oilseedrape

Organisation: n/a
Country: France
Type: Individual

a. Assessment:
4. Conclusions and recommendations

Ban it. Permanently. And ban all the other poison from this and every other company, right across Europe. Food is food. This is poison. Anyone approving this or having a hand in approving or marketing this for use in food or animal feed should be sent to jail.

6. Labelling proposal

All products which include GMOs at any percentage above 0, or animal products which have been fed on this poison must be labelled clearly in very large letters. POISON.

Organisation: GIET / France Nature Environnement
Country: France
Type: Association

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

Declaration of equivalence require equivalence tests, which are not provided.

b. Food Safety Assessment:
Toxicology

Statistical tests must include statistical power analysis, otherwise the results are meaningless. Therefore, the present results are meaningless and the application can't be approved.

Declaration of equivalence require equivalence tests, which are not provided.

Allergenicity

In vitro digestion assay has been shown to be irrelevant (digestion is at pH2,5 - 3 and the pepsine level is normally 3000 times less than in the assay as performed by the applicant...) Any conclusion based upon this assay is therefore meaningless.

Database analysis cannot predict three D epitopes (and can't predict much in fact).

It must be said that allergenicity of this product cannot be predicted, otherwise, it is not science but black magic.

Nutritional assessment

same remarks as about toxicology concerning statistics

Others

The reference system for colza is not specific. Therefore, traceability is not truely possible and this application do not satisfy the 1829 and 1930 regulation

Organisation: Individual
Country: Sweden
Type: Individual

a. Assessment:
Molecular characterisation

No comment

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

No comment

b. Food Safety Assessment:
Toxicology

We don't know the toxidity of the biocides that will be used combined with this GMO raps.

Allergenicity

-

Nutritional assessment

-

Others

Risk for future helth, risk of cross mixing with other raps types, and since this happens accidentally people can get sued even they could not do anything about it. All neighbours to GMO raps will be possible targets for sueing, even unguilty. They will therefore be forced to also use this not-for-free GMO raps.

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3. Environmental risk assessment

Obvious risk of increased use of biocides, that will kill lots of things on fields, and surrounding waters.

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4. Conclusions and recommendations

Do not allow GMO raps. The only winner will be the company(ies) that produce it!

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5. Others

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6. Labelling proposal

Do not allow GMO raps.

Organisation: Private person
Country: Sweden
Type: Individual

a. Assessment:
Others

We dont want this to invade swedish crops.

3. Environmental risk assessment

To much use of poisons represent health risks to population, enviroment, coming into ground-water, pollution of water etc.

4. Conclusions and recommendations

We dont need this product in Sweden or any other country that wants to protect the enviroment and the health of the population.

Organisation: Individual
Country: Sweden
Type: Individual

a. Assessment:
Molecular characterisation

I dont want GM in europe

Organisation: None, I'm a private citizen
Country: Sweden
Type: Individual

a. Assessment:
Molecular characterisation

N/A

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

N/A

b. Food Safety Assessment:
Toxicology

When considering to approve the actual oilseed rapes you also need to take into account how they will be used. My understanding is that these oilseed rape is to be used together with Monsanto's product "Roundup".

- There are indications that the active ingredient Glyphosate is causing birth defects (source: http://www.huffingtonpost.com/2011/06/07/roundup-birth-defects-herbicide-regulators_n_872862.html) - Greenpeace has also made ready a report which argues that Glyphosate brings increasing health, biodiversity and environmental concerns and the development of weed resistance. (source: http://www.greenpeace.org/international/en/publications/reports/Herbicide-tolerance-and-GM-crops). They also indicate links to cancer, birth defects and Parkinson's disease (source: http://www.theecologist.org/News/news_analysis/961236/greenpeace_takes_on_monsanto_over_pesticides_arms_race.html) - Roundup can alter the Morphology of animals (source: http://www.naturalnews.com/035533_Roundup_amphibians_deformities.html) - Monsanto's Roundup has been found to destroy testosterone and thereby male fertility (source: http://www.naturalnews.com/035135_Roundup_herbicide_testosterone.html) - Roundup diluted by 99.8 percent still destroys human DNA (source: http://www.naturalnews.com/035050_Roundup_Monsanto_DNA.html) - Several other negative indications are listed here: http://www.naturalnews.com/Roundup.html

Allergenicity

N/A

Nutritional assessment

N/A

3. Environmental risk assessment

It's also widely known, as in the case with Monsanto vs Schmeiser (source: http://www.percyschmeiser.com), that Monsanto's genetically manipulated plants tend to contaminate surrounding fields and thereby making it hard or impossible for other farmers to grow GMO-free food.

4. Conclusions and recommendations

I therefore urge you to NOT allow Ms8, Rf3 and Ms8 x Rf3 oilseed rape to be used within the European union

5. Others

N/A

6. Labelling proposal

N/A

Organisation: Individual
Country: Sweden
Type: Individual

a. Assessment:
Molecular characterisation

As a representative of the "public" I do not have a distinct notion of what molecular characterisation, nor many of the other section headers below, mean. I hold a masters degree, but in a different field. I do not expect the "public" to be able to respond in a meaningful way but feel obliged to try and will therefore skip ahead to section 3 and 4.

3. Environmental risk assessment

I've followed the GMO debate the last 10 years. So far the evidence seems to point towards there being other, proven, ways to solve foreseen future food supply issues. A reasonable approach in a situation like this is to apply a "guilty until proven otherwise" principle.

New species have been introduced in to ecosystems before in human history with known results. GMO is uncharted territory and we may not know the extent of adverse effects (if any) until far into the future.

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4. Conclusions and recommendations

Conclusion is not to grant the permission to introduce the modified rape into the european market.

Organisation: non
Country: Sweden
Type: Individual

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a. Assessment:
5. Others

I am very much against the use of any GM oilseed rape in Europe and Sweden, due to environmental and health risks!

Organisation: Swedish Small Farmers Association
Country: Sweden
Type: Non Profit Organisation

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a. Assessment:
b. Food Safety Assessment:
Toxicology

No long term tests have been done to assess the toxicological risks of the GMO or the herbicide round up.

Allergenicity

No long term tests have been done to assess the impacts on health - especially of the pollen that will spread through wild relatives and bees.

3. Environmental risk assessment

great risk for spread in the environment - the example of Switzerland is a case in point. Despite it's moratorium GMO raps has been found growing along railways. This will now cross pollinate with wild relatives and then with commercial crops. As raps is an important fodder crop for bees this is an extreme threat to beekeeping.

4. Conclusions and recommendations

Stop the introduction of all GM oilseed rape Ms8, Rf3 and Ms8 x Rf3

Organisation: Individual
Country: Sweden
Type: Individual

a. Assessment:
Others

GMO studies on hamsters in Russia has proven infertility.

GMO studies on rats in France has proven cancer.

That's enough for me to forbid ANY form of GMO products.

Organisation: Private citizen
Country: Sweden
Type: Individual

a. Assessment:

4. Conclusions and recommendations

I am very concerned that genetically modified material will wander in to gmo-free natural plants. This may have unknown drawbacks and may very well put farmers who have had their crops contaminated by gmo-crops at risk of prosecution from the owners of the gmo-crop seeds. I recommend that we do NOT allow gmo in EU.

Organisation: induvidual
Country: Sweden
Type: Individual

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a. Assessment:
b. Food Safety Assessment:
Toxicology

It is not proven that GMOs are safe in the long turn. Mice fed with GMO-corn developed tumor and cancer. After some generations they became sterile and could not get babys. What will happen to humans who eat GMO products? No babies for future generations?

Allergenicity

Allergies are rising, and GMO product can cause allergies. I am deeply concerned about this

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3. Environmental risk assessment

Bees and other pollinating insects are decreasing in number, specially in areas where GMO-food is growing. We all need pollinating insects to get good crops. With GMO the insects disappear and other crops are not giving good harvest.

Organic farmers cannot grow their food. GMOs are spreading and and the food cannot be considered as organic any longer, if there are GMO farmers near.

If bees are in fields with oilseed rape, their honey is not organic any longer

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4. Conclusions and recommendations

Please do not grow any GMO oilseed rape, or any other GMO! Nature cannot be reversed, earth that is destroyed by GMO, is not good for any food.

6. Labelling proposal

Big letters: CONTAIN GMO

Organisation: None
Country: Sweden
Type: Individual

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

For the first time, the health impact of a GMO and a widely used pesticide have been comprehensively assessed * in a long term animal feeding trial of greater duration and with more detailed analyses than any previous studies, by environmental and food agencies, governments, industries or researchers institutes.

The two tested products are in very common use : (i) a transgenic maize made tolerant to Roundup, the characteristic shared by over 80% of food and animal feed GMOs, and (ii) Roundup itself, the most widely used herbicide on the planet. The regulatory approval process requires these products to be tested on rats as a surrogate for humans.

The new research took the form of a two year feeding trial on 200 rats, monitored for outcomes against more than 100 parameters. The doses were consistent with typical dietary/ environmental exposure (from 11% GMO in the diet, and 0.1 ppb in water).

The results, which are of serious concern, included increased and more rapid mortality, coupled with hormonal non linear and sex related effects. Females developed significant and numerous mammary tumours, pituitary and kidney problems. Males died mostly from severe hepatorenal chronic deficiencies. Professor Seralini's team in the University of Caen is publishing this detailed study in one of the leading scientific international peer-reviewed journals of food toxicology, on line on Sept. 19, 2012.

Female (9255) fed with the GMO alone (22%) and developing a mammary adenocarcinoma in a fibroadenoma (day 645)

The implications are extremely serious. They demonstrate the toxicity, both of a GMO with the most widely spread transgenic character and of the most widely used herbicide, even when ingested at extremely low levels, (corresponding to those found in surface or tap water). In addition, these results call into question the adequacy of the current regulatory process, used throughout the world by agencies involved in the assessment of health, food and chemicals, and industries seeking commercialisation of products

In view of these findings, the researchers consider that market authorisations for these products should be immediately reviewed. The 90 day test duration should be extended to 2 years for agricultural GMOs. In addition, all pesticides should be tested in their formulations (not the active principle alone) for 2 years, including at very low levels. Furthermore, in future the regulatory testing process for biotech and pesticide products should be transparent, open to public scrutiny, subject to independent review and performed independently of their firms in the future.

In the meantime, labelling of all GMOs in the feed/food should be mandatory, including livestock products from animals that have been fed GMO's. Finally, the nature of all compounds present in pesticide formulations should be made public.

*"Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize". Food and Chemical Toxicology, Séralini G.E. et al. 2012.

The results of these experiments, the story and its implications have been explained in a book « Tous Cobayes ! » by Gilles-Eric Séralini, published on Sept. 26 by Flammarion. Simultaneously, a film adapted from this book "All guinea pigs ?" by Jean-Paul Jaud will be launched. A TV documentary "GMO, a World Alert ?" by François Le Bayon will be shown. The legal and social impact has been written « La vérité sur les OGM c'est notre affaire » by Corinne Lepage from the European Parliament, published by Charles Léopold Mayer.

For more details see www.criigen.org; contact This e-mail address is being protected from spam bots, you need JavaScript enabled to view it , +33 (0)2 31 56 56 84

Contact Laurent Payet Press Agent, Professor Gilles-Eric Séralini Phone: +33 6 89 95 48 87

Source:
http://www.criigen.org/SiteEn/index.php?option=com_content&task=view&id=366&Itemid=130

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b. Food Safety Assessment:
Toxicology

Russia has now officially banned all imports of genetically modified corn, citing concerns from a recent study by French researchers showing rats grew massive cancer tumors when fed a lifetime of Monsanto's genetically modified corn.

Russia's consumer protection group, Rospotrebnadzor, said it was halting all imports of GM corn while the country's Institute of Nutrition will be evaluating the results of the study.

"The Russian ban is the latest blow to Monsanto, a company desperately clinging to the myth that its genetically modified crops are "no different" than traditional crops and therefore long-term safety testing is completely unnecessary. Monsanto has assaulted the French study, claiming it did not use enough rats and that the duration of the study was too short -- an absurd claim, given that Monsanto's own studies on animals are only 90 days in duration, while the French study looked at the effects of rats eating GM corn (and drinking trace levels of Roundup herbicide) for two years.

Notably, the large cancer tumors did not begin to appear until after the rats reached adulthood. Monsanto's GM corn has been in the U.S. food supply for more than a decade, and its corn is found in many popular breakfast cereals."

Source: http://www.naturalnews.com/037328_Russia_GMO_Monsanto.html

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4. Conclusions and recommendations

Say NO Monsanto and BAN ALL GMO crops!

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5. Others

Monsanto Protection Act' to grant biotech industry total immunity over GM crops? "(NaturalNews) While millions of Americans were busy celebrating freedom from tyranny during the recent Independence Day festivities, Monsanto was actively trying to thwart that freedom with new attacks on health freedom. It turns out that the most evil corporation in the world has quietly attached riders to both the 2012 Farm Bill and the 2013 Agriculture Appropriations Bill that would essentially force the federal government to approve GMOs at the request of biotechnology companies, and prohibit all safety reviews of GMOs from having any real impact on the GMO approval process.

The Alliance for Natural Health - USA (ANH-USA), the Organic Consumers Association (OCA), and several other health freedom advocacy groups have been actively drawing attention to these stealth attacks in recent days, and urging Americans to rise up and oppose them now before it is too late. If we fail to act now as a single, unified community devoted to health freedom, in other words, America's agricultural future could literally end up being controlled entirely by the biotech industry, which will have full immunity from the law."

Source:
http://www.naturalnews.com/036477_Monsanto_immunity_GM_crops.html#ixzz20icc1TXJ

Monsanto trying a sneak attack through the new House Farm Bill "According to the Organic Consumers Association post just yesterday on their official Facebook page, Monsanto is trying another sneak attack on the American people. Their website stated, “The House Farm Bill contains HR 872, the so-called Reducing Regulatory Burdens Act, which stops the EPA from reviewing new and expanded uses of pesticides and requires the USDA to make the approval of new genetically engineered crops easier and faster, limiting USDA review to 180 days. While the USDA has never rejected a new GMO crop, public opposition, environmental concerns and litigation to protect farmers have slowed new approvals. This bill, to give Monsanto and the other biotechnology companies a free pass for new GMOs, includes a provision limiting USDA environmental review to a narrow evaluation of plant pest risks, even though the courts have ruled that a full environmental impact statement is required and must take into consideration the real threats of GMO crops, including "the potential elimination of a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food.""

Source: http://www.examiner.com/article/monsanto-trying-a-sneak-attack-through-the-new-house-farm-bill

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6. Labelling proposal

Hazardous, lethal, carcinogenic

Organisation: Individual
Country: Sweden
Type: Individual

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a. Assessment:
Molecular characterisation

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

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b. Food Safety Assessment:
Toxicology

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

Allergenicity

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

Nutritional assessment

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

Others

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

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3. Environmental risk assessment

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

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4. Conclusions and recommendations

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

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6. Labelling proposal

GMO oilseed rape is not natural and shall not be used in any way! Stopp all GMO plants and products now!

Organisation: *Biodlingsföretagarna* (Swedish Professional Beekeepers)
Country: Sweden
Type: Individual

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a. Assessment:
5. Others

As the cultivation of GM crops is prohibited, we should not allow them in food or feed either. This would make things more difficult for our own farmers, who have to compete against imported foods.

Organisation: Alliance for Natural Health International
Country: United Kingdom
Type: Non Profit Organisation

a. Assessment:
b. Food Safety Assessment:
Toxicology

Section 5.1.3.4 states that, “The EFSA GMO Panel previously concluded that oilseed rape Ms8, Rf3 and Ms8 x Rf3 are unlikely to have an adverse effect on human and animal health,” and later concludes that, “No additional animal safety studies are required”. This represents a clear presumption of safety of oilseed rape Ms8, Rf3 and Ms8 x Rf3, despite the fact that the safety of the GM crops on human and animal health has not been positively established. Compare this with the scientific substantiation required by EFSA for approval of health claims on foods and food ingredients – under the terms of Regulation (EC) No. 1924/2006 – under which a clear cause-and-effect relationship must be demonstrated between the food or ingredient and the claimed health benefit. This egregious double standard inflicts a double disservice on EU consumers, who are exposed to needless and unpredictable risks from Ms8, Rf3 and Ms8 x Rf3 oilseed rape – and, indeed, other GM crops – while being denied an informed choice about the foods they feed themselves and their families.

Allergenicity

Section 5.1.4.1 states that, “The PAT protein is the only newly expressed protein present in oilseed rape Ms8, Rf3 and Ms8 x Rf3 seed and pollen”. Since this conclusion does not appear to have been validated in any manner, and the EFSA opinion makes no reference to independent studies supporting its view, EFSA’s statement cannot be classed as anything more than an assumption. Furthermore, the remainder of EFSA’s conclusions on allergenicity are based on a second assumption: that foods, ingredients or oils made from Ms8, Rf3 and Ms8 x Rf3 oilseed rape are not contaminated with tapetum cells containing barnase and barstar proteins. Once again, EFSA has demonstrated a clear presumption of safety for proteins never before been seen in nature, which may have unpredictable consequences consistent with observation of other GM crops.

3. Environmental risk assessment

1) It is well known that European Union (EU) consumers are widely opposed to genetically modified (GM) foods. These concerns do not focus solely on the risks of GM to human health: they also recognise that GM presents a significant and unpredictable threat to the environment. Furthermore, EU consumers appreciate that the same environmental threat exists regardless of geographical location, and that it is essentially immaterial whether GM crops are grown in the EU, Australia, Canada, the USA, South America or elsewhere. In this context, splitting the registration of oilseed rape Ms8, Rf3 and Ms8 x Rf3, by authorising them for cultivation elsewhere in the world but only for food use via importation in the EU, is a knowing deception of EU consumers that does not in any way reduce concerns about the net risks of GM technologies.

2) EFSA acknowledges that the risk of genetic drift as a result of cultivation or transport of oilseed rape Ms8, Rf3 and Ms8 x Rf3 is very low. A low risk is still a risk, however, and the potential exists for cross-pollination between female Rf3 oilseed rape plants and male, non-GM Brassica napus plants. Bearing this uncertainty in mind, the precautionary principle should be invoked with respect to any usage or cultivation of Ms8, Rf3 and Ms8 x Rf3 oilseed rape, in place of EFSA's present presumption of safety approach.

3) A further important environmental consideration is that, in all probability, agricultural use of glufosinate-ammonium-containing herbicides will increase concomitantly in countries where Ms8, Rf3 and Ms8 x Rf3 oilseed rape are cultivated. This problem must be addressed alongside environmental exposure to GM material.

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

Due to the way the additional DNA was integrated, the event MS8 x Rf3 might produce fusion proteins, additional mRNA and also dsRNA. Also according to EFSA, the emergence of unintended fusion proteins cannot be excluded. Further endogenous gene activity might be changed. EFSA states that bioinformatics analyses of the DNA sequence at the insertion sites did not indicate changes in the expression of endogenous genes. However, no experiments were performed to find out if endogenous gene regulation is actually impacted. Further, the possible occurrence and biological relevance of unintended (short?) RNA molecules was not investigated. Despite the fact that some of the unintended effects caused by the insertion of the additional genes might occur under specific stress conditions, no investigations under defined environmental conditions were performed. Thus, the data as presented are not conclusive.

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

The data used for comparison came from Belgium, but Belgium is not the country that will be exporting the oil seed rape into the EU. The data from Canada that were presented, lack the isogenic line as a comparator. Therefore, the data as provided by the applicant are not sufficient and should not be accepted as reliable and sufficient.

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b. Food Safety Assessment:
Toxicology

The applicant explained that the purpose of this application concerned accidental unintentional presence of traces of oilseed rape Ms8, Rf3 and Ms8 × Rf3 seeds in food. However, according to EU legislation, market authorisation for food and feed is not restricted to a certain amount of commodities being marketed. Therefore, full risk assessment has to be conducted in every case. But no subchronic or chronic feeding study with the whole food was conducted by the applicant. In addition, to our knowledge, the parental plants were not assessed in any subchronic or chronic feeding study. Residues from spraying were not taken into account. So in conclusion, toxicological risks were not examined sufficiently.

Allergenicity

Immune reactions were not tested by experimental investigations, no tests were conducted with parental plants or the stacked events. The digestion of the PAT protein was not assessed under practical conditions. Changes in the expression of endogenous genes were not assessed by profiling methods. Thus, risk assessment cannot be regarded as being conclusive.

Nutritional assessment

The diets used in the 42 days broiler study were not properly described. No details are given as to whether further genetically engineered plants (such as soybeans) were part of the diet or about residues from spraying with glufosinate. Thus, the scientific standards of the nutritional study are not sufficient and its results should not be accepted.

Others

The market authorisation of stacked events requires the risk assessment and market authorisation of the parental plants first. However, in this case, it appears that the parental plants were not assessed and authorised before the stacked event. Thus, there seems to be a procedural flaw in this process.

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3. Environmental risk assessment

Spillage of whole seeds can render unintended cultivation of rape seed along transport lines. Pollen drift can create viable crossings with crops in the fields and wild relatives. From field tests, there is an indication of higher yield in the genetically engineered plants due to hybrid vigour. But no experiments were conducted to find out if offspring from unintended crossings (from parental plants or the stacked event) might have an increased potential for persistence and invasiveness. Thus, import of whole kernels cannot be allowed.

4. Conclusions and recommendations

The opinion of EFSA must be rejected.

5. Others

Monitoring has to be performed at the consumption stage, also taking into account residues from spraying. Further, a case specific monitoring has to be applied to make sure that no viable seeds are imported and/or released into the environment.