

Are rat organs damaged after feeding on GM soybeans?

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1. ISSUE:

Ermakova claims that HT-soybeans in the diet of experimental rats caused high death rates in pups and low growth rates. A group of international experts has criticized the work on the basis of an interview with Dr. Ermakova, done by the editor in chief of Nature Biotechnology, see

Marshall, A., Ermakova, I., Chassy, B., Giddings, V., McHughen, A., & Moses, V. (2007)

GM soybeans and health safety - a controversy reexamined. *Nature Biotechnology*, 25, 9, pp 981-987
10.1038/nbt0907-981

Ermakova, I.V. (2007)

GM soybeans - revisiting a controversial format. *Nature Biotechnology*, 25, 12, pp 1351-1354
10.1038/nbt1207-1351

Marshall, A. (2007)

GM soybeans - revisiting a controversial format - Response. *Nature Biotechnology*, 25, 12, pp 1359-1360
10.1038/nbt1207-1359

2. Summary

In an article of *Nature Biotechnology*, the editor in chief Andy Marshall produced a feature in form of an interview with *Dr. Irina V. Ermakova* with her statements concerning her rat experiments with RR soybeans, which appeared on over 500 internet websites but were not published in a peer reviewed journal. Ermakova describes experiments in which rats were fed Roundup Ready Soybeans. She reports having observed an rat infant mortality of over 50% when fed with GM soy-fed groups; she also claims the GM-soy fed pups gained weight more slowly than the controls.

The original interview of Irina Ermakova has been published by the editor in chief Andrew Marshall in *Nature Biotechnology* (Marshall et al., 2007), including some rebuttals.

Marshall, A., Ermakova, I., Chassy, B., Giddings, V., McHughen, A., & Moses, V. (2007)

GM soybeans and health safety—a controversy reexamined. *Nature Biotechnology*, 25, 9, pp 981-987
<http://dx.doi.org/10.1038/nbt0907-981>

This reference contains comments of the editor in chief of *Nature Biotechnology* Andrew Marshall, his interview questions and the summary of Dr. Ermakova's statements, and a critical comment of the following invited experts: Dr. Bruce Chassy, Dr. L. Val Giddings, Dr. Alan McHughen and Dr. Vivian Moses, see below their detailed affiliations.

In a second feature the editor in chief of *Nature Biotechnology* organized a follow up debate of the original participants: (Ermakova, 2007), (Chassy et al., 2007) and (Marshall, 2007) .

(Ermakova, 2007) replied to the criticism she has not seen before the first publication (details about the circumstances below).

She was seconded by colleagues (Cummings, 2007; Heinemann & Traavik, 2007; Ho & Saunders, 2007; John, 2007; Leifert, 2007), they were *all* indulging in procedural criticism, but strangely enough they avoided to go into the scientific details, which are so important in this case. It is part of the usual tactics of opponents of GM crops.

As a whole, it is a learning piece of a scientific debate for everybody involved, but at the end of the day some major scientific concerns about Ermakova's paper persist. The results obtained by Dr. Ermakova in these experiments are, up to this date (1. August 2009) not published as an original research paper in a pertinent and peer reviewed journal of wide distribution.

From the abstract :

"An unprecedented study claiming that transgenic soybeans compromise the fertility of rats and the survival and growth of their offspring has garnered widespread media and political attention but remains unpublished in the peer-reviewed literature. Here, an account of the work from the principal investigator, Irina Ermakova, is appended with comments from researchers in the field."

And from the response of A. Marshall (Marshall, 2007):

"The September Feature was a new format for Nature Biotechnology. My aim in publishing this Feature was to provide an informative presentation of the science behind Ermakova's work, the problems posed by publicizing original data to the media without first publishing it in the peer-reviewed literature, and to open this particular debate to a wider audience. Indeed, many investigators who were unaware of her results now have an opportunity to build on her work and attempt to reproduce it."

3. Comment

The Russian researcher and neurobiologist Dr. Irina Ermakova organized numerous press conferences on the results of experiments with rats and soybeans. Her news was distributed widely on the internet with a summary of her experimental research about feeding rats with RR soybeans. The news about the detrimental effects on rat organs after the animals were fed with transgenic soybeans was first launched publicly in REGNUM online, a Russian News Agency December 10, 2005 (Ermakova, 2005a). Ermakova has subsequently presented her results at several international conferences. The issue has been debated in numerous newspaper articles, three examples follow below:

The Russian 'Pravda' from 27 October 2005 (Ermakova, 2005b) , The Russian 'Neva News St. Petersburg' from April 1, 2006 (Solobaeva, 2006) in the St. Petersburg English Newspaper , the Neva News and the English 'The Independent' from Sunday January 8, 2006 (Lean, 2006), all with classic boulevard exaggerations that GM soybeans may be harmful for unborn babies – a classic scare monger slogan. Those newspapers presented the Ermakova report at face value and offered no analysis or comment – far from any peer review process. Critical review is best done by scientific journals using a peer review process (Ranade & Kumar, 2007) , but Dr. Ermakova did not place her text in such a journal. In a press statement, Dr. Ermakova confirmed in Despite this, the story spread rapidly and she presented her un-reviewed results at a Greenpeace sponsored event on 'Epigenetics 2005'; she also was subsequently invited to publish a longer summary in the conference report (Ermakova, 2006c). Another contribution

she gave at an international disaster reduction conference in Davos (Ermakova, 2006a), with basically the same statements and the same heavily biased list of publication references. A longer rebuttal to her critics has been launched on her own old website without peer review: (GM-Free-Cymru, 2007) and of (Ermakova, 2006b), here just one citation with the usual wild accusations:

“Scientists should be responsible for the obtained data, but are even more responsible for concealment of the received data, especially if somebody’s life depends on them. A lot of independent investigations showed hazard of GMO for alive organisms. I hope very much that ACNFP will help us to perform detailed and complex investigations and to stop uncontrolled distribution of and contamination by imperfect genetically modified organisms that can cause such human diseases as cancer, allergy, brain and heart diseases, can lead to disappearance of a great number of different species of useful bacteria, plants and animals and cause destruction of the nature and the biosphere.”

A visit in the old website of Dr. Ermakova (Ermakova, 2001 - 2008) reveals, that she has a clearly negative agenda on GM crops: In a rather strange mix she advocates a GM free Europe, on her page “my publications” there is not a single paper cited which has been published in a peer reviewed journal, a check on the Web of Science from 1. August 2009 confirms this, since the publication in Nature Biotechnology does not really count as a peer reviewed paper, see the statements of the editor in chief of the journal. In addition you can discover weird interviews she recently gave in an obscure Russian internet site “MK” such as "Russians threatened by GM Genocide" (Ermakova & Pichugina, 2007). It is therefore not credible, when Dr. Ermakova wants to make believe in her reply in Nature Biotechnology, that she is neutral in her view on GMO’s: “I am not against GMOs, but wish to promote more safe and effective approaches as much as I can” p. 1353. Interestingly enough there are not many traces on the soybean controversy on the new website of Irina Ermakova (Ermakova, 2001 - 2008).

4. A parallel case: the flawed rat experiments of Pusztai from 1998-1999

A parallel case of seemingly negative results of deeply flawed food safety experiments which have never passed proper peer review, but nevertheless published in a reputed journal (Lancet) is still today widely disputed: The editor of Lancet decided to publish a paper under the authorship of Ewen and Pusztai (Ewen & Pusztai, 1999), see separate ASK-FORCE blog (Ammann, 20110111) , although the peer review was not unequivocal, mainly for the reason because the experimental results have been publicly and widely disputed. The result of this doubtful editorial decision is now clearly visible after some years: The Ewen-Pusztai publication in Lancet is widely cited as a peer reviewed paper, and the very critical rebuttal of H. Kuiper (Kuiper et al., 1999) which was published in the same issue, as well as a critical analysis convened by the Royal Society (London) (Royal Society, 1999), are practically never cited by the GM opponents, although they can be found on the web.

Being aware of the pitfalls of publishing scientifically questionable findings under the name of the investigators as it has happened in the Pusztai case, editor in chief of Nature Biotechnology A. Marshall decided on another forum for debate. He invited Dr. Ermakova to participate in an *interview* in Nature Biotechnology and announced to her openly, clearly and in writing that he would allow experts in the field of nutrition and food safety to respond to her statements. With other words, the editor in chief of

Nature Biotechnology decided to organize something like a public peer review, where peer scientists would comment openly the results revealed in an interview. The result of this exercise has been published (Marshall et al., 2007), and (Marshall, 2007) led clearly to the rejection of the paper due to massive methodological flaws in the rat experimentation, and can be summarized here as follows:

5. Dr. Ermakovas statements in the interview with A. Marshall:

*“My experiments were designed to study the influence of a diet containing genetically modified (GM) soybeans (Roundup Ready (RR) line 40.3.2) on the physiological state and behavior of Wistar rats and their offspring. In addition to laboratory chow, one group of female rats was fed soy flour or seeds for 2 weeks before mating, during mating and pregnancy, and was fed an increased daily amount for every pup during lactation. At the same intervals, a second group of female rats receiving chow was fed conventional soy flour or seeds and a third group received protein isolated from RR GM soy. A fourth group of rats received only the laboratory chow and was considered to be a positive control. We analyzed the physiological state (weight, size and so forth), reproductive functions, rate of mortality and behavior of rats and their offspring. Experiments were repeated five times using soy flour, soy seeds, standard chow and chow mixed with GM soy (~14%) in different groups of rats. Standard chow contained wheat, wheat bran, sunflower, meat flour, animal fat, barley, fodder yeast, microelements and vitamins. RR soy flour genetically modified with the transgene 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) obtained from *Agrobacterium* sp. strain CP4 (Monsanto; St. Louis, MO, USA), its protein isolate and conventional soy flour (Arcon SJ 91-330), which has a similar composition and nutritional value to RR GM soy, were obtained from the Netherlands supplier of Archer Daniels Midland (ADM; Decatur, IL, USA). Analysis of soy flour by PCR showed the presence of the EPSPS transgene in all samples of RR GM soy. The chow was administered as dry pellets from a special container placed on the top of their cages and the (GM, GM protein isolate or conventional) soy flour mixed with water (20 g soy paste in 40 ml water) in a small container placed inside their cage for three rats. Each rat thus received 6–7 g flour every day. A similar scheme was used for soy seeds, which were kept in water for 1 day before feeding and then put into a small container inside the cage: four seeds for one female and six seeds for one male.”*

6. These statements and additional interview answers were responded to by the following scientists

Dr. Bruce Chassy of the University of Illinois at Urbana-Champaign says Ermakova’s work illustrates the need for the public and media to be cautious of scientific claims that have not been reproduced or passed the rigor of peer review.

Former Biotechnology Industry Organization (BIO; Washington, DC, USA) staffer and industry consultant *Dr. L. Val Giddings* believes Ermakova ignored the standard scientific practice of submitting research for peer review before publicizing her results.

The University of California’s *Dr. Alan McHughen* thinks that there are critical problems with Ermakova’s experimental design and research that throw doubt on the validity of her conclusions.

According to the University of London's *Dr. Vivian Moses*, in the context of published peer-reviewed studies as well as more than 10 years of real-world use of RR soybeans and the products derived from them, the claims of Ermakova seem implausible at best.

In order to read the full criticism and more interview answers of Dr. Ermakova, you need to consider the full texts of (Chassy et al., 2007; Ermakova, 2007) and (Marshall, 2007), here only some important facts from this remote debate moderated by A. Marshall as the editor of *Nature Biotechnology* are summarized:

"Ermakova made erroneous statements about the rat feedstuff, which she claimed to have obtained from Archer Daniels Midland (ADM; Decatur, IL, USA, but inquiries revealed that this company never has sold the 100% RR-soybeans that Ermakova claims were obtained from them. She has no evidence that the same varieties were compared, and she did no compositional analysis of either the soybeans or rat diets. It is thus unclear what exactly was fed to the rats. It should be noted that in high quality animal studies investigators usually have isogenic varieties cultivated for their experiments and perform an analysis on them to ensure that diets are equivalent and that no toxic, anti-nutrient or hormonal substances are present. In contrast to Ermakova, the four experts conclude that no meaningful inferences can be drawn from these results (the important data are given in tables XX. The experimental design does not follow internationally recognized protocols that were developed to guide researchers in proper design. The nature of the source material is unknown, the consumption by each animal is unknown and the composition of the diet is unknown. Too few animals were studied and gender differences were not recorded. The abnormally high mortality and low growth rates of the control groups point to poor animal stewardship."

"Ermakova did not follow the OECD, FDA and EPA guidelines cited in the NB article extensively (literature items 7-11, 13-14, 16-19) in (Marshall et al., 2007). The nature of the source material is unknown, the consumption by each animal is unknown and the composition of the diet is unknown. This is a critical point, because soy product and rat chow were offered in separate containers and there were three rats in each cage, it is impossible to know even if every animal ate soy products and it is equally impossible to compare groups because per animal consumption cannot be calculated. Too few animals were studied and gender differences were not recorded. The abnormally high mortality and low growth rates of the control groups point to poor animal stewardship. The wide variance of data in Table 3 and the high percentage of low-weight animals are clear indicators of malnutrition and/or poor environmental conditions."

For a better understanding those guideline citations from the original article are repeated here:
(EPA Guidelines Food Toxicity, 1998; FDA, 2000; OECD, 1983, 1997, 1998a, b, c, d, 2003, 2007, all years)

The maybe most important sentence in this paper taken from the expert comments.

No conclusion can be made about abnormal development unless the controls conform to internationally observed norms.

7. Second publication in *Nature Biotechnology*

In this second round, Dr. Ermakova got a chance to reply to her critics (Ermakova, 2007) and she made an attempt to clarify some misunderstandings also in procedural questions. From the remarks of (Marshall, 2007) it is crystal clear that he as an editor in chief does not consider the reply of Ermakova as a regular peer reviewed publication in *Nature Biotechnology*. Just take all the critical remarks of (Chassy

et al., 2007), which have been answered by Dr. Ermakova in a blatantly unsatisfactory way, the judgement of the peers and the editor in chief are unanimously supported by anybody who has experience in animal experimentations: her paper would still have been rejected by Nature Biotechnology.

The main problem for Dr. Ermakova was that she was left inadvertently in the dark about her status as an author, and although the editor in chief Dr. Marshall was clear about his attempt to interview Dr. Ermakova *in his original invitation* to her, and that he would then invite some scientists to comment on the interview statements. Unfortunately, the Nature Biotech correspondence secretariat (not tightly enough controlled by Dr. Marshall himself – for which he apologized) sent to her print proofs mentioning her innocently as an author of the first feature. This was clarified and corrected in the second publication by the editor himself (Marshall, 2007), gave Dr. Ermakova ample time and space to answer her critics in printing, and also letting the critics answer to her (Chassy et al., 2007). The main points Ermakova made are still open for scientific criticism after this exchange of opinions. Nevertheless, on an international level Dr. Ermakova is now in events organized by GM opponents appraised as a renowned author with a publication in Nature Biotechnology, it so happened in a Eco-Action meeting in Kiev, Ukraine in February 2008. In these circles she is even mentioned as a member of the Russian Academy of Science, which is according to active members of the Academy clearly falsified. In the community of international food science, still waiting for 3 years to see a publication of the results in a peer reviewed paper, she has no scientific credibility regarding soybean experiments.

It is therefore important, to summarize the second round of the controversy with the main highlights, but it is recommended to read the full accounts anyway.

Abbreviations used below:

(E. for Ermakova, CMMG for Chassy/Moses/McHughen/Giddings, KA for the author of this contribution Klaus Ammann)

Instead of going into great length and repeat the second controversy between E and DMMG, here just one example is given: the debate on the origin of the feedstuff used for the experiment:

7.1. Debates on scientific issues, between Dr. Ermakova and experts invited by Nature Biotechnology: origin of feedstuff used for experiment

E. defends her claim with PCR analysis, revealing 100% purity,

On p. 981, Chassy et al. note that it was “not possible for me” to have obtained Roundup Ready (RR) line 40.3.2 soybeans from the Netherlands supplier of Archer Daniels Midland (ADM; Decatur, IL, USA), adding “the best that can be said is that commercial products sold by ADM would have been an indeterminate and variable mixture of conventional and non-GM soybeans.”

Ermakova answered:

“I can only state that my laboratory did receive soy clearly labeled as GM and non-GM soy. Quantitative analysis of RR soy using the ‘CP4-LEC-RTPCR’ construct confirmed the presence of this transgene in 100% of the GM soy flour. In the traditional, non-GM soy flour, only traces ($0.08 \pm 0.04\%$) of the same construct were present. In fact, we checked all kinds of soy. The analysis of GM soy and non-GM soy was performed by ‘blinded’ operators”

KA: Note that Ermakova does not explicitly confirm the source of her feed stuff used for the experiment.

CMMG say E’s statement is scientifically incorrect, since labeling alone and the analytical method used does not guarantee the quality, purity and homogeneity required in the international protocol of the

OECD, see (OECD, 1998b), where the precise details are given for the description of the diet rules:
“details of test substance formulation/diet preparation, achieved concentration, stability and homogeneity of the preparation”

CMMG: They re-iterate their criticism about the origin and quality of feed in their reply:

“she still has not established the identity of the material tested, which is of paramount importance to an animal feeding study. The methodology and materials described by Ermakova are fatally flawed in several additional respects and as a consequence invalidate the experimental results. One of the basic issues is the content of the feed. The Archer Daniels Midland (ADM) catalog states and Bruce Chassy contacted ADM on October 20 and November 5, 2007, to verify that they do not sell—and have never sold—a 100% GM-soy product containing the RR-40-3-2 line to which Ermakova refers.”

KA: It is really astounding to see the way Dr. Ermakova insists despite clear evidence to her statements, which are falsified by two simple phone calls of Bruce Chassy to ADM, and even more so her inert reaction about such behavior – or – to give her the benefits of doubt: she actually did not understand the point made – namely that the international protocol related to the feeding source certification was not respected in the procedures of her experiments.

There are many other detailed exchanges of opinions, but it’s clear that CMMG keep to the international standards of experimental procedures, and E. considers herself to be free enough to change those rules in many details. The correct procedures of food safety experiments have now been explained in lots of details in a draft text by (Chassy & Parrott, 2009). This study is commented with lots of examples in the revised ASK-FORCE contribution of the food safety experiments of A. Pusztai.

However, there is one item which should not be omitted here: E. cites a range of experimental papers demonstrating negative effects on rat organs related to GM feed. She cites explicitly the papers of the research lab of Malatesta (Malatesta et al., 2003; Malatesta et al., 2002a; Malatesta et al., 2002b; Malatesta et al., 2005), which demonstrate some slight negative effects on lab mice organs. CMMG show in their analysis, that the Italian group also did not comply with international laboratory standards, but in contrast to Ermakova the results were interpreted with caution – facts which are usually not communicated by the opponents of GM crops. As a whole the citation habits of Ermakova can be described only as unethical filtering away unwelcome science.

KA agrees therefore with CMMG about their general conclusions, given here in full length:

CMMG: “All scientific work can and should be subject to the full force of reasoned criticism. Ermakova’s remarks that there is an industry conspiracy to criticize and suppress articles containing evidence of the negative effects of GMOs is refuted by Ermakova herself when she cites published work on GMOs (albeit flawed) that shows negative effects. Rather than a worldwide conspiracy, we deduce there are few publications showing harm because GM soy is safe and does not cause harm. We conclude then, that Ermakova’s research relied on experimental designs that fall short of internationally accepted norms, with animals handled in such a way that even control lines were negatively affected. The feeding studies used materials that were characterized inadequately, incorrectly or not at all. Thus, no scientific conclusions can be drawn from the work.

We must stress again that GM soy has been thoroughly studied in the peer-reviewed literature, by regulators around the globe and by the cruel testing place of the real world. More than 500 million hectares were cultivated over the past decade. Much of this has been fed at high concentration to domestic animals, poultry and fish. There have been no reports of stunted growth or reproductive failure as one might expect if Ermakova were correct.”

7.2. Opponents of GM crops supporting Dr. Ermakova in Letters to Nature Biotechnology

In the same second round of papers in Nature Biotechnology, there were a number of opponents of GM crops and from the organic farming scene who criticized heavily the procedure on how Dr. Ermakova was treated in the first feature in Nature Biotechnology. Without repeating all the letters (Cummings, 2007; Heinemann & Traavik, 2007; Ho & Saunders, 2007; John, 2007; Leifert, 2007), here the last one in full extent:

"I was very disappointed by your September Feature critiquing the results of Irina Ermakova, especially as I had previously considered Nature Biotechnology one of the best scientific journals in the area of biotechnology."

"I feel that publishing selected extracts of Ermakova's results and experimental methods was inappropriate. These results should have been published as a full paper with a detailed description of the methods. Presenting the work in this manner would have allowed everybody in the scientific world to assess Ermakova's methodologies and results. Indeed, the author herself feels that her data set does not give all answers and, due to limited resources, was constrained in what she could do. After publication of her paper, comments could have been invited from the scientific community, which could also have been published by the journal."

Publishing edited extracts of her work together with comments of scientists who are well known to uncritically reject even the notion that there may be risks associated with GM crops gives me the strong impression that your journal is politically motivated to (i) defend the dogma that there are no potential health risks associated with GM crops, (ii) destroy the reputation of scientists that dare to challenge that dogma and (iii) prevent such scientists from gaining the resources to continue their work on risks of GM crops and how to avoid them. There are many analogies to the treatment that Arpad Pusztai received after he reported negative effects of GM crops on rats. His work was criticized without him being given a chance to defend himself or publish his work until much later. Also, he has until this date not been given the opportunity to repeat and/or continue his work and no one else was commissioned to repeat it either. Your treatment of Irina Ermakova will confirm the views of many in civil society in the following two respects: first, you reinforce the idea that the scientific community as a whole is dogmatic rather than objective when it comes to GM crops; and second, that the scientific establishment tries to suppress data and rubbish scientists when they report data indicating risks associated with GM crops, rather than applying the 'precautionary principle' and doing further research to investigate the mechanisms underlying such phenomena. I feel that the most honorable way forward for Nature Biotechnology would be to invite Ermakova to submit her results as a full paper to the journal, for the journal to select 'non-dogmatic reviewers' for the paper, and for the paper to then undergo the normal peer-review process. If the paper were rejected, Ermakova could be given clear indications as to why and how the issues criticized should be addressed. If she were unable to address the criticisms and do the extra experimental work as a result of the difficulty of getting hold of the materials (e.g., GM and near isogenic non-GM lines) because biotech companies refuse to supply her with them, then this could also be published by Nature Biotechnology. Arpad Pusztai was never allowed to repeat and do supplementary studies to address the criticisms of his work (and other laboratories were also not given the chance to repeat his work due to GM-crop materials and other resources not being made available). It would be a great shame if this were to happen again, particularly if one of the most respected scientific journals was implicated in suppressing such work." Carlo Leifert.

The comment is similar for all the above cited letters:

There is no word about the scientific quality of the experiments of Ermakova, although there was valid criticism in the first NB paper. All letter writers insist, without knowing the details, on the 'unfair' treatment of E., which was then explained with an apology to E. by Marshall and corrected in the second publication. In referring to the case of A. Pusztai, Leifert reveals his own heavy bias and deep mistrust about GM crops, he describes the case as if no valid criticism would have been published about Pusztai's work. In both cases he deplores that those experiments have not been repeated or published – true - but: how can you repeat or publish experiments with such clear methodological flaws? With all letter writers the syndrome of ignoring criticism of methodological flaws and follow-up scientific literature on food biosafety experiments is evident. In the way, Leifert is dismissing some of the most reputed scientists in experimental food biosafety science, he again demonstrates strong political bias.

7.3. Correspondence of Dr. Ermakova with Monsanto in 2010

An interesting email exchange (Ermakova, 20100623) can be downloaded from her new website:

http://www.irina-ermakova.ru/en/index.php?option=com_content&task=view&id=28&Itemid=2

See also <http://www.ask-force.org/web/Ermakova/Ermakova-Monsanto-Mail-Exchange-20100623.pdf>

In this letter she starts with a positive declaration on GM crops, which contrasts heavily with her earlier condemnations, painting a catastrophic picture for Russia and the world when GM crops would be adopted ¹, here a citation:

"I hope very much that ACNFP will help us to perform detailed and complex investigations and to stop uncontrolled distribution of and contamination by imperfect genetically modified organisms that can cause such human diseases as cancer, allergy, brain and heart diseases, can lead to disappearance of a great number of different species of useful bacteria, plants and animals and cause destruction of the nature and the biosphere. this is a major shift in her opinion on GM crops:" (Ermakova, 2006b)

And some 4 years later a citation from her mail letter to Monsanto:

I am absolutely sure that the biotechnology is the future of humanity and like the idea of gene introduction. However we must think about biosafety. My opinion is that the main reason of the negative effect obtained by independent scientists and by me also is the imperfection of gene introduction procedure used for GMO creation. (Ermakova, 20100623)

No wonder, that Monsanto answered in a polite, but clearly noncommittal way.

8. Rebuttals to Dr. Ermakovas work by science committees and experts

8.1. EFSA: European Food Safety Agency

As usual, the EFSA was also asked by the European Commission for an opinion on the work of Dr. Ermakova, which was – no surprise – thoroughly negative: (EFSA, 2006):

"The European Commission has asked EFSA to investigate the data presented by Dr. Ermakova (from Russia) on a six times higher mortality rate in progeny of rats fed GM soya and to report back on this matter to the Commission. The GMO Panel discussed these data and has searched for all available information relating to these recent revelations. The data which were published on the internet have not been reported in any scientific journal or report, nor have they been endorsed by a scientific

¹ Ermakova, Reply to ACNFP: <http://www.botanischergarten.ch/Ermakova/Ermakova-GMO-Reply-ACNFP-2006.pdf>

organization. The GMO Panel is unable to conclude on the study on GM soya conducted by Dr. Ermakova because of lack of details on the experiments presented. For example, the author has not indicated which GM soya was used in the study and there is no detailed information on the test diet and controls used. EFSA has been in close contact with the secretariat of the ACNFP (UK) on this matter. In a statement⁵, published on the UK website, the ACNFP similarly has concluded that ‘without information on a range of important factors conclusions cannot be drawn from this work’. The Panel drew the attention to a previous study by (Brake & Evenson, 2004) published in a peer-reviewed paper showing no adverse effects of GM glyphosate-tolerant soya on multiple generations in mice.

The GMO Panel expressed concerns about the frequent ad hoc consultations of the Panel on data/allegations that are not scientifically founded.”

This last sentence can also be seen as an indirect criticism of the European Commission, in particular of Commissioner Stavros Dimas, since it was him demanding an opinion from EFSA, although the work of Ermakova has not been published in a peer reviewed journal.

8.2. ACNFP Advisory Committee on Novel Foods and Process

The Advisory Committee on Novel Foods and Processes (ACNFP) is a non-statutory, independent body of scientific experts that advises the Food Standards Agency of the United Kingdom on any matters relating to novel foods (including genetically modified foods) and novel processes (including food irradiation).

The ACNFP issued a short report fully refuting the results of Dr. Ermakova’s rat experiments:

(ACNFP, 2005) Citation:

“In conclusion, there are a number of possible explanations for the results obtained in this preliminary study, apart from the GM and non-GM origin of the test materials. Without information on a range of important factors conclusions cannot be drawn from this work. The Committee Secretariat is contacting Dr Ermakova to obtain further information on this study and the Committee will consider any further information that can be obtained and review the position if a full report of the study is published in the peer-reviewed literature.”

The Committee also notes that Dr Ermakova’s findings are not consistent with those described in a peer-reviewed paper published in 2004. (Brake & Evenson, 2004). In a well controlled study no adverse effects were found in mice fed on diets containing 21% GM herbicide-resistant soya beans and followed through up to 4 generations.

8.3. More scientific feeding studies without negative effects in peer reviewed journals

The answer of Dr. Ermakova: (Ermakova, 2006b) is with good reason to point out the many differences of the (Brake & Evenson, 2004) paper, which makes it difficult use the paper for comparison, but at the same time she is again revealing that her work does not comply in numerous incidences with the international procedures which *need* to be adopted for reliable results.

“The results showed that the transgenic foodstuffs had no effect on macromolecular synthesis or cell growth and differentiation as evidenced by no differences in the percentages of testicular cell populations (haploid, diploid, and tetraploid) between the transgenic soybean-fed mice and those fed the conventional diet. Additionally, there were no differences in litter sizes and body weights of the two groups. It was concluded that the transgenic soybean diet had no negative effect on fetal, postnatal, pubertal or adult testicular development .”

Without going into the details of food safety experiments published in peer reviewed journals and complying to the international experimental procedures as cited above, here an example demonstrating, that there is *no difference* between herbicide resistant soybeans and conventional traits: (Appenzeller et al., 2008). The abstract:

*“Optimum(TM)GAT(TM) 1 soybean is a genetically modified (GM) soybean containing event DP-356043-5 (356043) that was produced by integration of the coding sequences of the GAT4601 and GM-HRA proteins. In planta expression of these proteins confers tolerance to glyphosate and sulfonylurea/imidazolinone herbicides, respectively. This paper reports the results from a subchronic rat feeding study conducted with 356043 soybeans. Dehulled/defatted toasted meal and toasted ground hulls were prepared from soybeans from untreated plants (356043), herbicide-treated plants (356043 + Gly/SU), non-transgenic isoline control (091), and three commercial non-transgenic reference varieties (93B86, 93B15, and 93M40). Individual diets conforming to standard certified rodent chow formulation (Purina Rodent LabDiet® 5002) were prepared with 20% meal (w/w) and 1.5% hulls (w/w). Diets were fed to young adult Sprague-Dawley rats (12/sex/group) for at least 93 days. **Compared with rats fed the isoline control or conventional reference diets, no biologically-relevant, adverse effects were observed in rats fed diets containing 356043 or 356043 + Gly/SU soybean with respect to body weight/gain, food consumption/efficiency, clinical signs, mortality, ophthalmology, neurobehavioral assessments (sensory response, grip strength, motor activity), clinical pathology (hematology, coagulation, serum chemistry, urinalysis), organ weights, and gross and microscopic pathology. The results from this study indicate that 356043 soybeans are as safe and nutritious as conventional non-GM soybeans.**”*

In another recent study, again no meaningful differences between rats fed with transgenic or non-transgenic soybeans have been found (Sakamoto et al., 2008), the full abstract:

*“A chronic feeding study to evaluate the safety of genetically modified glyphosate-tolerant soybeans (GM soybeans) was conducted using F344 DuCrj rats. The rats were fed diet containing GM soybeans or Non-GM soybeans at the concentration of 30% in basal diet. Non-GM soybeans were a closely related strain to the GM soybeans. These two diets were adjusted to an identical nutrient level. In this study, the influence of GM soybeans in rats was compared with that of the Non-GM soybeans, and furthermore, to assess the effect of soybeans themselves, the groups of rats fed GM and Non-GM soybeans were compared with a group fed commercial diet (CE-2). General conditions were observed daily and body weight and food consumption were recorded. At the termination (104 weeks), animals were subjected to hematology, serum biochemistry, and pathological examinations. There were several differences in animal growth, food intake, organ weights and histological findings between the rats fed the GM and/or Non-GM soybeans and the rats fed CE-2. **However, body weight and food intake were similar for the rats fed the GM and Non-GM soybeans. Gross necropsy findings, hematological and serum biochemical parameters, and organ weights showed no meaningful difference between rats fed the GM and Non-GM soybeans. In pathological observation, there was neither an increase in incidence nor any specific type of non-neo-plastic or neo-plastic lesions in the GM soybeans group in each sex. These results indicate that long-term intake of GM soybeans at the level of 30% in diet has no apparent adverse effect in rats.**”*

“In conclusion, dietary FFSBM might result in a mild stress response in liver and distal intestine, evaluated by normalized mRNA levels of the biomarker proteins CAT and HSP70, but were independent of the soy being GM or not.”

(Sagstad et al., 2008) again came to the same results feeding GM and non-GM soybeans to salmon:

“In conclusion, results obtained from this study showed that RRS did not affect growth, feed utilization, most organ weights, proximate composition or haematology. Changes observed in normalized expression of the antioxidant enzymes CAT and SOD in liver and HSP70 in liver and distal intestine were independent of the soy being GM or nGM. GM FFSBM did not affect fish health in any negative way, when compared to FFSBM from the conventional nGM parental line. Enlarged spleen and lowered plasma TAG levels were identified as a GM effect, but both GM and nGM values were equal to the values in fish fed the standard fish meal control diet.”

(Bakke-McKellep et al., 2008) have also done experimental work with salmon, in the abstract again the authors demonstrate that there are no differences detected between GM and non-GM soybeans in the experiments:

“Physiological and health related responses to dietary inclusion of genetically modified (GM) full-fat soybean meal (Roundup Ready (R); GM-soy) and maize (MON810 (R) Bt-maize; GM-maize), as well as non-parental, untransformed lines (nGM-soy and nGM-maize D2), were evaluated in farmed Atlantic salmon (Salmo salar L.) parr during the first 8 months of feeding. Significant effects of dietary GM presence were only found in intestinal Na⁺-dependent D-glucose uptake and SGLT1 protein level in the region pyloric caeca in which the highest values were found in the GM-soy, intermediate in the nGM-soy, and lowest in the standard FM fed groups. Data from this study confirm that GM soybeans (RRS (R)) and maize (MON810 (R)) at inclusion levels of about 6% appear to be as safe as commercially available nGM soy and maize in diets for Atlantic salmon parr. Results from studies with higher inclusion levels and with non-modified, isogenic or near-isogenic parental lines as control groups are pending.”

It is also interesting to note, that on the transcriptomic level, herbicide resistant soybeans are not different from non-transgenic ones (Zhu et al., 2008): end of abstract:

“Quantitative real-time reverse-transcribed Polymerase Chain Reaction was conducted on selected genes and yielded results consistent with those from the microarrays. Collectively, these data indicate that there are no major transcriptomic changes associated with currently used glyphosate-resistant soybean.”

In a recent extensive literature review about facts and fiction in safety research about GM food (Batista & Oliveira, 2009) are not naming one single case of correctly carried through toxicological experiment with a detrimental outcome for GM soybeans (and other regulated crops). The general conclusion cited: *“Genetic engineering is a very recent technology. Every new technology raises fear, and it is understandable that consumers have doubts about potential health, environmental and ethical implications. Nevertheless, the beneficial effects of genetic engineering are unquestionable, not only in developing novel crops but also in developing new medical products. Across human history, we have already faced several similar situations, such as the discovery of electricity and antibiotics and the invention of cars and planes, to name a few, and despite the potential risks, which undoubtedly exist, we have always decided to go ahead in the name of progress. In this respect, genetic engineering should simply be seen as another humanmade discovery that has tremendous potential not only for developing but also for developed countries.”*

As one example a study of GM soy feed safety, on whether transgenes or fragments thereof can be detected in animals having been fed with GM soy: (Jennings et al., 2003): The result was negative.

*“A 185-bp fragment of the porcine preprolactin (prl) gene, used as a positive control, was amplified from all samples showing that the DNA preparations were amenable to PCR amplification. Using a competitive immunoassay with an LOD of approximately 94 ng of CP4 EPSPS protein/g of pork muscle, neither the CP4 EPSPS protein nor the immune-reactive peptide fragments were detected in loin muscle homogenates from pigs fed RR soybean meal. **Taken together, these results show that neither small fragments of transgenic DNA nor immune-reactive fragments of transgenic protein are detectable in loin muscle samples from pigs fed a diet containing RR soybean meal.”***

Beneficial effects of transgenic soybeans:

Soybean has intrinsic allergens which can be eliminated by genetic engineering: (Herman, 2003):

“Allergenic reactions to proteins expressed in GM crops has been one of the prominent concerns among biotechnology critics and a concern of regulatory agencies. Soybeans like many plants have intrinsic allergens that present problems for sensitive people. Current GM crops, including soybean, have not been shown to add any additional allergenic risk beyond the intrinsic risks already present. Biotechnology can be used to characterize and eliminate allergens naturally present in crops. Biotechnology has been used to remove a major allergen in soybean demonstrating that genetic modification can be used to reduce allergenicity of food and feed. This provides a model for further use of GM approaches to eliminate allergens.”

All the cited studies have been done according to the required international experimental protocols.

Finally (although this is not the main topic of this feature) one of the major reviews on the sustainable use of transgenic soybeans with a broad focus have been recently published: (CAST et al., 2009) and a paper to rebuff the myth that transgenic soybeans are the cause of a growing use of herbicides. (Carpenter & Gianessi, 2000).

9. About regulatory rules when working with food safety experiments and publications

Many of the test procedures have now been published and are easy to access, the most important ones are: (EPA Guidelines Food Toxicity, 1998; FDA, 2000; OECD, 1983, 1997, 1998a, b, c, d, 2003, 2007, all years). There are also important papers describing some of those rules, two examples: (van Haver et al., 2008) with extensive descriptions of experimental rules and a summary:

- *The comparative approach to safety and nutritional testing of food and feed derived from GM plants.*
- *In silico and in vitro tools available for safety and nutritional testing of GM plant derived food and feed.*
- *Testing of defined single substances from GM plant derived food and feed in in vivo studies.*
- *Testing of whole GM plant derived food and feed in animal feeding studies.*
- *Importance of a structured approach for development of data for the pre-market safety and nutritional testing of GM plant derived food and feed.*
- *Role of post-market monitoring.*

Another instructive paper is now circulating as a draft (Chassy & Parrott, 2009), their thoughts will soon be published on an open website. They cite (Ronald & Adamchak, 2008) with a remarkable checklist on whether you can trust an author and paper:

1. *"Determine the primary source of information"*
2. *"Check if the work was published in a peer-reviewed journal"*
3. *"Check if the journal has a good reputation for scientific research"*
4. *"Determine if there is an independent confirmation by another published study"*
5. *"Assess whether a potential conflict of interest exists"*
6. *"Assess the quality of institution or panel"*
7. *"Examine the reputation of the author"*

The Ermakova experience underscores the need for scientists to submit their research to their peers for review. While papers that employ improper methods or which draw incorrect conclusions can slip through peer review, rigorous review is an essential first step in separating good research from bad one. Peer-reviewed papers must stand the tests of repetition and gain acceptance by the wide scientific community to be considered valid. In the age of instant electronic publishing and journalists to whom truth is not important, claims such as Ermakova's will predictably continue to appear. The scientific community must learn to actively police the frontiers of science as has been done in this case by Andy Marshall and Nature Biotechnology who are to be commended for saying no to propaganda about fatally-flawed experiments.

After all, it was *Karl Popper* who introduced an important principle to distinguish between science and pseudoscience, for a precise philosophical discussion see Hull (Hull, 1999): *Scientific theories, in order to*

be genuinely scientific, must be falsifiable. This is actually the foundation of a truly workable peer review process. The caveat: The peer review process is only as good as the reviewers involved, this and much more details and rules are given by (Grainger, 2007).

10. Statements of GM crop opponents on websites

Two of the most blatant examples of blindly following the conclusions of Dr. Ermakova, and exaggerating them grossly is given by Jeffrey Smith (Smith, 2005, 2006), without even a shred of attempt to scientifically review Ermakova's results and methods from the point of view of accurate experimentation with rats.

Also the statement of the ISIS website of Mae van Ho (Ho, 2007) is interesting: It does not go into scientific argumentation, instead, it indulges in to grotesque factual exaggeration.

10.1. Some helpful powerpoint slides you can find under:

<http://www.botanischergarten.ch/Ermakova/Ermakova-Powerpoints.pdf>
<http://www.botanischergarten.ch/Ermakova/Ermakova-Powerpoints.ppt>

11. Scientific rebuttals of Ermakovas experiments from websites with direct access

(Preston, 2005; Strauss, 2006; Tribe, 2006)

More details and links can be seen under the GMO Pundit of David Tribe (a highly recommendable blog, often working together with AgBioWorld, a listserv, which also posted details about the Ermakova case.

<http://gmopundit2.blogspot.com/search?q=ermakova> and <http://gmopundit2.blogspot.com/2007/07/full-monty-on-animal-feeds.html>

Thanks go to Bruce Chassy, Mark Cantley and Vivian Moses for helpful comments.

12. References cited

ACNFP (2005)

STATEMENT ON THE EFFECT OF GM SOYA ON NEWBORN RATS, ACNFP pp 1 (Report)

<http://www.acnfp.gov.uk/acnfppapers/gmissues/acnfpgmsoya> AND

<http://www.botanischergarten.ch/Ermakova/ACNFP-Statement-Ermakova-2005.pdf>

Ammann, K. (20110111)

Review: Arpad Pusztai's Feeding experiments of GM potatoes with lectins to rats: Anatomy of a controversy 1998 - 2009. In ASK-FORCE contribution AF-2, Vol. AF-9, pp. 57. Ammann K., Neuchatel

Appenzeller, L.M., Munley, S.M., Hoban, D., Sykes, G.P., Malley, L.A., & Delaney, B. (2008)

Subchronic feeding study of herbicide-tolerant soybean DP-356043-5 in Sprague-Dawley rats. Food and Chemical Toxicology, 46, 6, pp 2201-2213

doi: DOI: 10.1016/j.fct.2008.02.017

Bakke-McKellep, A.M., Sanden, M., Danieli, A., Acierno, R., Hemre, G.I., Maffia, M., & Krogdahl, A. (2008)

Atlantic salmon (*Salmo salar* L.) parr fed genetically modified soybeans and maize: Histological, digestive, metabolic, and immunological investigations. *Research in Veterinary Science*, 84, 3, pp 395-408
10.1016/j.rvsc.2007.06.008

Batista, R. & Oliveira, M.M. (2009)

Facts and fiction of genetically engineered food. *Trends in Biotechnology*, 27, 5, pp 277-286
10.1016/j.tibtech.2009.01.005

Brake, D.G. & Evenson, D.P. (2004)

A generational study of glyphosate-tolerant soybeans on mouse fetal, postnatal, pubertal and adult testicular development. *Food and Chemical Toxicology*, 42, 1, pp 29-36

Carpenter, J. & Gianessi, L. (2000)

Herbicide use on roundup ready crops. *Science*, 287, 5454, pp 803-804
<Go to ISI>://000085136400019

CAST, Heatherly, L., Dorrance, A., Hoefft, R., Onstad, D., Orf, J., Porter, P., Spurlock, S., & Young, B. (2009)

Sustainability of U.S. Soybean Production: Conventional, Transgenic, and Organic Production Systems, CAST, Council for Agricultural Science and Technology pp 106 Ames, Iowa, USA (Report)

Chassy, B., Moses, V., McHughen, A., & Giddings, V. (2007)

GM soybeans - revisiting a controversial format - Response. *Nature Biotechnology*, 25, 12, pp 1356-1358
10.1038/nbt1207-1356b

Chassy, B. & Parrott, W. (2009)

Is This Study Believable? Examples from Animal Studies with GM Foods. In *Agricultural Biotechnology*, pp. 9. University of California, Davis, Davis, California

Cummings, J. (2007)

GM soybeans—revisiting a controversial format. letter to the editor. *Nature Biotechnology*, 25, 12, pp 1356

EFSA (2006)

Draft Minutes, Chapter 15, Any Other Business: Ermakova. EU- EFSA
http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/gmo_minutes_23rd_plenmeet1.1.pdf?ssbinary=true
AND <http://www.botanischergarten.ch/Ermakova/EFSA-Draft-Minutes-23rd-Plenary-Ch.15-Ermakova-2006.pdf>

EPA Guidelines Food Toxicity (1998)

OPPTS Harmonized Test Guidelines, Series 870 Health Effects Test Guidelines -- 6200 Neurotoxicity, EPA, Office of Prevention, Pesticides and Toxic Substances pp 13 (Report)
http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/ AND
<http://www.botanischergarten.ch/EPA/EPA-870-6200-Neurotoxicity-1998.pdf>

Ermakova, I. (20100623)

Letter of Irina Ermakova to Monsanto: New Idea, including answer of Monsanto. Ermakova, I., Moscow, St. Louis
<http://www.irina-ermakova.ru/en/index.php?option=com_content&task=view&id=28&Itemid=2> See also
<<http://www.ask-force.org/web/Ermakova/Ermakova-Monsanto-Mail-Exchange-20100623.pdf>>

Ermakova, I.V. (2001 - 2008)

Electronic Source: Ecology and our Life. Irina Ermakova's Homepage, published by: Svetlana Varchenko now living in North Carolina, USA and Dmitry Rumyantsev 2003 - 2006
<http://www.irina-ermakova.by.ru/eng/index.htm> AND new website <http://www.irina-ermakova.ru/en/>

Ermakova, I.V. (2005a)

Electronic Source: Genetically modified soy affects posterity: results of Russian scientists' studies. Report from a Symposium On October 10, over genetic modification, organized by the National Association for Genetic Security (NAGS), published online December 11, 2005 (ed R.N. Agency), REGNUM online

Ermakova, I.V. (2005b)

People eating genetically modified food may have rat-short lifespan, Prawda 27.10.2005 pp (Prawda Article)

Ermakova, I.V. (2006a)

Genetically modified organisms and biological risks, Davos, Switzerland, Proceedings of International Disaster Reduction Conference (IDRC) August 27th – September 1st, 2006,, Ed. pp 168-172
<http://www.irina-ermakova.by.ru/eng/art/art16.html> AND <http://www.botanischergarten.ch/Ermakova/Ermakova-Proceedings-Davos-2006.pdf>

Ermakova, I.V. (2006b)

Electronic Source: Genetically modified organisms could be real threat to the life. {Reply to ACNFP on the "Statement on the effect of GM soy on newborn rats"}, <http://irina-ermakova.by.ru/eng/art/art15.html> AND <http://www.botanischergarten.ch/Ermakova/Ermakova-GMO-Reply-ACNFP-2006.pdf> AND <http://www.botanischergarten.ch/Ermakova/Ermakova-Cummings-Reply-to-ACNFP-2006.pdf>

Ermakova, I.V. (2006c)

Influence of genetically modified soya on the birth-weight and survival of rat pups., Frankfurt am Main Oekoinstitut e.V. Institute for Applied Ecology in Freiburg and Greenpeace, Proceedings of the Conference Epigenetics, Transgenic Plants and Risk Assessment, December 1st., Ed. K. Moch pp 41-48
<http://www.oeko.de/files/forschungsergebnisse/application/octet-stream/download.php?id=277> full report
<http://www.oeko.de/oekodoc/277/2006-002-en.pdf>

Ermakova, I.V. (2007)

GM soybeans - revisiting a controversial format. Nature Biotechnology, 25, 12, pp 1351-1354
 10.1038/nbt1207-1351

Ermakova, I.V. & Pichugina, E. (2007)

Russians threatened by GM Genocide "MK" 26. January 2007 Interview pp ("MK" Article)

Ewen, S.W.B. & Pusztai, A. (1999)

Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. The Lancet, 354, 9187, pp 1353-1354

FDA (2000)

Redbook 2000 Chapter IV.C.9.a.: Guidelines for Reproduction Studies, FDA pp (Report)
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/ucm078396.htm> AND <http://www.botanischergarten.ch/FDA/FDA-Redbook-IV-C-9a-Reproduction-2000.pdf>

GM-Free-Cymru (2007)

Electronic Source: NATURE BIOTECHNOLOGY FACILITATES PREMEDITATED GM ROTTWEILER ATTACK, How a well-known scientific journal "set up" an honest scientist through a conspiracy of lies and deception,
http://www.gmfreecymru.org/pivotal_papers/rottweiler.htm AND <http://www.botanischergarten.ch/Ermakova/GM-Free-Rottweiler-Attack-Ermakova-20070917.pdf>

Grainger, D.W. (2007)

Peer review as professional responsibility: A quality control system only as good as the participants. Biomaterials, 28, pp 5199-5203

Heinemann, J. & Traavik, T. (2007)

GM soybeans—revisiting a controversial format. letter to the editor. Nature Biotechnology, 25, 12, pp 1355-1356

Herman, E.M. (2003)

Genetically modified soybeans and food allergies. Journal of Experimental Botany, 54, pp 1317-1319
<http://www.ingentaconnect.com/content/oup/exbotj/2003/00000054/00000386/art01317>

Ho, M.W. (2007)

GM Soya Fed Rats: Stunted, Dead, or Sterile, ISIS Press Release 28. 11. 2007 pp (ISIS Press Release 28. 11. 2007 Article)

Ho, M.W. & Saunders, P. (2007)

- GM soybeans—revisiting a controversial format. letter to the editor. *Nature Biotechnology*, 25, 12, pp 1355
- Hull, D.L. (1999)**
The Use and Abuse of Sir Karl Popper. *Biology and Philosophy*, 14, 4, pp 481-504
- Jennings, J., Kolwyck, D., Kays, S., Whetsell, A., Surber, J., Cromwell, G., Lirette, R., & Glenn, K. (2003)**
Determining whether transgenic and endogenous plant DNA and transgenic protein are detectable in muscle from swine fed Roundup Ready soybean meal. *JOURNAL OF ANIMAL SCIENCE*, 81, 6, pp 1447-1455
<http://jas.fass.org/cgi/content/full/81/6/1447> and <http://www.botanischergarten.ch/Feed/Jennings-Anim-Science-2003.pdf>
- John, B. (2007)**
GM soybeans—revisiting a controversial format. letter to the editor. *Nature Biotechnology*, 25, 12, pp 1354-1355
- Kuiper, H., Noteborn, H., & Peijnenburg, A.C.M. (1999)**
Adequacy of methods for testing the safety of genetically modified foods *Lancet*, 354, 9187, pp 1315-1316
- Lean, G. (2006)**
GM; New study shows unborn babies could be harmed, *The Independent on Sunday* 8. January 2006 pp 1 (The Independent on Sunday Article)
<http://www.commondreams.org/headlines06/0108-01.htm> AND <http://www.botanischergarten.ch/Ermakova/Lean-GM-New-Study-Unborn-Babies-2006.pdf>
- Leifert, C. (2007)**
GM soybeans—revisiting a controversial format. letter to the editor. *Nature Biotechnology*, 25, 12, pp 1355
- Malatesta, M., Biggiogera, M., Manuali, E., Rocchi, M.B.L., Baldelli, B., & Gazzanelli, G. (2003)**
Fine structural analyses of pancreatic acinar cell nuclei from mice fed on genetically modified soybean. *European Journal of Histochemistry*, 47, 4, pp 385-388
- Malatesta, M., Caporaloni, C., Gavaudan, S., Rocchi, M.B.L., Serafini, S., Tiberi, C., & Gazzanelli, G. (2002a)**
Ultrastructural morphometrical and immunocytochemical analyses of hepatocyte nuclei from mice fed on genetically modified soybean. *Cell Structure and Function*, 27, 4, pp 173-180
- Malatesta, M., Caporaloni, C., Rossi, L., Battistelli, S., Rocchi, M.B.L., Tonucci, F., & Gazzanelli, G. (2002b)**
Ultrastructural analysis of pancreatic acinar cells from mice fed on genetically modified soybean. *Journal of Anatomy*, 201, 5, pp 409-415
- Malatesta, M., Tiberi, C., Baldelli, B., Battistelli, S., Manuali, E., & Biggiogera, M. (2005)**
Reversibility of hepatocyte nuclear modifications in mice fed on genetically modified soybean. *European Journal of Histochemistry*, 49, 3, pp 237-241
- Marshall, A. (2007)**
GM soybeans - revisiting a controversial format - Response. *Nature Biotechnology*, 25, 12, pp 1359-1360
10.1038/nbt1207-1359
- Marshall, A., Ermakova, I., Chassy, B., Giddings, V., McHughen, A., & Moses, V. (2007)**
GM soybeans and health safety - a controversy reexamined. *Nature Biotechnology*, 25, 9, pp 981-987
10.1038/nbt0907-981
- OECD (1983)**
OECD Guidelines for the Testing of Chemicals, Test No. 415: One-Generation Reproduction Toxicity Study pp 8 (Report)
<http://puck.sourceoecd.org/vl=4722122/cl=14/nw=1/rpsv/ij/oecdjournals/1607310x/v1n4/s16/p1> AND
<http://puck.sourceoecd.org/vl=4722122/cl=14/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s16/p1.idx> AND
<http://www.botanischergarten.ch/OECD/OECD-415-One-Generation-Repro-Tox-Study-1983.pdf>
- OECD (1997)**
Report of the OECD Workshop on the Toxicology and Nutritional Testing of Novel Foods, 5-8 March 1997., OECD Paris pp Aussois, France, (Report)

OECD (1998a)

407 Repeated Dose 28-Day Oral Toxicity Study in Rodents, Adopted by the Council on 27th July 1995 pp OECD GUIDELINE FOR THE TESTING OF CHEMICALS (Report)

<http://www.botanischergarten.ch/OECD/OECD-Repeated-Dose-Toxicity-407.pdf>

OECD (1998b)

408 Repeated Dose 90-Day Oral Toxicity Study in Rodents (Updated Guideline, adopted 21st September 1998) pp (Report)

<http://www.botanischergarten.ch/OECD/OECD-Repeated-90day-on-Rodents-408-1998.pdf> AND complete list under <http://caliban.sourceoecd.org/vl=3523981/cl=15/nw=1/rpsv/cw/vhosts/oecdjournals/1607310x/v1n4/contp1-1.htm>

OECD (1998c)

OECD Principles on Good Laboratory Practice (as revised in 1997), OECD. No.1 pp 41 Oecd Series On Principles Of Good Laboratory Practice And Compliance Monitoring Number 1 Paris (Report)

[http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/NT00000C5A/\\$FILE/01E88455.PDF](http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/NT00000C5A/$FILE/01E88455.PDF) AND <http://www.botanischergarten.ch/OECD/OECD-Food-Safety-Principles-1998.pdf>

OECD (1998d)

Test Guideline 408. OECD Guideline for Testing of Chemicals. Repeated dose 90-day oral toxicity study in rodents., OECD pp 10 OECD Guidelines for the Testing of Chemicals Paris (Report)

<http://lysander.sourceoecd.org/vl=2531000/cl=18/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s9/p1.idx> AND <http://www.botanischergarten.ch/OECD/OECD-Repeated-90day-on-Rodents-408-1998.pdf>

OECD (2003)

Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (eds Environment), Vol. 9, pp. 46. OECD Environmental Health and Safety Publications.ENV/JM/MONO(2003)10

[http://www.olis.oecd.org/olis/2003doc.nsf/43bb6130e5e86e5fc12569fa005d004c/4502bee1ca16c943c1256d520028e259/\\$FILE/JT00147696.PDF](http://www.olis.oecd.org/olis/2003doc.nsf/43bb6130e5e86e5fc12569fa005d004c/4502bee1ca16c943c1256d520028e259/$FILE/JT00147696.PDF) AND World Wide Web site (<http://www.oecd.org/biotrack/>) AND <http://www.botanischergarten.ch/OECD/OECD-Safety-2003.pdf>

OECD (2007)

Draft Guidance Document On Mammalian Reproductive Toxicity Testing And Assessment (eds Environment), Vol. 9, pp. 73. OECD Environmental Health and Safety Publications <http://www.oecd.org/dataoecd/5/61/39813058.pdf> AND

<http://www.botanischergarten.ch/OECD/OECD-Draft-Guidance-43-2007.pdf>

OECD (all years)

Electronic Source: OECD Guidelines for the Testing of Chemicals, Section 4: Health Effects, No. 401 - 486,

<http://puck.sourceoecd.org/vl=4722122/cl=14/nw=1/rpsv/cw/vhosts/oecdjournals/1607310x/v1n4/contp1-1.htm>

Preston, C. (2005)

Electronic Source: Genetically-modified Soy Affects Posterity? , published by: AgBioWorld

<http://gmopundit2.blogspot.com/2005/11/russian-super-myth-resprouts.html> AND <http://www.botanischergarten.ch/Ermakova/Preston-GM-Soy-Posteriority-AgBioWorld-20051027.pdf>

Ranade, S.A. & Kumar, N. (2007)

Improved system of anonymous peer review of manuscripts. Current Science, 93, 12, pp 1659-1660

Ronald, P.C. & Adamchak, R.W. (2008) Tomorrow's Table: Organic Farming, Genetics, and the Future of Food Oxford University Press, USA (April 18, 2008) IS: ISBN-10: 0195301757 ISBN-13: 978-0195301755 pp 232

Royal Society (1999)

Review of data on possible toxicity of GM potatoes, The Royal Society pp 5 Ref. 11/99 London (Report)

<http://royalsociety.org/displaypagedoc.asp?id=6170> AND <http://www.botanischergarten.ch/Pusztai/Royal-Society-Review-Pusztai-1999.pdf>

Sagstad, A., Sanden, M., Krogdahl, A., Bakke-McKellep, A.M., Froystad, M., & Hemre, G.I. (2008)

Organs development, gene expression and health of Atlantic salmon (*Salmo salar* L.) fed genetically modified soybeans compared to the near-isogenic non-modified parental line. Aquaculture Nutrition, 14, 6, pp 556-572

10.1111/j.1365-2095.2008.00630.x

Sakamoto, Y., Tada, Y., Fukumori, N., Tayama, K., Ando, H., Takahashi, H., Kubo, Y., Nagasawa, A., Yano, N., Yuzawa, K., & Ogata, A. (2008)

A 104-week feeding study of genetically modified soybeans in F344 rats. *Journal of the Food Hygienic Society of Japan*, 49, 4, pp 272-282

Smith, J. (2005)

Most Offspring Died When Mother Rats Ate Genetically Engineered Soy. *Spilling the Beans newsletter*, October 2005, January-February, pp 1-4

<http://gmfreeireland.org/downloads/Deadrats.pdf> AND <http://www.botanischergarten.ch/Ermakova/Smith-Most-Offspring-died-2005.pdf>

Smith, J. (2006)

She fed the rats GM soy, most offspring died. *Watershed Sentinel*, 16, January-February, pp 24-26

<http://www.botanischergarten.ch/Ermakova/Smith-page-26-Ermakova-2006.pdf>

Solobaeva, T. (2006)

GM Food, *Neva News*, St. Petersburg First Monthly Newspaper 1. April 2006 pp 2 (*Neva News*, St. Petersburg First Monthly Newspaper Article)

http://www.nevanews.com/index.php?id_article=415§ion=4 AND <http://www.botanischergarten.ch/Ermakova/Solobaeva-GM-Food-2006.pdf>

Strauss, S. (2006)

Electronic Source: Don't swallow genetically modified statistics (ed C. News), published by: CBC

http://www.cbc.ca/news/viewpoint/vp_strauss/20060203.html AND <http://www.botanischergarten.ch/Ermakova/Strauss-Dont-Swallow-GM-Statistics-20060203.pdf>

Tribe, D. (2006)

Electronic Source: All you wanted to know about killing Russian rats with GM soybeans? , published by: GMO Pundit David Tribe

<http://gmopundit.blogspot.com/2006/12/all-you-wanted-to-know-about-killing.html> AND <http://www.botanischergarten.ch/Ermakova/Tribe-GMO-Pundit-20061216.pdf>

van Haver, E., Alink, G., Barlow, S., Cockburn, A., Flachowsky, G., Knudsen, I., Kuiper, H., Massin, D.P., Pascal, G., Peijnenburg, A., Phipps, R., Potting, A., Poulsen, M., Seinen, W., Spielmann, H., van Loveren, H., Wal, J.M., & Williams, A. (2008)

Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. *Food and Chemical Toxicology*, 46, pp S2-S70

10.1016/j.fct.2008.02.008

Zhu, J., Patzoldt, W.L., Shealy, R.T., Vodkin, L.O., Clough, S.J., & Tranel, P.J. (2008)

Transcriptome response to glyphosate in sensitive and resistant soybean. *Journal of Agricultural and Food Chemistry*, 56, 15, pp 6355-6363

10.1021/jf801254e