Soybean MON 87705 x MON 89788

Organisation: The European GMO-free Citizens
Country: The Netherlands
Type: Others...

---

a. Assessment:
Molecular characterisation

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific
WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

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

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's

unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

---

b. Food Safety Assessment:
Toxicology

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific
WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-

center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

Allergenicity

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific
WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely

not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

Nutritional assessment

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct

such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

Others

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here (http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

3. Environmental risk assessment

Systems Biology Group, International Center for Integrative Systems: GMO Soy Accumulates Formaldehyde & Disrupts Plant Metabolism, Suggests Peer-Reviewed Study, Calling For 21st Century Safety Standards

Study Concludes FDA GMO Approval Process is Flawed, Outdated, and Unscientific
WASHINGTON, July 14, 2015 /PRNewswire/ -- A new study published today in the peer-reviewed journal AGRICULTURAL SCIENCES reveals genetic engineering of soy disrupts the plant's natural ability to control stress, and invalidates the FDA's current regulatory framework of "substantial equivalence" used for approval of genetically engineered food (GMOs).

The study, led by Dr. V.A. Shiva Ayyadurai, Ph.D., an MIT-trained systems biologist, utilizes his latest invention, CytoSolve, a 21 century systems biology method to integrate 6,497 in vitro and in vivo laboratory experiments, from 184 scientific institutions, across 23 countries, to discover the accumulation of formaldehyde, a known carcinogen, and a dramatic depletion of glutathione, an anti-oxidant necessary for cellular detoxification, in GMO soy, indicating that formaldehyde and glutathione are likely critical criteria for distinguishing the GMO from its non-GMO counterpart. Dr. Ayyadurai stated, "The results demand immediate testing along with rigorous scientific standards to assure such testing is objective and replicable. It's unbelievable such standards for testing do not already exist. The safety of our food supply demands that science deliver such modern scientific standards for approval of GMOs."

"The discovery reported by Dr. Ayyadurai reveals a new molecular paradigm associated with genetic engineering that will require research to discover why, and how much formaldehyde and glutathione concentration, and what other cellular chemicals relevant to human and animal health, are altered. We need the kinds of standards Dr. Ayyadurai demands to conduct such research," stated Dr. Ray Seidler, a former EPA Senior Scientist. "Formaldehyde is a known class1 carcinogen. Its elevated presence in soybeans caused by a common genetic engineering event is alarming and deserves immediate attention and action from the FDA and the Obama administration. Soy is widely grown and consumed in the U.S., including by infants fed baby food products, with 94% of soy grown here being genetically engineered," declared Seidler.

The study concludes the U.S. government's current standards for safety assessment of GMOs, based on the principle of "substantial equivalence," is outdated and unscientific for genetically engineered food since it was originally developed for assessing the safety of medical devices in the 1970s. The current criteria for assessing "equivalence" considers only basic nutritional and superficial characteristics such as taste, sight, smell and touch, for declaring GMOs safe for human consumption, allowing them to be fast-tracked to market without independent scientific testing. If formaldehyde and glutathione were criteria, then the GMO would likely not be deemed "equivalent" to its non-GMO counterpart. This finding calls into question the FDA's food safety standards for the entire country. The publication of the paper coincides with release of a bulletin by the Obama Administration on July 2, 2015, calling for "Improving Transparency and Ensuring Continued Safety in Biotechnology." Ayyadurai shares, "This is not a pro- or anti-GMO question. But, are we following the scientific method to ensure the safety of our food supply? Right now, the answer is 'no'. We need to, and we can, if we engage in open, transparent, and collaborative scientific discourse, based on a systems biology approach." The full study can be read here

(http://www.integrativesystems.org/systems-biology-of-gmos/). Contact Information: Nathan Nye: nnye@fenton.com (http://www.prnewswire.com/news-releases/mailto:nnye@fenton.com), (910)876-2601; Alison Channon: achannon@fenton.com (http://www.prnewswire.com/news-releases /mailto:achannon@fenton.com), (202)789-7752 SOURCE Systems Biology Group, International Center for Integrative Systems Find this article at: http://www.prnewswire.com/news-releases/systems-biology-group-international-center-for-integrative-systems-gmo-soy-accumulates-formaldehyde-- disrupts-plant-metabolism-suggests-peer-reviewed-study-calling-for-21st-century-safety-standards-300112959.html Check the box to include the list of links referenced in the article.

---

4. Conclusions and recommendations

Others

On 14 July, a new scientific study was published which shows that genetically modified (GM) soya accumulates formaldehyde and contains considerably less glutathione. Formaldehyde is carcinogenic and glutathione is an antioxidant; antioxidants are needed for cell detoxification. The natural breakdown of formaldehyde in cells is also blocked.

This accumulation of formaldehyde could perhaps be characteristic of GM crops and definitively puts an end to the equivalence principle, on the basis of which GM crops have been authorised.

As the press release states, the results indicate that further research is needed.

---

5. Others

Don't approve this.

---

6. Labelling proposal

Don't authorise it, labelling not relevant.

Organisation: LA NATURE
Country: France
Type: Individual

---

a. Assessment:
5. Others

I object to the spread of GM plants and seeds; they can only disrupt what NATURE has created. The financial artificialisation of the land can only result in future disaster: So, for the sake of my children, I say 'No' to GMOs and to MONSANTO: they would sell their children to make money.

Organisation: Citoyen
City: 56250 MONTERBLANC
Country: France
Type: Individual
Public: Yes

---

a. Assessment:
Molecular characterisation

Conclusions too quick

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

Insufficient

---

b. Food Safety Assessment:
Toxicology

Bad

Allergenicity

Bad

Nutritional assessment

Insufficient

---

3. Environmental risk assessment

Insufficient, the risks are too great and unacceptable.

---

4. Conclusions and recommendations

Any introduction, marketing or use of this product, which is dangerous and unfit for use, should be refused.

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

---

a. Assessment:

Molecular characterisation

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). This issue does not appear to have been investigated. The information provided on composition and hence the exposure scenarios may therefore be incomplete. A full proteomic analysis should be requested from the applicant. Such an analysis would be able to better characterise any 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)

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. The field trials were performed at nine separate sites within the soybean cultivation areas of the USA. Eight of the nine sites were used for the agronomic and phenotypic comparison, and eight were used for comparative compositional studies of soybean seed and forage. Seven of the nine field trials were used for both compositional and agronomic/phenotypic analysis. It is questionable whether this data set is sufficient to establish variability of nutrient levels between different sites and growing conditions. More data should be requested from the applicant, particularly in relation to studies on the effect of food processing on nutrient profiles.

---

b. Food Safety Assessment:
Toxicology

EFSA should have published detailed Guidance on the assessment of nutritionally-altered crops.

The animal studies provided are inadequate to support the conclusions made by EFSA. In the rat study reported for the single event (EFSA 2012 Scientific Opinion on MON 87705), no soybean oil from MON87705 was tested, only defatted soybean meal and hence the only conclusion that was drawn by EFSA referred to defatted soybean meal. The same problem occurs with the chicken study reported here for the stacked event, which again uses toasted defatted soybean meals. This is a critical omission because the soybean oil is the main product intended to be fed to humans. It is hard to understand how EFSA can reach any conclusion on the safety of the product, and particularly its altered nutritional profile, if no studies are conducted! New animal feeding studies should be requested from the applicant which test all the food products (including oil and whole soybeans) which fall within the scope of the application and which include endpoints relevant to the assessment of the safety of nutrient profile of the oil.

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.

Nutritional assessment

There is no nutritional assessment as such included in the scientific assessment for the single event MON 87705 or the stacked event MON 87705 × MON 89788 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.

EFSA has also failed to publish any Guidance on the assessment of nutritionally altered crops.

GeneWatch UK considers the lack of any proper nutritional assessment to be a serious omission. 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) also exist. In addition, no data has been provided for different age groups, needed to assess risk to specific subgroups of consumers. Some such information (including intakes for toddlers, children, teenagers, adults and the elderly, before and after the substitution of foods containing the GM soybean oil) was provided in the EFSA's statement complimenting its scientific opinion for Pioneer's GM

soybean 305423. The lack of any such data here raises questions about consistency and the need for a level playing field. The applicant should be required to supply this information as it is essential to underpin any nutritional assessment.

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 MON 87705 × MON 89788; (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. Prior Guidance on the assessment of nutritionally altered crops should have been published by EFSA.

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 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 MON87705) (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 for the single event did not include soybean oil from soybean MON87705 nor did the chicken study added here; (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 MON 87705 × MON 89788 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. As noted above, no data has been supplied on estimated daily intakes for toddlers, children, teenagers, adults and the elderly, making a safety assessment for such groups impossible. In addition, 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 MON 87705 × MON 89788 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 MON 87705 × MON 89788 should be allowed on the market, particularly when the options for recall or consumer avoidance may be difficult (see comments on labelling below).

Others

No analysis was provided of the fatty acid of the final products for which the applicant is seeking approval (e.g. salad dressings and margarines, or products fried in the oil). Nor was any data supplied on bioavailability and bioefficacy taking onto account the potential influences of transport, storage and expected treatments of the food. More data should be requested from the applicant if the food safety assessment is to be meaningful.

The applicant has applied for an authorisation which covers the GMO and foods containing it. Nutritional composition has not been supplied for all the relevant foods containing the GMO. 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 MON 87705 × MON 89788. 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.

Since the application covers the authorisation covers 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 containing increased oleic acid oil” or “increased oleic acid oil produced from genetically modified soybean” 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 soybean 305423) and several could be described as containing “increased oleic acid” despite having substantially different fatty acid profiles (and in some cases other altered nutrients). 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). 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 MUFAs and breast 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 MON 87705 × MON 89788 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: t
Country: Germany
Type: Non Profit Organisation

---

a. Assessment:
Molecular characterisation

The purpose of this stacked event seems to be to enhance the concentration of EPSPS protein in the plants. This protein renders them resistant to glyphosate. However, the expression data of the stacked event show that the level of EPSPS is not enhanced in comparison to the parental plants. This is a surprising result that should have triggered a lot more investigation into potential silencing effects in the plants that can affect the level of EPSPS enzyme, and also the overall food quality and food safety. However, EFSA did not ask for any explanation of this surprising effect.

Further, EFSA did not assess the molecular data in regard to food safety and the occurrence of the intended small biologically active RNA molecules. The change in the oil composition in the soybeans is based on an inhibition of endogenous plant genes due to RNAi interference (RNAi). The mechanism results in reduced levels of the corresponding plant enzymes. (Short inhibitory) siRNA molecules which are part of this mechanism may both cause intended gene

silencing and have off-target effects, i.e. may silence genes other than those intended (Senthil-Kumar et al., 2011). Small biologically active RNA molecules 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 (see, for example, Zhang et al., 2011; Lukasik & Zielenkiewicz, 2014). Thus, for the risk assessment of plants that produce specific small double stranded RNAs, it is necessary to conduct bioinformatics studies to identify any likely unintended targets in humans or animals. But no such studies have been conducted.

Further, the emergence of new variations, combinations and concentrations of unintended small, biologically active RNA molecules such as microRNA was neither assessed in the single plants nor in the stacked event. These molecules are likely to emerge as unintended side products at the insertion sites of the additional DNA. They can interfere with each other on the level of the stacked event. Their concentration, structure and potential biological effects should be assessed before any conclusion is drawn upon safety of the plants. Uncertainties related to the emergence of these molecules were not addressed.

Both the content of the EPSPS enzyme and the concentration of small biologically active RNA molecules should have been tested under a wide range of defined environmental conditions, taking into account stressful conditions that, for example, emerge under ongoing climate change. It is known that under stress conditions, genetically engineered plants can show reactions that are not obvious under normal agricultural conditions, and can be very different from those of plants stemming from conventional breeding. Environmental stress can cause unexpected patterns of expression of the newly introduced DNA (Trtikova et al., 2015). Since the intended change in the oil content is related to health effects, it is important to know if genetic stability is maintained under stressful conditions. However, the plants were only tested in the US (not in other relevant soy producing countries) and only under “normal” agricultural conditions.

Lukasik, A, & Zielenkiewicz, P. (2014) In Silico Identification of Plant miRNAs in Mammalian Breast Milk Exosomes – A Small Step Forward? PLoS ONE 9(6): e99963.

Senthil-Kumar, M., Kirankumar, S., Mysore, K.S. (2011) Caveat of RNAi in Plants: The Off-Target Effect. In: H. Kodama, A. Komamine (eds.), RNAi and Plant Gene Function Analysis, Methods in Molecular Biology 744, DOI 10.1007/978-1-61779-123-9_2, © Springer Science+Business Media, LLC 2011

Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene Expression and Bt Protein Content in Transgenic Bt Maize (MON810) under Optimal and Stressful Environmental Conditions. PloS one, 10(4): e0123011. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011

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)

Compositional analysis revealed a high number of significant differences (in addition to the expected changes in oil composition) between the stacked event and its comparator. According to EFSA, 16 compounds in kernels were identified. Furthermore, several agronomic characteristics showed significant differences. Contrary to the opinion of EFSA, the occurrence of these high number differences together can indicate metabolic impacts and changes in MON87705 × MON89788, which may well go beyond the set of compounds selected for analysis. For example, the differences in plant components can indicate further changes affecting the level of anti-nutritionally, hormonally or immunologically active substances in the plant. These differences must therefore be investigated further to assess in detail their causes and biological relevance.

It is possible that some of the relevant changes in plant composition and plant characteristics may only be observed under specific environmental conditions. Thus, the observed differences should have triggered a request from EFSA for more studies, for example, to grow the plants under defined environmental extreme stress conditions.

However, EFSA has assumed without sufficient reason that these differences are not relevant for the food safety of soybean MON87705 x MON89788.

---

b. Food Safety Assessment:
Toxicology

There are three main characteristics of these plants that are relevant for toxicology assessment: - The plants are changed in their oil content - The plants seem to be intended to render a higher level of resistance to glyphosate - The plants produce specific siRNA, which also might be biologically active in mammals at the stage of consumption.

None of these characteristics were taken into account in toxicology assessment: Neither the parental plants MON87705 nor the stacked event were tested in animal feeding studies to assess health effects of the changed oil content. The feeding studies that were performed were based on usage of defatted soybeans, and therefore with only minimal concentrations of the relevant oil in the diet. The potentially higher dosage of glyphosate that might be sprayed on the plants was not taken into account. According to the comments of experts from Member States, the amount of glyphosate sprayed onto the stacked event was even lower than the one applied to the parental plants. Higher levels of residues from glyphosate (which is under discussion as possibly carcinogenic, IARC, 2015) and their impact on plant composition, its nutritional characteristics and potential health effects still have to be assessed. The structure, concentration and potential effects of small biologically active RNA molecules produced in the plants was left aside (see molecular assessment).

As a result, the most relevant characteristics of this stacked event were not assessed in regard to toxicology.

One reason for this flaw in risk assessment is the lack of sufficient interplay between the pesticide assessment and the GMO assessment at EFSA, which in itself creates a high level of uncertainty. EFSA carries out the risk assessment of herbicide resistant, genetically engineered plants, without taking into account the specific risks that emerge from the residues from the spraying with complementary herbicides. These risks are only partially assessed as part of EU pesticide regulation. However, if commercially traded herbicide formulas are applied in specific combinations to herbicide resistant plants, there are specific patterns of residues that need to be assessed.

Herbicide resistance in weeds is increasingly becoming a problem in areas where genetically engineered plants are cultivated. In response, several other genetically engineered plants with tolerance to various herbicides have been developed and are pending for market authorisation in the EU, or have already been authorised. This is making it necessary to develop a new systematic approach in dealing with new patterns of exposure, interactions between the substances and the accumulated impact on human and animal health.

Another reason for the flaws in this risk assessment is that EFSA has failed to develop specific guidance on the risk assessment of genetically engineered plants that are changed in their nutritional quality. As a recent dossier prepared by GeneWatch UK & Testbiotch (2015) shows, risk assessment of the parental plant MON87705 (and therefore also risk assessment of the stacked event) is flawed for the following reasons: - Inadequate or missing literature reviews on health impacts - Inadequate food safety and nutritional assessment - Inadequate consideration of the potential impact of altered nutritional content on potentially vulnerable subpopulations - Failure to consider all processed forms of foods - Inadequate feed safety and nutritional assessment

GeneWatch UK & Testbiotech (2015) Request for a review of the authorisations for GM crops with altered oil content, http://www.testbiotech.org/node/1284

IARC (2015) Glyphosate Monograph.
http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf

---

Allergenicity

Most relevant for health risk assessment in this context are the naturally occurring allergens present in soybeans. A change in the plants composition might also lead to a higher concentration of the endogenic plant allergens. Further, it is known that toxicants, if applied together with the allergens, can have an adjuvant effects, triggering a stronger immune reaction to the proteins. This is a specific risk that needs to be addressed in the context of residues from spraying with the complementary herbicides.

Monsanto presented data that are meant to show that the concentration of the endogenic proteins in the plants was not enhanced. However, soybeans are known to have a substantial variation in their natural concentrations, depending on specific varieties and on interaction with the environment. Monsanto failed to show that the level of endogenic allergens in specific varieties and/ or under specific environmental conditions is not increased. For this purpose, further crossing with other varieties should have been carried out as well as subjecting the soybeans to suitable stress tests. Further, the risk assessment completely failed to take into account potential interactions between the residues from spraying and the immune reaction to the soybean allergens.

No blood samples were taken from individuals known to have allergenic reactions in order to investigate clinical effects of the stacked event. No analysis was undertaken of the risks for individuals with an impaired immune system such as the elderly or infants, as requested by the EFSA guidance (EFSA, 2010).

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

---

Others

The applicant should provide methods to distinguish the presence of the stacked events from those of the mixture of the parental plants. Without such a method no surveillance and no monitoring can be performed on the stacked event.

As a legal dossier compiled by Professor Ludwig Kraemer (Kraemer, 2012) shows, where there are uncertainties EU regulations require the monitoring of effects on health at the stage of consumption. Thus, for example, requirements must include the monitoring of health effects and take residues from spraying with herbicides into account. Epidemiological parameters that are suitable for detecting relevant health effects need to be defined.

Further, any spillage from the kernels has to be monitored closely.

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

EFSA risk assessment is failing to deal properly with findings from the comparative analysis. The assessment of toxicological, hormonal and immunological effects is inadequate. Further, risk

assessment did not take into account relevant safety issues regarding the usage of the complementary herbicide.

A systematic approach to risk assessment has to be developed to deal with the health effects of plants that are changed in their nutritional characteristics, that raise specific questions regarding residues from spraying with complementary herbicides and that produce small double stranded RNA.

Further, interactions and accumulated effects from the usage of such plants in food and feed have to be assessed systematically before any decision is taken on market authorisation.

In conclusion, the application has to be rejected.