Factor GMO Project: Is the 'largest independent' study on crop biotechnology in limbo?

The Factor GMO is a project primarily organized by a Russian NGO called the National Association for Genetic Safety (NAGS) and claims to be the worlds largest independent study of GMO safety. Its leaders promise to release the results with all transparency and details in the coming years.

[Read Genetic Literacy Project Biotech Gallery profile of the National Association for Genetic Safety]

In November 2014, the group <u>announced</u> it would undertake a \$25 million study of 6,000 rats, which were to be fed a GMO corn diet for a two to three year period with a goal of providing an independent examination of the health impacts of GMO corn and the herbicide used on it. The research is to be done in Russia and western Europe.

As of June 2016, no updates, subsequent findings or details of the study's methodology have been released or provided. The organization has not issued any new releases since April of 2015, when it praised the the classification of glyphosate as 'probably carcinogenic to humans' by the World Health Organization's IARC (a designation the WHO disagrees with). Factor GMO's social media pages show little-to-no activity, posting just once to both Twitter and Facebook combined from December 2015 to June 2016. Its last release was in March 2015, when it announced the study would start later in 2015 (other sections of the site claim the study would start in Spring 2015).

The group continues to solicit donations via its website.

Much of the criticism surrounding the organization is that the group was founded on preestablished conclusions about the negative effects of GMOs and pesticides on human health and the positive health benefits of organic farming. For example, NAGS states on its site that Russia should prioritize organic farming. Lead US scientist on the project, University of California-Irvine biologist Bruce Blumberg, has Ing rejected the scientific consensus that GMOs are safe. Another scientist on the project, Oxana O. Sinitsy, director for science at the Russian Federal State Organization Ministry of Health, is a critic of crop biotechnology. At the announcement, scientist Fiorello Belpoggi, a Fellow of the Collegium Ramazzini Italy, was noted as a Review Board member but her name was removed from the Factor GMO website sometime in 2015.

Others have criticized its lack of funding transparency. The organizers claim the study will be fully transparent in regards to funders, promising a list of financial backers when the study commences in 2015. To date though, no such list has ever been published. Factor GMO also promises on its site the study will not take any money from "industry that manufactures GM crops and their associated pesticides." However, it is unclear if it will take money from organizations and industries that would financially benefit from study results that paint GMOs in a negative light—like the organic food industry.

History

2012

• September 29 – In response to the threatened retraction of the Seralini rat study, NAGS director Elena Sharoykina tells Russia Television (RT) that researchers are planning their own "public experiment reality show" that will "prove or deny GMO's health-threatening influence." They claimed that web cameras, installed in cages with rats, would broadcast all stages of the experiment online and be available on the Internet 24/7 worldwide. The RT report claimed, 'These Russian scientists, who oppose genetically modified organisms (GMO) in food, expect that their year-long experiment will show whether the controversial cultivation process has effects as dangerous as French revelations claimed on September 19." NAGS reported the research would be launched in March 2013 and would cost up to US\$1 million raised through commercial sponsors, government grants and internet financing. Additional details of the study were reported by the Natural Society here. (Note: this reported study and GMO testing reality show have not materialized)

2013

• December 7 – In an article entitled Genetic mutated plants kill people Elena Sharoykina tells the Voice of Russia: "The Russian National Association of Genetic Safety has decided that it was time to put an end to that dispute: to ban GMOs, if they are harmful, or appease the people, if there is no danger, Director of the Association Elena Sharoykina told the Voice of Russia. "We must carry out an experiment based on the rules, which opponents and proponents of GMOs as well as those, who are indifferent to this technology, will agree upon. This year, we carried out a great work with participation of international and Russian scientists. In the summer, we were visited by specialists from the USA, France, and Great Britain. A working group was established. Today, the protocols are ready. I think this experiment will become a global sensation, because until now, during 20 years of commercial use of GMOs, nobody in the world has united scientists of different countries and different scientific disciplines in order to fully, with absolute certainty investigate GMOs' impact on organisms."

2014

- May 17 RT reports Russian anti-GMO activists raise funds for 'first-ever' independent international research noting about NAGS, "The NGO has already enrolled a team of researchers from the US, France, the UK, China and Russia and will make sure the experiment will comply with all international standards. It's also going to be available for everyone to follow online. The GSPA is raising funds from as many sources as possible for the experiment to come up to the group's claims the first-ever independent international research on GMO."
- May 22 The Natural Society reports <u>Russian Activists to Conduct Independent Studies Proving</u>
 <u>GMOs Could be Genetic Weapon</u> quoting Elena Sharoykina stating, "that GMO could be used as a genetic weapon..." supporting a Russian bill that would criminalize the planting of GMOs. Adding,

"The GSPA is raising funds from multiple sources as a means to conduct – the first-ever independent international research on GMO" to have some hard, solid evidence that can counteract the propaganda which has been circulated by Monsanto's shills.

- July 11 FactorGMO.com domain name registered to National Association for Genetic Safety (NAGS) director Elena A. Sharoykina in Moscow. This website currently has one page announcing the Factor GMO report will be issued on November 11, 2014.
- August 6 FactorGMO.eu domain name registered to NAGS director Elena Sharoykina at address:
 2 Willow Road, SL3OBS Slough, UK (Note: this is the address for Norsk Global Wholesale, LTD a cargo and export consultancy). This website is current set up as a protected WordPress (blog platform) site with no content other than a login page.
- October 22 Henry Rowlands via Sustainable Pulse reports claim he "received a media advisory regarding the launch of a \$25 Million international study on GMO and pesticide safety in Central London, UK on November 11." Noting, "Henry Rowlands, Sustainable Pulse's Director, stated Wednesday; "It is with optimism that I welcome this opportunity to find out the full truth about the possible harm caused by GMOs and pesticides to human health. This is the Ultimate Study that we have all waited 20 years for. I have always supported 'neutral' science." Sustainable Pulse will keep our readers updated with all of the details surrounding the study when they are announced." This post includes announced location change "due to the amount of interest according to the Factor GMO organizers."
- October 23 GM Watch (an affiliate of Henry Rowlands and co-member of Global GMO-Free Coalition) posts Factor GMO press release including location change update. Some agriculture trade publications and other anti-GMO advocacy groups, alternative and natural health marketing sites similarly syndicate the Rowlands article.
- October 28 Biology Fortified blogger, and plant scientist Karl Haro von Mogel posts, "
 Questions arise about upcoming 'Factor GMO' study" raising issues of predetermined outcomes and bias with NAGS study
- November 3 Genetic Literacy Project director Jon Entine posted "\$25 million for <u>'Factor GMO'</u> study Are the results pre-determined?"
- November 10 Genetic Literacy Project publishes profile on Factor GMO study sponsor NAGS
- November 11 Factor GMO press conference in London with livestreaming via NAGS YouTube channel and newly launched Facebook fan page and Twitter account (see summary below for details). The announcement coincided with the delivery of an anti-GMO campaign "Letter from America" to UK elected officials signed by various celebrities, alternative health and organic food advocates.

March 2 – Factor GMO press release announces Mahmoud Kabil joins the board of Factor GMO claiming, "the World's largest and most comprehensive study on GMOs and their associated pesticides – Factor GMO. The experimental phase of the study, costing \$25 million, will begin later in 2015..."

Study Background

Although the study was initiated by NAGS, however, study spokesman Ivan Lambert claimed, "NAGS has no and will have no involvement in designing the study, in the day-to-day running of the experiment, or in the gathering, interpretation, or publication of the scientific results." NAGS is a member of the GMO-Free Global Coalition which first promoted the study press conference announcement.

"This of course means that all results will be published, if they show the GM crop or associated pesticide to be 'safe' or 'harmful'," said Lambert.

The public record, website registrations and past statements by NAGS dating back to 2012 appear to contradict this claim of independence. In addition to the prior statements by NAGS showing they are behind this pending study report, media interviews with NAGS director Elena Sharoykina indicate a predetermined outcome and anti-GMO bias. Karl Haro von Mogel, founder of Biology Fortified, has noted his concerns about the project's independence:

The NAGS has a questionable history when it comes to scientific claims about genetically engineered crops. They organized the conference where Russian scientist Irina Ermakova publicized her heavily-criticized claims that rats fed genetically engineered soy were infertile. The NAGS is also the source for a second "study" (translated) claiming that hamsters had altered sex ratios and infertility. The second one was publicized by Jeffrey Smith, who said that they also found hair growing in the mouths of these hamsters. Neither study has ever been published in a peer-reviewed scientific journal, and the history of producing far-reaching claims based on these science-by-press-release studies does not inspire confidence.

Initial reports by NAGS claimed this study would cost up to US\$1 million and be done with complete transparency – including live web streaming video. In addition to cost claims and independent source, NAGS has also reported conflicting details on the scope, protocols and timing involved in the study.

Study facilitators conducted a press conference on November 11, 2014 with simultaneous release of updated press materials. The press conference was attended by about 25-30 people including NAGS and Global GMO-Free coalition staff, other activist group representatives and individuals and journalists. The presenting panel representing the GMO Factor study included:

- Elena Sharoykina, head of NAGS and co-chair of Global GMO-Free coalition
- Bruce Blumberg, PhD biology, University of California Irvine. Blumberg coined the term "obesogens" and has been criticized for his claims about BPA and other endocrine-related health risk allegations

- Fiorella Belpoggi, director and Chief of Pathology at the Cesare Maltoni Cancer Research Centre of the Ramazzini Institute in Bentivoglio, Italy. Belpoggi is a member of ENNSER and signer of their statement claiming that there is no scientific consensus on GMO safety. She is also an aspartame critic who claims it causes cancer and whose work is promoted by the alternative health, dietary supplements and natural products industries.
- Oxana Sinitsyna, Deputy Director for Science at the Federal State Organization "A. N. Sysin Research Institute of Human Ecology and Environmental Health" of the Ministry of Health of the Russian Federation, Moscow, Russia

Key points conveyed during the question and answer session:

- The projected start date for the research is March 2015 (although this date passed without an announcement to the study's initiation and other dates have been hinted at by organizers) and the group claims to have received funding commitments of nearly US\$25 million from "private donors" whom they declined to name stating "contractual obligations" prevented such disclosure at this time. They said they would disclose donor information sometime in 2015. They also noted they still needed to raise additional funds to close the gap and ensure they had the resources needed to start the first rounds of research needs anticipated in the spring.
- They reported that the study protocols and methodology have been decided; however, they are not yet being released. The panel members would only state that study participants operating at undisclosed laboratories around the world would follow "OECD-plus" protocols and research guidelines. They reported the research will involve long-term animal feeding trials using a reported 6,000 Spragues Dawley rats fed one undisclosed Monsanto variety of GMO corn, glyphosate, and an undescribed control group. They claimed the studies will test the rats for toxicity, carcinogenicity and multi-generational developmental factors related to endocrine disruption. When asked if the study "raw data" would be reported, panelist Blumberg only responded that it would be nice if the reporters would ask the other study publishers if they would release their raw data.
- On rationale, transparency and bias Blumberg added he believed these longer term studies had been conducted by GMO and pesticide companies, but that they've not been disclosed implying the companies are aware of negative health risks so this study is necessary. Blumberg also noted that billions of pounds of GMOs and pesticides have been consumed during a time which correlates with increased incidence of virtually every chronic disease so their study is designed to definitively answer the questions and concerns about correlation. He and the panel said their science would stand on its own and thus address any concerns about bias.

Responses to study

Contrary to the claims made by NAGS, the Factor GMO coordinated study scheme is neither the first nor the largest such undertaking. Numerous independent, long term and larger studies of GMO safety have in fact been conducted:

 The European Commission published a report summarizing the results of 50 research projects addressing the safety of GMOs for the environment as well as for animal and human health. These

- projects received funding of €200 million from the EU and are part of a 25-year long research effort on GMOs.
- Snell C, Berheim A, Berge´ JB, Kuntz M, Pascal G, Paris A, et al. Assessment of the health impact of GE plant diets in long term and multigenerational animal feeding trials: a literature review. Food and Chemical Toxicology 2012;50(3–4):1134–48.) of well-designed, long-term and multigenerational animal feeding studies comparing GM and non-GM potatoes, soy, rice, corn and triticale found that GM crops and their non-GM counterparts are nutritionally equivalent and can be safely used in food and feed.
- Alessandro Nicolia, Alberto Manzo, Fabio Veronesi, and Daniele Rosellini of the Department of Applied Biology, Faculty of Agriculture, University of Perugia, Perugia, Italy and Ministry of Agriculture, Food and Forestry Policies (MiPAAF) published study, September 2013, <u>Journal of</u> <u>Critical Reviews in Biotechnology</u>: "We have reviewed the scientific literature on GE crop safety for the last 10 years that catches the scientific consensus matured since GE plants became widely cultivated worldwide, and we can conclude that the scientific research conducted so far has not detected any significant hazard directly connected with the use of GM crops."
- Agnes E. Ricroch, Chair of Evolutionary Genetics and Plant Breeding, AgroParis Tech, University of Paris-Sud. Research Paper published May 2013, New Biotechnology: "The (research) comparisons revealed that the genetic modification has less impact on plant gene expression and composition than that of conventional plant breeding. Moreover, environmental factors (such as field location, sampling time, or agricultural practices) have a greater impact than transgenesis. None of these 'omics' profiling studies has raised new safety concerns about GE varieties; neither did the long-term and multigenerational studies on animals. Therefore, there is no need to perform such long-term studies in a case-by-case approach, unless reasonable doubt still exists after conducting a 90-day feeding test."
- United States <u>National Academies of Sciences</u>, <u>Engineering</u>, <u>and Medicine</u> reviewed more than 900 studies and data covering the 20 years since genetically modified crops were first introduced and found zero evidence of health effects on humans from the crops.

Criticisms

- Gregory S. Lewis, PhD, Editor in Chief, *Journal of Animal Science*: "The scientific evidence indicates clearly that the health, wellbeing, and productivity of animals consuming GE feeds are at least comparable to those of animals consuming conventional feeds."
- Karl Haro von Mogel, Phd Biology Fortified: "The NAGS has a questionable history when it comes to scientific claims about genetically engineered crops."
- Bruce Chassy, PhD Academics Review: "There is a global expert academic and regulatory consensus that there is no scientific reason to believe plant biotechnology bred crops pose any new or different risks than conventionally bred plant varieties. This purported video webcast approach to represent transparency described by NAGS would make a circus out of serious science. This is a publicity stunt intended to create the impression that needed studies haven't been done which more than 20 years of accepted scientific literature, peer reviewed publication and extensive regulatory reviews clearly shows and supports the safety of GMOs..".
- Jon Entine, Genetic Literacy Project: "As Biofortified notes, the press release by Sustainable plus

claims that will be the first ever independent international study. That's not true, and according to Lambert, who reached out to Karl Haro von Mogel and the GLP, they never made that assertion. There have been hundreds of independent international studies conducted on GE crops over the years, some of which are in the GENERA database. Independent research is more common than is often claimed,"

See Also

- Henry Rowlands
- National Association for Genetic Safety

Resources

- Factor GMO Facebook
- Factor GMO on Twitter