Assessment:
Toxicology

See section "5. Others"

Allergenicity

See section "5. Others"

Nutritional assessment

See section "5. Others"

Others

See section "5. Others"

3. Environmental risk assessment

See section "5. Others"

4. Conclusions and recommendations

See section "5. Others"

This product cannot be authorised and we strongly urge you to reject this application. It is unacceptable for the EU to continue to promote its green credentials while it is effectively exporting the damage caused by GM agriculture to other communities.

5. Others

text of Food & Water Watch submission to Aphis *** July 17, 2013

Docket Clerk Regulatory Analysis and Development PPD, APHIS, Station 3A–03.8 4700 River Road Unit 118 Riverdale, MD 20737–1238

Re: Docket No. APHIS-2013-0043

On behalf of the nonprofit consumer advocacy organization Food & Water Watch, I respectfully submit comments to the United States Department of Agriculture's Animal and Plant Health Inspection Service for its preparation of an Environmental Impact Statement for Monsanto's dicamba-tolerant soybeans and cotton.

Food & Water Watch urges the USDA to consider the following risks in its upcoming Environmental Impact Statement for dicamba-tolerant soybeans and cotton:

• Dicamba-resistant cotton and soybeans will lead to an increase in dicamba use, which will spur the evolution of dicamba resistant weeds and the abandonment of conservation tillage practices;

• Higher volumes of dicamba will lead to pollution of surface water, which will impact non-target plants and animals, including endangered species;

• The volatility of dicamba will result in more occurrences of pesticide drift into neighboring fields, affecting plant health and the livelihoods of nearby farmers;

• Dicamba-tolerant crops will cost farmers more through higher seed prices, the loss of export markets due to contamination of non-genetically engineered (GE) or organic seed and through the presence of dicamba-resistant weeds; and

• Dicamba is dangerous to human health and its continued use will endanger agricultural workers and the general public.

Dicamba-Tolerant Crops Will Increase Use of Dicamba Dicamba was the 16th most sprayed herbicide in 1997 and use had declined so much by 2007 that the herbicide was no longer among the top 25 used herbicides. Dicamba use has slowed steadily since 1994, but this decline would rapidly reverse if the USDA approves dicamba-tolerant soybeans and cotton. The approval of dicamba-tolerant crops that are engineered to work with this drift-prone herbicide could seriously threaten nearby specialty crop growers and any plants and animals that are exposed to higher concentrations of these dangerous chemicals. Steve Smith, Agriculture Director for Red Gold — the largest privately held U.S. canned tomato processing company — stresses that "the widespread use of dicamba herbicide possesses the single most serious threat to the future of the specialty crop [fruit and vegetable] industry in the Midwest."

For every 1 million acres of dicamba-tolerant soybeans planted, there could be an additional 2 million pounds of dicamba applied to crops. Even if just a million dicamba-tolerant soybean acres are planted, it would be 17 times the current dicamba volume used on soybeans. USDA must evaluate the impact that increased dicamba use on soybeans and cotton would have on

total herbicide use and the risks that are posed by the more frequent spraying on a greater area of farmland in the United States.

Dicamba-resistant weeds will threaten farms Monsanto's petition for its Dicamba-tolerant soybean affirms that, "since its introduction in 1967, only four species with known dicamba-resistant biotypes have been identified in North America." But amplified use and the use of dicamba later in the growing season is sure to spur the resistance of more weeds to this herbicide, just as we have seen with Roundup. When Roundup Ready corn and soybeans were approved in 1996, there were no cases of glyphosate-resistant weeds, but today there are now 14 weed species resistant to glyphosate in the United States (24 species worldwide), including aggressive weeds like ragweed, horseweed, kochia, Palmer amaranth and waterhemp.

Not only will there be weeds resistant to dicamba alone, but weeds will develop resistance to all of the stacked herbicides used on these cotton and soybean varieties. As mixtures of herbicides are used on crops, some weeds are developing multiple resistance — meaning that they can survive being sprayed with two or more herbicides. Nearly two-thirds of weeds with glyphosate resistance will develop resistance to other herbicides. Prior to the introduction of Roundup Ready crops (1991–1995), the International Survey of Herbicide Resistant Weeds found only about one weed infestation per year (1.2 reports) that was resistant to multiple herbicides. A decade after the GE crops were introduced (2007–2011), the survey found almost three times as many multiple herbicide-resistant weed infestations (3.25 reports annually).

Some of the first states to begin to see multiple resistances were Michigan, Ohio and Illinois — all among the first adopters of GE corn and soybeans. Academic experts expect multiple resistances in weeds to occur more frequently as the USDA approves crops engineered to tolerate different herbicides. Thus, the USDA should carefully look at how dicamba-tolerant soy and cotton will impact the rise in weeds resistant to multiple herbicides. Dicamba Drift Will Pose Risks to a Range of Farmers and Non-target Plants

Dicamba belongs to the synthetic auxins family of herbicides, known for their negative impacts on target and nontarget plant development, causing abnormal growth and death. Since dicamba is especially prone to drift, any specialty crops — like tomatoes, grapes and potatoes — that are grown near fields sprayed with this herbicide could be damaged by the herbicide, causing yield losses. A 2004 study modeled that dicamba had 75 times the risk of impacting non-target plants than glyphosate. In 2010, an Indiana farmer testified at a Congressional hearing that dicamba drift destroyed over 20 acres of his tomatoes. An Association of American Pesticide Control Officials survey from 2002 to 2004 found that dicamba was the third most commonly involved herbicide in drift occurrences. The USDA must take the drift risk of dicamba very seriously and analyze how increased dicamba use associated with dicamba-tolerant cotton and soybeans will impact neighboring farmers, the environment and the general public.

Socioeconomic Effects Domestic Although it may be true that organic crops make up a small percentage of overall soybean and cotton totals in the United States, any contamination or damage to organic soy and cotton could result in huge economic losses for farmers. Data supplied by the Organic Trade Association illustrates that some grain buyers reject loads with more than 0.9 percent GE presence, resulting in 0.25 percent non-GE soybean and 3.5 percent non-GE corn rejections. A rejection from the loads' intended market means a lost premium for that non-GE product. The estimated loss from market rejections alone is $40 million

annually. USDA must fully evaluate the economic impacts of GE contamination for organic and non-GE growers.

In addition to contamination risks, the presence of dicamba-resistant weeds that will arise soon after the introduction of these crops will cost farmers millions of dollars. An analysis of the costs of herbicide-resistant weeds showed that farmers face significant costs from herbicide-resistant weeds from reduced yields and increased production costs to combat weed infestations. These costs can range from $12 to $50 an acre, or as much as $12,000 for an average-sized corn or soybean farm or $28,000 for an average cotton farm. In 2010, herbicide-resistant weeds cost farmers $17 an acre from reduced yields. In 2012, 92 percent of surveyed cotton farmers reported that their losses due to weed control were at least $50 per acre. In Tennessee, glyphosate-resistant horseweed has increased soybean farmers' production costs by $12 per acre; and Georgia and Arkansas cotton producers have seen additional costs of $19 per acre due to glyphosate-resistant Palmer amaranth.

Since U.S. farmers have found herbicide-resistant weeds in their fields, they have changed farming methods to control them, resulting in higher weed-control costs and even a return to tillage and hand hoeing. In 2009, farmers in Georgia were forced to weed half of the state's 1 million acres of cotton due to the spread of pigweed, costing $11 million. Dicamba-tolerant cotton and soybeans will increase costs for U.S. farmers, whether in the cost of the technology agreement, the loss of export markets through contamination or due to the presence of dicamba-resistant weeds on their fields. The USDA must take an in-depth look at all of these economic risks in their Environmental Impact Statement for Monsanto's dicamba-tolerant cotton and soybeans.

Export market Although the United States has rapidly approved GE crops and products, many countries, including key export markets, have not approved GE foods. More than three quarters of consumers in Japan, Italy, Germany and France are skeptical of the safety of GE foods.

Europe has been restrictive in its approval of biotech foods because of uncertainty over the safety of the products for human consumption. European Union (EU) member states currently only allow animal feed imports to contain up to 0.1 percent trace GE material. Additionally, the EU requires all foods, feeds and processed products containing more than 0.9 percent biotech content to bear GE labels. Japan does not grow GE crops and requires mandatory labeling of GE foods. Countries that ban GE foods typically have strict rules to prevent unauthorized GE imports. The cost of tracing and separating these various GE crops to avoid contamination of non-GE crops and its effect on exports are not evaluated in USDA's analyses and must be considered.

Human Health Impacts Dicamba is a known carcinogen and must be adequately tested for human safety based on the proposed application rates if dicamba-tolerant cotton and soybeans were to be approved. The USDA is responsible for protecting the public and absolutely must consider human health impacts of increased dicamba use associated with these crops in its Environmental Impact Statement.

Conclusion USDA must recognize that dicamba-tolerant cotton and soybeans are not a sustainable solution to the problem of resistant weeds and examine the potential for increased herbicide use associated with the herbicide-resistant varieties in the pipeline. Herbicide-resistant weeds force farmers to return to increased tillage, so Monsanto's new dicamba-

tolerant crops will only address the glyphosate resistance problem until new weed resistance arises. In the meantime, the health of the public and the environment as well as the livelihoods of farmers will be imperiled by increased dicamba use. The USDA's Environmental Impact Statement, must include, at a minimum:

• An analysis on how dicamba-tolerant soybeans and cotton will facilitate increased use of dicamba, leading to the evolution of dicamba-resistant weeds and the abandonment of conservation tillage practices;

• Data on the potential carcinogenicity and long-term risks to human health that dicamba would pose at new application levels and the cumulative effects of its interaction with other herbicides on human health and the environment;

• Studies on the effects of increased application of dicamba on surface water quality and impacts on non-target plants and animals, including endangered species;

• A detailed evaluation of the volatility of dicamba, including a map of potentially affected specialty crop growing regions that would be in the proximity of dicamba-tolerant cotton and soybean growing areas. The USDA must look at the impacts of pesticide drift onto neighboring conventional specialty crop and organic fields, including its effects on plant health and farmer costs;

• Research on how the ingestion of foods manufactured from this crop would affect human health and how the continued use of the herbicide in agriculture could endanger agricultural workers and the public; and

• A detailed examination of the cumulative effects of stacking dicamba-tolerant corn with other herbicide tolerances, including the costs of contamination to non-GE farmers and the costs that dicamba and glyphosate resistant weeds would impose on these growers. Thank you for your consideration of these comments.

Sincerely, Wenonah Hauter Executive Director

References - as noted above since this form does not permit proper referencing I would be happy to provide a fully formatted version of this submission on request to emitchell@fweurope.org

Aspelin, Arnold L. and Arthur H. Grube. U.S. Environmental Protection Agency (EPA). "Pesticides Industry Sales and Usage: 1996 and 1997 Market Estimates." November 1999 at 21; Grube et al. EPA. "Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates." February 2011 at 14.

Food & Water Watch analysis of USDA National Agricultural Stastistics Service (NASS). Quickstats. Agricultural Survey, Planted Acres (Corn, Upland Cotton, Soybean), Chemical Use, Number of Applications and Average Applications of Active Ingredient (Dicamba) in lbs. per acre. Available at http://quickstats.nass.usda.gov/results/C0504BE2-7B91-3349-8E78-1CF2A4300F93, Accessed May 6, 2013.

Smith, Steve. Red Gold. "Deployment of Dicamba-resistant soybeans and what it will mean to canned and frozen food processors and specialty crop growers in the Midwest." Testimony

before the Domestic Policy Subcommittee of the Committee on Oversight and Government Reform. U.S. House of Representatives. September 30, 2010.

The manufacturers of Dicamba recommend that a maximum of 2 lbs. of active ingredient be used per acre of corn, cotton and soybeans each year. Agri Star. “Dicamba HD.” Specimen Label at 22. On file and available at http://www.cdms.net/LDat/ld4JF001.pdf.

Monsanto data report that in 2008, the volume of dicamba used on soybeans was 118,000 lbs. Monsanto. “Petition for the Determination of Nonregulated Status for Dicamba-Tolerant Soybean MON 87708.” July 6, 2010 at 199. Food & Water Watch analysis of USDA NASS data.

Monsanto. “Petition for the determination of nonregulated status for Dicamba-tolerant soybean MON 87708.” Revised March 26, 2012 at 33.

Food & Water Watch analysis of Heap, Ian. The International Survey of Herbicide Resistant Weeds. “Herbicide-Resistant Weeds by Site of Action.” Available at www.weedscience.com. Accessed May 2, 2013.

Food and Water Watch analysis of Heap (2013); USDA, Economic Research Service (ERS). “Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000–12.” Data set. Updated July 3, 2012. On file and available at http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx#.UUd2M1u4Elg. Accessed May 18, 2013.

Sfiligoj, Eric. “The Next Steps in Weed Control.” CropLife. March 1, 2013.

Food and Water Watch analysis of Heap (2013); USDA ERS (2012).

Mortensen, David et al. “Navigating a Critical Juncture for Sustainable Weed Management.” BioScience. Vol. 62, No. 1. January 2012 at 76, 79 and 84.

Ibid. at 76.

Ibid. at 76 to 77.

Peterson, R.K.D. and A.N.G. Hulting. “A comparative ecological risk assessment for herbicides used on spring wheat: The effect of glyphosate when used within a glyphosate-tolerant wheat system.” Weed Science. Vol. 52, No. 5. 2004 at 839. Roush, Troy. “Are Superweeds an Outgrowth of USDA Biotechnology Policy.” Testimony before the Domestic Policy Subcommittee. House Oversight and Government Reform Committee. U.S. House of Representatives. July 28, 2010 at 3. Association of American Pesticide Control Officials (AAPCO). “2005 AAPCO Pesticide Drift Enforcement Survey Report.” 2005. On file and available at http://aapco.ceris.purdue.edu/doc/surveys/DriftEnforce05Rpt.html. Accessed May 3, 2013.

Advisory Committee on Biotechnology and 21st Century Agriculture (AC21). “Meeting Summary.” March 5-6, 2012 at 3-4.

Food & Water Watch Analysis of USDA NASS. 2007 Census of Agriculture. 2007 at Table 33.

Rathai, Kenna. "'Quadstack' Waterhemp: New herbicide-resistant waterhemp biotypes call for new management strategies." Corn & Soybean Digest. February 15, 2011.

Robinson, Elton. "Resistant weeds changing the way we farm." Southwest Farm Press. February 19, 2013.

Mueller, Thomas C. et al. "Proactive versus reactive management of glyphosate-resistant or –tolerant weeds." Weed Technology. Vol. 19, Iss. 4. 2005 at 928 to 929; J.K. Norsworthy et al. "Reducing the risks of herbicide resistance: Best management practices and recommendations." Weed Science. Vol. 60, Special Issue. 2012 at 33.

Robinson, Elton. "Resistant weeds changing the way we farm." Southwest Farm Press. February 19, 2013.

Haire, Brad. "Pigweed threatens Georgia's cotton industry." Southeast Farm Press. July 6, 2010.

Pew Global Attitudes Project. "Views of a Changing World." June 2003 at 90 to 91.

European Parliament and Council. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union. October 18, 2003 at L 268/9.

Henshaw, Caroline. "EU to admit GM material in animal feed." Wall Street Journal. February 22, 2011.

European Parliament and Council. (EC) No 1829/2003; Article 7.1 European Commission. (EC) No. 1830/2003. Article 12.2. October 18, 2003.

International Service for the Acquisition of Agri-biotech Applications. "Global Status of Commercialized Biotech/GM Crops 2010." Issue Brief 42-2010. February 22, 2011 at Executive Summary; United States Trade Representative. "2010 Report on Technical Barriers to Trade." 2010 at 52.

Cox, Caroline. "Dicamba Factsheet." Journal of Pesticide Reform, Vol. 14, No. 1. 1994 at 30 to 35.

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6. Labelling proposal

What labelling proposal?

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

a. Assessment:
Molecular characterisation

The molecular characterisation should take the emergence of new double stranded RNA that might be transmitted as a biologically active substance at the consumption level into account.

A request should be made for data on the impactof the newly introduced DNA, its gene products and the new metabolic pathway in the plants own gene regulation.

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

The outcome of the comparative analysis shows that several of the endpoints measured were significantly and consistently different. Differences were observed, for example, in the levels of carbohydrates, protein, arginine, aspartic acid, glutamic acid, histidine, phenylalanine, proline, palmitic acid, oleic acid, eicosenoic acid and behenic acid. EFSA, however, simply assumes that these differences are not relevant for the food safety of soybean MON87708.

The EU comparative analysis should be regarded as nothing more than a starting point to define further steps in risk assessment. Significant observable differences must be investigated further to find the reason why they are happening, and their impact on relevant plant characteristics. Observable differences in plant components can indicate other changes affecting the level of anti-nutritional, hormonal or immunologically active substances in the plant. It is possible that any such relevant changes in plant characteristics may only be observed under specific environmental conditions. The dossier forwarded to the authorities, however, only contains data from US fields (none from South America) and only for one year (2009). Thus, prior to drawing any conclusions on safety, the observed differences should have triggered a request from EFSA for more studies, for example, under defined environmental stress conditions.

b. Food Safety Assessment:
Toxicology

The outcome of the 90 days feeding study showed several changes in two of the four groups

fed with genetically engineered plants. More detailed and long-term investigation of the health impact of the MON87708 soybeans should have been requested.

Allergenicity

The digestion test as performed with the newly introduced enzymes does not allow any conclusions on the fate of the protein under realistic conditions in the gut of humans or animals.

The number of blood samples from individuals used for testing is very low. No analysis of risks for individuals with an impaired immune system such as elderly or infants was undertaken.

Others

If MON87708 is authorised, the pattern of exposure to dicamba (and its residues) in the food chain will be changed. Further interactions between the residues from spraying with the plants metabolism and components will become an issue that cannot be left aside in risk assessment of these soybeans.

In parallel to the GMO panel, the pesticide panel of EFSA published a Reasoned opinion on the modification of the MRL for dicamba in genetically modified soybean (EFSA Journal 2013;11(10):3440). Taken together the two EFSA opinions show substantial gaps in the overall risk assessment of this product:

> Due to the inserted DMO proteins, the herbicide dicamba is metabolised to 3,6-dichlorosalicylic acid (DCSA) and formaldehyde. The formaldehyde component was not part of the EFSA risk assessment. According to the IARC, formaldehyde I a human carcinogen (IARC 20121), and therefore the additional exposure through residues must be addressed. see http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf

> The way how ADI and MRL were established is confusing and shows too many untertainties: The metabolism pattern of the active substance in genetically modified plants was shown to be different and the available data did not allow EFSA to conclude whether dicamba and DCSA act through the same toxicological mode of action. Another metabolite, DCGA, was identified but there was insufficient toxicological data to set a specific ADI. The acceptable daily intake (ADI) proposed for the metabolite DCSA is much lower than the one proposed for dicamba. However the proposed maximum residue level (MRL) for DCSA is higher (0,4 mg/kg in soybean) than for dicamba (0,05 mg/kg in soybean). This seems to be a contradiction. In any case, the load of residues from spraying with dicamba will be increased significantly within the food chain, if MON87708 comes on to the market.

> There was no assessment of interaction between plant components such as immunological or anti-nutritional, hormonal or immunologically active substances with the residues form spraying.

Several other genetically engineered plants with tolerance to various herbicides have pending market authorisations for the EU, making a systematic approach necessary to deal with new patterns of exposure, interactions between the substances and the accumulated impact on human and animal health. Risk assessment of MON87708 should take into account potential interactions and accumulated effects between the residues from spraying with dicamba and residues from spraying with other herbicides. Furthermore, the residues left in other genetically engineered plants from spraying with herbicides and potential interactions and accumulated effects should be taken into account as these plants can be mixed with MON87708 in food and feed.

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4. Conclusions and recommendations

Risk assessment by EFSA is failing to deal properly with findings from the comparative analysis. The assessment of toxicological, hormonal and immunological effects is inadequate. Further, risk assessment does not take the many safety issues regarding the usage of the complementary herbicide into account. In conclusion, there are too many uncertainties remaining and the application should be rejected.

A systematic approach has to be developed to deal with interactions and accumulated effects from the usage of these plants in food and feed before any decision is taken on genetically engineered plants that are resistant to herbicides,.

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5. Others

Monitoring taking residues from spraying with herbicides into account must be undertaken at the consumption stage. If authorised, soybean MON 87708 will mainly be used in feed products so the national veterinary networks and services should be involved in the monitoring of effects on animal health.
