cotton-T304-40

Organisation: GratisGrönt Country: Sweden Type: Non Profit Organisation

a. Assessment:3. Environmental risk assessment

High, the cotton is made to be herbicide tolerant. But the rest of nature isn't modified to handle herbicide. Therefor it is dangerous to use this modification of cotton since it will result in the modified cotton being sprayed with herbicide.

4. Conclusions and recommendations

Don't allow this modified crop to be grown anywhere since there is a high risk of cross contamination and risk of unwanted side effects in nature.

Organisation: private Country: Sweden Type: Individual

a. Assessment: Molecular characterisation

Genetic modification should be banned altogether, I believe that things are best left to nature. If the world comes to an end it will be because of this folly. NOW is the time to return to healthy common sense. We must live <u>with</u> our planet, not against it. You can see yourselves that the ice-caps are melting, bees and insects are dying. How do you think humanity is going to survive? I am sick and tired of all the stupidity that is descending on the planet.

a. Assessment: Molecular characterisation

Genetic modification should be banned altogether, I believe that things are best left to nature. If the world comes to an end it will be because of this folly. NOW is the time to return to healthy common sense. We must live <u>with</u> our planet, not against it. You can see yourselves that the ice-caps are melting, bees and insects are dying. How do you think humanity is going to survive? I am sick and tired of all the stupidity that is descending on the planet.

Organisation: private Country: Sweden Type: Others...

a. Assessment:3. Environmental risk assessment

If the plant is totally sterile and can't produce any pollen..... then it can be called safe but what happens with the animals when they get this GM food? and what will happen in us who eat the animals and if the plant tolerates more pesticides than normal cotton plants can stand... Why? What has been put into the modified plant from where does the modification come? Is it possible that it might cause changes in other organisms or loss of important insects in the surrounding area? Will it be dangerous over time.... like in 30-100years? Has that been properly investigated?

4. Conclusions and recommendations

No thank you

5. Others

Please save the insects needed for pollination, the natural insects and the water we desperately need on this planet from more pesticides.

Organisation: Uppsala University Country: Sweden Type: Scientific Institution

a. Assessment:3. Environmental risk assessment

The report (purposely) fails to do an assessment of the side-effects of cultivating the GMO cotton. From the report: "The application EFSA-GMO-NL-2011-97 concerns food and feed uses, import and processing. Therefore, there is no requirement for scientific information on possible environmental effects associated with the cultivation of cotton T304-40 in Europe.".

This means that the largest problem with GMO cultivation is completely ignored in the assessment, namely the loss of biodiversity through the INCREASED use of pesticides (Benbrook 2012). Simultaneously it has been reported that organic farming with proper management in most cases can produce almost as high yields (up to 85% typically) as conventional crops, without the drawbacks to biodiversity (Seufert et al. 2012). Following the Gothenburg 2001 treaty on biodiversity, and the Nagoya 2010 treaty it is clear that the direction for agriculture should steer away from the usage of pesticides to a more varied use of cultivars. This will increase resilience against changes in climate directly (through more varied crops) and indirectly due to increased level and quality (diversity) of ecosystem services. Therefore the proposed GMO cotton should not be allowed to be cultivated or imported to the EU in my opinion.

References: Benbrook, Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years, Environmental Sciences Europe 24 (2012) page 24

Seufert et al., Comparing the yields of organic and conventional agriculture, Nature 485 (2012) page 229

Organisation: KTH City: Nacka Type: Others...

a. Assessment: Molecular characterisation Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

b. Food Safety Assessment: Toxicology

I think the whole approach with GM foods is wrong. It is like fighting against nature to make more profit and it will only lead to misery. One of the obvious reasons on the surface level of the problem are the use of more harmful substances, the overall use of more oilbased energy (harvesting, nutrition, etc.) If there is a problem with the cotton farms and production why not question the production method? Maybe use a different plant? There are millions of ways but a lot of them are not economically motivated to use and it is a lot cheaper to use GM. Are we willing to take the risk of indirectly GM ourselves through food and plants for the sake of economical profit? Where is the limit for profit? As long as the people doesn't notice and can go on with their daily lives? Slowly making them and their minds toxified through the slow increase of more harmful substances and GM? The toxic intention with the use of GM and its effects are beyond this comment and what I am allowed or supposed to write in this box.

Allergenicity

I believe it well can create new non-discovered allergies in places we do not expect.

Nutritional assessment

Others

3. Environmental risk assessment

It is a big threat to the biodiversity and all life on the planet. If you want to live a thriving life

of love on this planet this is not the answer. This has nothing to do with the love for cotton, clothes or the people using it.

4. Conclusions and recommendations

Do not use it.

5. Others

-

6. Labelling proposal

If used, products containing this or traces of it has to be labelled.

Organisation: Individual Country: Sweden Type: Individual

a. Assessment:b. Food Safety Assessment: Toxicology

It's killing our insects and the farmers that keeps the crops.

Nutritional assessment

Animals prefer non-gmo so why would we prefer gmo?

Others

3. Environmental risk assessment

It may spread beyond the farmers boundaries and destroy their crops. The farmer might even get sued because they have these kind of crops even thought they didn't want it in the first place. How are you going to control the natural movements of nature? How are you going to provide safety to the farmers around the GMO -cotton?

4. Conclusions and recommendations

Stop killing bees, spread seeds that destroys eco-system and stop the companies that sues farmers for seeds they never planted. Ban it!

5. Others

Hello

I would like to give my input about the GMO-cotton. 1. I would never wear it/use it. 2. It may spread beyond the farmers boundaries and destroy their crops. The farmer might even get sued because they have these kind of crops even thought they didn't want it in the first place. How are you going to control the natural movements of nature? How are you going to provide safety to the farmers around the GMO -cotton? 3. We have no idea how this play with genes will end but seriously stop it. I'm greatly concerned and fear for what will come. 4. What will you do when the bugs like bees dies and with them the rest of earth? Might seem distant? Well so did environment pollution when oil first came, now we know better, right?

Sincerely Lovisa Karlsson

6. Labelling proposal

Label it with a sign that it contains GMO and information about what it does to nature and everything living in it so others may avoid it.

Organisation: None Country: Sweden Type: Others...

a. Assessment:

Molecular characterisation

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term - for humans, animals and our earth. The people want clean, organic products, not products that's been tampered with.

Stop listening to the companies who makes a profit from GMO and start listening to the people!!!!!!!!!

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

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

b. Food Safety Assessment: Toxicology

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

Allergenicity

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

Nutritional assessment

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

Others

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

3. Environmental risk assessment

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

4. Conclusions and recommendations

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

5. Others

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered

with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

6. Labelling proposal

STOP playing with our lives!! We don't want GMOs in anything! Where GMOs has already been around for a long time (USA) devastating results have occurred. It makes me so mad and sad that you could even consider introducing them in EU. No one knows how they will affect us long term. The people want clean, organic products, not products that's been tampered with. Stop listening to the companies who makes a profit from GMO and start listening to the people!!

Organisation: Naturskyddsföreningen Country: Sweden Type: Non Profit Organisation

a. Assessment: Molecular characterisation

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

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

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

b. Food Safety Assessment: Toxicology

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

Allergenicity

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

Nutritional assessment

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

Others

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

3. Environmental risk assessment

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

4. Conclusions and recommendations

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

5. Others

Honestly! I speak for the big part of the whole "Naturskyddsföreningen" in Nora and Örebro. We do NOT want any GMO crops, trees or any other material what so ever. Stop GMO and look at the real reasons of poverty and famine.

6. Labelling proposal

No GMO. Hence no labelling needed.

Organisation: Member of healthy environment Country: Sweden Type: Individual

a. Assessment:5. Others

Your role within EC and our wellbeing - that is something to stand up for! Do not sell us out where short term economics is in charge. What does these chemicals and GMO do to our bodies, our health and our living planet? Everything is connected to one another, take good care of this fragile chain. Please!

Organisation: Testbiotech Country: Germany Type: Non Profit Organisation

a. Assessment: Molecular characterisation

Unintended read-through RNA was observed due to truncated stop codons. Several open reading frames were also identified that could generate further unintended RNA products in the plants. Even though no fusion proteins were identified and no RNA from the open reading frames was found, uncertainties cannot be ruled out. The plants might up- or down-regulate gene activity under certain environmental conditions and produce RNA and proteins not observed so far. Additionally, small double stranded RNA might be produced that could be transmitted as a biologically active compound at the stage of consumption. Consequently, the identifiable uncertainties require further detailed investigation, in particular into unintended products from the foreign DNA. The plants showed highly variable Bt protein expression levels (the level of Bt proteins in the plant was much higher when cultivated in Spain than in the US). They should therefore undergo a stress test under defined environmental conditions, to explore the true range of variability and to identify unintended effects in the plants that only might occur in specific environments.

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

The outcome of the field trials is very clear. Cotton T304-40 is not equivalent to its isogenic line. EFSA summarised consistent significant differences in the comparison: "The level of calcium, zinc, linoleic acid, palmitic acid and stearic acid showed statistically significant differences in cotton T304-40 and Coker 315 over all three seasons of field trials and both treatment regimes with herbicides."

Nevertheless, EFSA decided these differences are of no biological relevance. Instead of requesting further investigations, EFSA referred to the data from various reference lines, which do not have a similar genetic background to T304-40. From a scientific point of view, a clear set of data stemming from the true comparator, which is the isogenic line, cannot be devaluated by simply adding more data from other varieties. By doing so, EFSA demonstrates its comparative risk assessment is mostly based on assumptions and arbitrary data interpretation.

b. Food Safety Assessment: Toxicology

The assessment of feeding studies is a new low-point in the case history of EFSA opinions. Both feeding studies with plant material, the subchronic 90 day feeding study with rats and the 42 day feeding study with poultry, were completely or largely rejected by EFSA because of flaws in the design of the study. At the same time, EFSA did not ask for any new investigations. The Food Authority simply assumed that the new proteins as expressed in the plants were safe and at the same time ignored the observed differences in plant composition. Any further testing of the whole plant material was deemed unnecessary. The lesson for industry was, of course: Products can easily escape detailed risk assessment by providing data with no scientific value from feeding trials.

Allergenicity

Under normal circumstances, EFSA bases its weight of evidence approach on methods such as the pepsin test, which are known to be unreliable. No conclusions can be drawn from the pepsin test on the degradation of the foreign proteins under realistic conditions if the proteins are ingested with many other components. Further, no tests were performed to investigate adjuvant effects that can enhance immune reaction to known endogenous plant allergens. As a result, the allergenicity risk assessment is not conclusive.

Nutritional assessment

see Toxicology

Others

Residues from spraying with glufosinate are plant constituents that are relevant for the risk assessment of these plants. T 304-40 raises specific safety concerns such as combinatorial effects with the insecticidal protein, which are not addressed by pesticide regulation. EFSA has not carried out such an assessment.

3. Environmental risk assessment

Testbiotech agrees with the comments of several Member States that spillage, persistence and invasiveness are relevant risks in certain countries. No viable seed should be imported into countries or regions where cotton plants can survive and spread into the environment, such as Italy, Greece and Spain.

4. Conclusions and recommendations

This risk assessment is a new low-point in the case history of EFSA opinions. The opinion should be rejected completely. Instead of identifying uncertainties and knowledge gaps and requesting relevant investigations as requested by experts from several EU Member States, EFSA is simply hiding behind the wording of its controversial Guidance. As a result, the opinion is an attempt to window dressing the issue but not a reliable risk assessment.