This opinion is related to an application for authorisation of genetically modified soybean MON87708 for food, feed uses, import and processing.

GeneWatch UK
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3. Comments

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.

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: such data 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.

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

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.