

Comments from the public : LLRice62

Organisation: agernova

Country: Italy

Type: Association

a. Assessment:

Molecular characterisation

La coltura non rispetta i criteri del principio di precauzione i rischi per la salute sono duplici - connessi alla modificazione del Dna - connessi all'elevato impiego di dissecanti - effetti pleiotropici e produzione di neosostanze incognite e non prevedibili

The crop does not comply with the criteria of the precautionary principle. The health risks are twofold (*sic*) – linked to DNA modification – linked to the large-scale use of desiccants – pleiotropic effects and the creation of new, unknown and unpredictable substances.

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

non c'è necessità di riso resistente al dissecante, in quanto si produce abbastanza col metodo biologico il mercato europeo rischia dei forti danni economici dall'invasione di colture gm che vengono prodotte in paesi dove i costi di produzione sono minori e rischiamo il tracollo della risicoltura europea colture gm vengono brevettate e ciò danneggia i produttori europei...il brevetto tra l'altro non dovrebbe essere legittimo in quanto gli ogm si modificano nel tempo e non sono stabili inoltre i geni sono scoperte e non invenzioni per cui non dovrebbero essere brevettabili

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods. The European market risks suffering serious financial damage from an invasion of GM crops produced in countries where production costs are lower, and we risk the collapse of the European rice growing sector. GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be capable of being patented.

b. Food Safety Assessment:

Toxicology

Nuove tossicologie incognite e imprevedibili e non analizzabili in quanto non si hanno sistemi di analisi di sostanze non conosciute alterazioni nello sviluppo degli organi sono state già notate nei tests su altri ogm

New, unknown and unpredictable toxic effects, which cannot be analysed due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been noted in tests on other GMOs.

Allergenicity

nuove allergie sono altamente probabili

New allergies are highly probable.

Nutritional assessment

nessun incremento, bensì riduzione del valore nutritivo degli ogm

No improvement, but rather reduced nutritional value with GMOs.

Others

nessuna necessità degli ogm in base al criterio di comparative assessment

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

contaminazione delle filiere europee ogm free e perdita della biodiversità autoctona

Contamination of European GMO-free farming and loss of native biodiversity.

4. Conclusions and recommendations

moratoria europea agli ogm

European moratorium on GMOs.

5. Others

Effettuare i referendum popolari nazionali in base a quanto previsto dalla direttiva comunitaria in materia di ogm prima di ogni decisione

Hold national referendums on the basis of the provisions of the Community Directive on GMOs prior to each decision.

6. Labelling proposal

Chiudere le frontiere europee agli ogm in modo che gli altri paesi produttori di ogm smettano di esportare in uE inserire l'etichettatura obbligatoria di ogni traccia di presenza di ogm negli alimenti convenzionali tolleranza zero di ogm negli alimenti biologici con test di presenza/ assenza

Close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU. Introduce the compulsory labelling of all traces of GMOs in conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present.

Organisation: Individual

Country: Italy

Type: Individual

a. Assessment:

Molecular characterisation

La coltura non rispetta i criteri del principio di precauzione, i rischi per la salute sono duplici - connessi alla modificazione del Dna - connessi all'elevato impiego di disseccanti - effetti pleiotropici e produzione di neo-sostanze incognite e non prevedibili

The crop does not comply with the criteria of the precautionary principle. The health risks are twofold (*sic*) – linked to DNA modification – linked to the large-scale use of desiccants – pleiotropic effects and the creation of new, unknown and unpredictable substances.

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

Non c'è necessità di riso resistente al disseccante, in quanto si produce abbastanza col metodo biologico

Il mercato europeo rischia dei forti danni economici dall'invasione di colture gm che vengono prodotte in paesi dove i costi di produzione sono minori e rischiamo il tracollo della risicoltura europea

Le colture gm vengono brevettate e ciò danneggia i produttori europei...il brevetto tra l'altro non dovrebbe essere legittimo in quanto gli ogm si modificano nel tempo e non sono stabili Inoltre i geni sono scoperte e non invenzioni per cui non dovrebbero essere brevettabili

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods.

The European market risks suffering serious financial damage from an invasion of GM crops produced in countries where production costs are lower, and we risk the collapse of the European rice growing sector.

GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be capable of being patented.

b. Food Safety Assessment: Toxicology

Nuove tossicologie incognite e imprevedibili, non analizzabili in quanto non si hanno sistemi di analisi di sostanze non conosciute Alterazioni nello sviluppo degli organi sono state già notate nei tests su altri ogm

New, unknown and unpredictable toxic effects, which cannot be analysed due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been noted in tests on other GMOs.

Allergenicity

Nuove allergie sono altamente probabili

New allergies are highly probable.

Nutritional assessment

Nessun incremento, bensì riduzione del valore nutritivo degli ogm

No improvement, but rather reduced nutritional value with GMOs.

Others

Nessuna necessità degli ogm in base al criterio di comparative assessment

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

Contaminazione delle filiere europee ogm free e perdita della biodiversità autoctona

Contamination of European GMO-free farming and loss of native biodiversity.

4. Conclusions and recommendations

Moratoria europea agli ogm

European moratorium on GMOs.

5. Others

Effettuare i referendum popolari nazionali in base a quanto previsto dalla direttiva comunitaria in materia di ogm prima di ogni decisione

Hold national referendums on the basis of the provisions of the Community Directive on GMOs prior to each decision.

6. Labelling proposal

Chiudere le frontiere europee agli ogm, in modo che gli altri paesi produttori di ogm smettano di esportare in UE Inserire l'etichettatura obbligatoria di ogni traccia di presenza di ogm negli alimenti convenzionali Tolleranza zero di ogm negli alimenti biologici con test di presenza/assenza

Close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU. Introduce the compulsory labelling of all traces of GMOs in conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present.

Organisation: luomuliitto

Country: Finland

Type: Individual

a. Assessment:

Molecular characterisation

Hei!

Aika hölmöä pyytää ihmisten kommentteja jo pääteystä asiasta. Ja jälleen kerran tutkimus ja perustelu oli kovin huteralla pohjalla. Visa

Hello,

It is rather stupid to ask for people's comments when the matter has already been concluded. And once again the research and reasoning were built on shaky foundations.

Visa

Organisation: Individual

Country: Finland

Type: Individual

a. Assessment:

Molecular characterisation

Huom! EFSA:n lausunnon mukaan viranomainen "katsoo, että muuntogeenisellä riisillä LLRICE62 ei todennäköisesti ole haitallisia vaikutuksia aiotuissa käyttötarkoituksissa ihmisten ja eläinten terveydelle tai ympäristölle". Aika vaarallisesti sanottu. Siis ei todennäköisesti.

NB: According to the EFSA's statement, it "concludes that LLRICE62 genetically modified rice is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses". The word "unlikely" is a rather dangerous one.

Organisation: Kurmakka - Organic Food Ltd

Country: Finland

Type: Consultant

a. Assessment:

Others

Food safety of GMO varieties in general and specifically rice LLRICE62 can not be guaranteed.

3. Environmental risk assessment

Environmental safety of GMO varieties in general and specifically rice LLRICE62 can not be guaranteed.

4. Conclusions and recommendations

Rice LLRICE62 should NOT be allowed on the EU market for use in food nor in feed.

Organisation: Individual

Country: Finland

Type: Individual

a. Assessment:

Nutritional assessment

Peoples have used food and herbs as medicine for centuries. All the food what we eat, has, even small effect to some part of our body. (Chemistry, entzymes etc...) our bodies has unknown numbers of enzymes which are activated by vitamins and nutritions we get from our food. The truth is that the science doesn't know the long term GM food caused effects to human being. What if GM food activate or bring some strange proteins in our body? Effects can be seen only when it is too late.

Others

Peoples have used food and herbs as medicine for centuries. All the food what we eat, has, even small effect to some part of our body. (Chemistry, entzymes etc...) our bodies has unknown numbers of enzymes which are activated by vitamins and nutritions we get from our food. The truth is that the science doesn't know the long term GM food caused effects to human being. What if GM food activate or bring some strange proteins in our body? Effects can be seen only when it is too late.

People must get choise, GM free food possible to them who wants it and those who doesn't care, can buy GM marked food.

3. Environmental risk assessment

Not studied carefully. Studies have to be made by accredited third party organisations.

4. Conclusions and recommendations

GM marking, even smallest amount of GM ingredients, have to be mentioned.

5. Others

Please, make the " Genetically Modified" marking mandatory.

6. Labelling proposal

Genetically modified rice LLRICE62 should not get approval by EC for any kind of use.

Organisation: privé

Country: Italy

Type: Individual

a. Assessment:

Molecular characterisation

La coltivation de riz OGM ne respecte pas les critères de précaution et les risques liés à la santé sont nombreux: - liés à la modification de l'ADN - causés par l'utilisation massive de siccatifs - effets pleiotropici et production de substances nouvelles inconnues et non prévisibles

The cultivation of GM rice does not comply with the precautionary criteria. There are many health risks: linked to DNA modification – caused by the large-scale use of desiccants – pleiotropic effects and the creation of new, unknown and unpredictable substances

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

*** Comparative analysis**

Il n'y a pas besoin d'un riz résistant aux siccatifs, car la production de riz bio est suffisante. Le marché européen risque des graves dommages économiques à cause de l'invasion de coltivations GM qui sont produites dans de pays où les couts de productions sont inférieurs et nous risquons l'écroulement des rrizières eurpéennes En plus les cultures GM sont brevetées ce qui nuit aux producteurs européens...le brevet ne devrait d'ailleurs pas etre légitime en ce que les OGM se modifient avec le temps et ne sont pas stables. En plus les gènes sont découverts et non pas des inventions ce qui fait qu'ils ne devraient pas etre brevetées.

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods. The European market risks suffering serious financial damage from an

invasion of GM crops produced in countries where production costs are lower. The European rice growing sector risks collapse. GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be capable of being patented.

b. Food Safety Assessment: Toxicology

b. Food Safety Assessment: * Toxicology

Nouvelles toxicologies inconnues et imprévisibles ni analysables en ce que nous n'avons pas les systèmes d'analyse de substances non connues. Altérations dans le développement des organes ont déjà été observées sur d'autres OGM.

New, unknown and unpredictable toxic effects, which cannot be analysed due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been observed in other GMOs.

Allergenicity

* Allergenicity

Grande probabilité de création de nouvelles allergies.

The development of new allergies is highly probable.

Nutritional assessment

* Nutritional assessment

Aucune valeur ajoutée nutritionnelle, au contraire réduction de la valeur nutritionnelle des OGM

No added nutritional value, but rather reduced nutritional value with GMOs.

Others

* Others

Il n'y a aucun besoin des OGM sur la base du critère de comparative assessment

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

3. Environmental risk assessment

Contamination certaine des filières européennes OGM free et perte de la biodiversité autochtone

Certain contamination of European GMO-free farming and loss of native biodiversity.

4. Conclusions and recommendations

4. Conclusions and recommendations

Moratoire européenne à tous les OGM

European moratorium on all GMOs.

5. Others

5. Labelling proposal

Nous voulons des referendums populaires nationaux sur la base de ce qui a été prévu par la directive communautaire en matière OGM avant de prendre toute décision en la matière

We want national referendums on the basis of the provisions of the Community Directive on GMOs prior to the taking of any decisions in this field.

6. Labelling proposal

Nous volons fermer les frontières européennes aux OGM de façon que les autres pays producteurs d'OGM arrêtent d'exporter dans l'UE. Etiquetage obligatoire de toutes traces de présence de OGM dans les aliments conventionnels. Tolérance zéro de tout OGM dans les aliments bio, avec test de présence et de l'absence.

Effets désastreux sur les économies rurales locales et générales. Nous ne voulons pas la brevetabilité de la matière vivante, et avec ces produits OGM c'est les portes grandes ouvertes à ce phénomène.

We want to close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU. Compulsory labelling of all traces of GMOs in conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present.

Disastrous effects on the rural, local and general economies. We are opposed to living things being able to be patented, and these GMOs represent a major step towards this phenomenon.

Organisation: OGMfree

Country: Italy

Type: Individual

a. Assessment:

Molecular characterisation

La coltura non rispetta i criteri del principio di precauzione. I rischi per la salute sono molteplici. Sono - connessi alla modificazione del Dna - connessi all'elevato impiego di dissecanti con effetti pleiotropici e produzione di neosostanze incognite e non prevedibili.

The crop does not comply with the criteria of the precautionary principle. There are many health risks. They are linked to DNA modification, the large-scale use of desiccants with pleiotropic effects and the creation of new, unknown and unpredictable substances.

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

Non c'è necessità di riso resistente al dissecante, in quanto se ne produce abbastanza col metodo biologico. Il mercato europeo rischia dei forti danni economici dall'invasione di colture gm, che vengono prodotte in paesi dove i costi di produzione sono minori. C'è il rischio del tracollo della risicoltura europea. Le colture gm vengono brevettate e ciò

danneggia i produttori europei. Il brevetto tra l'altro non dovrebbe essere legittimo in quanto gli ogm si modificano nel tempo e non sono stabili. Inoltre i geni sono scoperte e non invenzioni per cui non dovrebbero essere brevettabili.

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods. The European market risks suffering serious financial damage from an invasion of GM crops produced in countries where production costs are lower. The European rice growing sector risks collapse. GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be capable of being patented.

b. Food Safety Assessment:

Toxicology

Nuove tossicologie incognite e imprevedibili né analizzabili in quanto non si hanno sistemi di analisi di sostanze non conosciute. Alterazioni nello sviluppo degli organi sono state già notate nei tests su altri ogm.

New, unknown and unpredictable toxic effects, which cannot be analysed due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been noted in tests on other GMOs.

Allergenicity

Sono altamente probabili nuove allergie.

New allergies are highly probable.

Nutritional assessment

Nessun incremento, bensì riduzione del valore nutritivo degli ogm.

No improvement, but rather reduced nutritional value with GMOs.

Others

Nessuna necessità degli ogm in base al criterio di comparative assessment.

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

Contaminazione delle filiere europee ogm free e perdita della biodiversità autoctona.

Contamination of European GMO-free farming and loss of native biodiversity.

4. Conclusions and recommendations

Moratoria europea agli ogm.

European moratorium on GMOs.

5. Others

Effettuare i referendum popolari nazionali in base a quanto previsto dalla direttiva comunitaria in materia di ogm prima di ogni decisione.

Hold national referendums on the basis of the provisions of the Community Directive on GMOs prior to each decision.

6. Labelling proposal

Chiudere le frontiere europee agli ogm in modo che gli altri paesi produttori di ogm smettano di esportare in UE. Inserire l'etichettatura obbligatoria di ogni traccia di presenza di ogm negli alimenti convenzionali. Tolleranza zero di ogm negli alimenti biologici con test di presenza/ assenza.

Close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU. Introduce the compulsory labelling of all traces of GMOs in

conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present.

Organisation: association

Country: Italy

Type: Individual

a. Assessment:

Molecular characterisation

La coltura non rispetta i criteri del principio di precauzione i rischi per la salute sono dupli - connessi alla modificazione del DNA - connessi all'elevato impiego di dissecanti - effetti pleiotropici e produzione di neosostanze incognite e non prevedibili

The crop does not comply with the criteria of the precautionary principle. The health risks are twofold (*sic*) – linked to DNA modification – linked to the large-scale use of desiccants – pleiotropic effects and the creation of new, unknown and unpredictable substances.

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

non c'è necessità di riso resistente al dissecante, in quanto si produce abbastanza col metodo biologico il mercato europeo rischia di subire forti danni economici dall'invasione di colture OGM che vengono prodotte in paesi dove i costi di produzione sono minori e che rischiamo di provocare il tracollo della risicoltura europea colture gm vengono brevettate e ciò danneggia i produttori europei...il brevetto tra l'altro non dovrebbe essere legittimo in quanto gli ogm si modificano nel tempo e non sono stabili inoltre i geni sono scoperte e non invenzioni per cui non dovrebbero essere brevettabili

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods. The European market risks suffering serious financial damage from an invasion of GM crops produced in countries where production costs are lower, and we risk causing the collapse of the European rice growing sector. GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be capable of being patented.

**b. Food Safety Assessment:
Toxicology**

Nuove tossicologie incognite e imprevedibili che non saranno nppure analizzabili in quanto non si hanno sistemi di analisi di sostanze non conosciute le alterazioni nello sviluppo degli organi sono state già notate nei tests su altri ogm

New unknown and unpredictable toxic effects, which cannot even be analysed due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been noted in tests on other GMOs.

Allergenicity

nuove allergie sono altamente probabili

New allergies are highly probable.

Nutritional assessment

nessun incremento, bensì riduzione del valore nutritivo degli ogm

No improvement, but rather reduced nutritional value with GMOs.

Others

nessuna necessità degli ogm in base al criterio di comparative assessment

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

contaminazione irreversibile delle filiere europee ogm free e perdita irreversibile della biodiversità autoctona

Irreversible contamination of European GMO-free farming and irreversible loss of native biodiversity.

4. Conclusions and recommendations

moratoria europea agli ogm pubblicazione obbligatoria delle consultazioni EFSA su tutti i quotidiani principali e nei telegiornali di ogni paese europeo

European moratorium on GMOs. In all European countries, the EFSA's consultations must be published in all the main newspapers and broadcast on television news.

5. Others

inserire l'etichettatura obbligatoria di ogni traccia di presenza di ogm negli alimenti convenzionali tolleranza zero di ogm negli alimenti biologici con test di presenza/ assenza

Introduce the compulsory labelling of all traces of GMOs in conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present.

6. Labelling proposal

prima di ogni decisione Rendere obbligatori i referendum popolari nazionali in base a quanto previsto dalla direttiva comunitaria in materia di ogm

Obbligo di pubblicare sui quotidiani nazionali i risultati dei referendum di ogni paese e di tutti gli altri paesi europei

Chiudere le frontiere europee agli ogm in modo che gli altri paesi produttori di ogm smettano di esportare in UE

Compulsory national referendums on the basis of the provisions of the Community Directive on GMOs prior to each decision.

Compulsory publication of the results of each country's referendums in the national newspapers of all European countries.

Close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU.

Organisation: Individual
Country: Finland
Type: Individual

a. Assessment:
Molecular characterisation

Use of transgenic elements is not proved be stable and safe. The transgenic elements combining DNA of various life forms can pass the boundaries between species in the nature. this has been proved in several studies by now. Using this technique in plants which are used in the field, in the nature, is not safe for the environment.

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

Transgene technique is not quaranted to be stable. A new gene combination introduced in to the genome can alter the function of other genes. This may result the production of new substances in the plant. These substances may be completely new, and they may be harmful to human or to the nature.

b. Food Safety Assessment:
Toxicology

The safety has not been proven.

Allergenicity

The safety has not been proven.

Nutritional assessment

The safety has not been proven.

Others

The safety to the nature has not been proven.

3. Environmental risk assessment

The safety has not been proven. Effects to the living beings has not been studied properly.

4. Conclusions and recommendations

This variety is not needed, it is not useful enough, and the safety is not fully proven. It should not be taken to the market of EU. Canadian experience shows clearly, that gmo:s mix with all other farming, and true separation is not possible. To keep our food clean, please, deny the product from the market.

Organisation: my family

Country: Italy

Type: Individual

a. Assessment:

Molecular characterisation

Ora mi dovete spiegare come un semplice cittadino che si dichiara contrario agli OGM come la maggior parte dei cittadini europei, possa rispondere ai quesiti che ponete di seguito. Trovo questo sistema una misera presa di posizione dietro un aria saccente tanto da far sembrare stupidi coloro che contestano senza aver alcun titolo. Un sistema assai raffinato per imporsi alle masse nonostante il parere contrario della maggioranza. Viva la democrazia. Vorrei sapere se quando fate la spesa per voi e i vostri bambini preferite alimenti naturali o OGM.

Now you must explain to me how a normal citizen who is opposed to GMOs, like the majority of European citizens, can answer the questions that you have set out below. I consider this system to be a cowardly stance behind a self-important air that is enough to make those who are opposed, but unqualified, seem stupid. This is a rather cunning way of imposing your position on the masses despite the contrary opinion of the majority. Long live democracy! I would like to know whether, when you shop for yourself and your children, you prefer natural foods or GMOs?

Organisation: Consiglio Diritti Genetici

Country: Italy

Type: Non Profit Organisation

a. Assessment: Molecular characterisation

The molecular characterization turned out to be accurate, and the data (attached) presents the insert as essentially matching our expectations; the insertion site is mapped in an untranscribed region on chromosome 6, although the fine characterization of the abovementioned site, as well as the transgene expression data, have been considered confidential, hence not accessible and verifiable on our side.

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

The compositional analysis shows statistically significant differences (like calcium, potassium, pantothenic acid, vitamin B1 and E) between rice LLRICE62 and non-transgenic counterpart. It could mean a changing in the biochemical pathway of the GM rice. Therefore it seems necessary a deeper evaluation of the characteristics of this product.

b. Food Safety Assessment: Toxicology

A repeated dose oral toxicity study (PAT protein) on rodents over 14 days and a feeding study over 96-day (the whole feed) on pigs show modifications of some parameters (total cholesterol and phospholipids for the rodents and weight for the pigs). These results confirm the differences between GM rice and the control one showed in the compositional analysis and point out the presence of unwanted effects due to the genetical modification. For this reason, it seems necessary the 90-day toxicological study on rodents with the whole GM food/feed, however recommended by EFSA.

Allergenicity

The allergenicity of the whole rice LLRICE62 has not been evaluated with experimental tests: the conclusions of safety are based only on deductions. Since substantial equivalence between conventional and GM rice has not been demonstrated, and since there is evidence of some toxicity, more analysis should be conducted on the whole GM plant to check the possibility of any allergenic effect.

3. Environmental risk assessment

Even if with a low frequency, there could be the possibility of unintended loss of this rice during the transportation, storing, processing and use by farmer, especially if GM rice is imported as paddy rice, with viable grains. In environments particularly favourable for germination and spontaneous growth of GM rice, like some rice-growing areas of Spain and Italy, there is the real risk of genetic pollution of rice cultivars and/or weedy red rice plants. This risk could increase by using glyphosate in the same areas, because the rice would gain a great selective advantage in case it would acquire tolerance to glyphosate by hybridisation. On this basis it would be necessary an adequate monitoring plane, with the aim of controlling the possible unintended release of paddy rice with viable seeds, above all in the aforesaid critical points.

6. Labelling proposal

Vogliamo sottolineare il fatto che, ancora una volta, è stata pubblicata un'opinione il venerdì pomeriggio, il che significa sottrarre due giorni al mese che si ha a disposizione per intervenire nel processo di consultazione pubblica. Questa procedura (che, evidentemente, ormai è una prassi) risulta estremamente scorretta

We would like to highlight the fact that, yet again, an opinion was published on a Friday afternoon, thereby deducting two days from the month available to take part in the public consultation process. This procedure (which, clearly, is now standard practice) is extremely underhand.

Organisation: n/a
Country: Finland
Type: Individual

a. Assessment:

3. Environmental risk assessment

To the commission,

I quote from Annex F - Post-market monitoring plan (LLRICE62):

"Direct and immediate effects refer to primary effects on human health and the environment that, if they occur, are likely to be observed during the period of release of the genetically modified crop. Market introduction of a specific genetically modified crop is a gradual process and the placing on the market might be very low during the initial time period of the consent. Therefore, it is proposed to submit a general surveillance report on an annual basis, following the initial placing on the market (first import). A final report will be made at the end of the consent."

Such yearly reports in the beginning may not outline the true risk posed, if any, since the placing on the market is low, and there are not many consumers of this product yet. "Indirect effects refer to a causal chain of events with an effect on human health and the environment. Observations of indirect effects might, in some cases, be delayed. Since surveillance will also include the observation of potential indirect and/or delayed effects, we propose to include a report covering potential indirect or delayed effects, if any, on a yearly basis as it is proposed for the direct/immediate effects, following the initial placing on the market (first import). A final report will be made at the end of the consent. "

If a report of potential indirect effects or delayed effects can be made without real life data, then it should be made before the rice or rice seed of LLRICE62 is introduced to the market, so these risks can be evaluated.

"The conclusion of the risk assessment was no adverse effects assumed and as a consequence there is no need for a case specific monitoring plan relating to import of herbicide tolerant ACS-OSØØ2-5."

The risk assessment only explained the low possibility of cross-pollination, but not the potential to threat to human health through consumption. No tests or explanations were demonstrated upon this. Also, without labelling, the market knows of no separation between the GMO rice and the non-GMO rice. If people have health problems from the consumption of this GMO rice, it would be undetectable and inseparable from the consumption of non-GMO rice, since no labelling has been proposed for the consumer product LLRICE62. If there was a general decline in the health of a population, it would not be detectable whether it was caused by GMO rice, without labelling, or a vast number of other foods available on the market. The suggestion that Mayer CropSciences brings, to monitor and create annual reports on the health effects of the introduced GMO rice is infeasible without labelling, since the product will be consumed alongside other foods, without detection, and unknowing to both Mayer CropSciences or the consumers, what consumers are consuming.

Therefore I strongly urge for the labelling of the market sold LLRICE62 as GMO, or of GMO-origins.

5. Others

Dear Commission,

I think it is vitally important for GM LLRICE62 to be labelled as genetically modified rice on the package.

"The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No. 1829/2003. On the basis of the scientific opinion of the GMO Panel that GM LLRICE62 is compositionally and phenotypically equivalent to its non-genetically modified LLRICE62 except for the introduced traits, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C). "

It is exactly the fact that "phenotypically" LLRICE62 looks like other rice, that it should be labelled as GMO. Consumers have no way of knowing that the rice they buy is of GMO origin without labelling, should they object to GMO rice, and many do.

Organisation: Mediterranean seed association

Country: Italy

Type: Association

a. Assessment:

Molecular characterisation

La coltura non rispetta i criteri del principio di precauzione e i rischi per la salute sono duplici - connessi alla modificazione del Dna - connessi all'elevato impiego di dissecanti ed ha effetti pleiotropici e produzione di neosostanze incognite e non prevedibili

The crop does not comply with the criteria of the precautionary principle. The health risks are twofold (*sic*) – linked to DNA modification – linked to the large-scale use of desiccants and with pleiotropic effects and the creation of new, unknown and unpredictable substances.

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

Non c'è necessità di riso resistente al dissecante, in quanto si produce abbastanza col metodo biologico. Il mercato europeo rischia dei forti danni economici dall'invasione di colture GM che vengono prodotte in paesi dove i costi di produzione sono minori e rischiamo il tracollo della risicoltura europea. Le colture GM vengono brevettate e ciò danneggia i produttori europei. Il brevetto tra l'altro non dovrebbe essere legittimo in quanto gli OGM si modificano nel tempo e non sono stabili. Inoltre i geni sono delle scoperte e non delle invenzioni per cui non dovrebbero essere brevettati.

There is no need for rice that is resistant to desiccants, since enough is already produced with organic methods. The European market risks suffering serious financial damage from an invasion of GM crops produced in countries where production costs are lower, and we risk the collapse of the European rice growing sector. GM crops are patented, which harms European producers. In any case, such patents should not be valid since GMOs change over time and are not stable. Furthermore, genes are discoveries and not inventions and, as such, should not be patented.

b. Food Safety Assessment:

Toxicology

Possano sviluppare nuove neuro-tossine incognite e imprevedibili. Ne possono essere analizzabili in quanto non si hanno sistemi di analisi di sostanze non conosciute Alterazioni nello sviluppo degli organi sono state già notate nei tests su altri OGM

It is possible for new, unknown and unpredictable neurotoxins to develop. These cannot be analysed, due to the absence of systems for analysing unknown substances. Alterations in the development of the organs have already been noted in tests on other GMOs.

Allergenicity

Nuove allergie sono altamente probabili

New allergies are highly probable.

Nutritional assessment

Nessun incremento, bensì riduzione del valore nutritivo degli OGM

No improvement, but rather reduced nutritional value with GMOs.

Others

Nessuna necessità degli OGM in base al criterio di comparative assessment

No need for GMOs on the basis of the comparative assessment criterion.

3. Environmental risk assessment

Contaminazione delle filiere europee OGM free e perdita della biodiversità autoctona e trasferimento orizzontale

Contamination of European GMO-free farming, loss of native biodiversity and horizontal transfer.

4. Conclusions and recommendations

Moratoria europea agli OGM Le colture GM non sono sicure.

European moratorium on GMOs. GM crops are not safe.

5. Others

Effettuare i referendum popolari nazionali in base a quanto previsto dalla Direttiva CE n. 2001/18 in materia di OGM, prima di ogni decisione

Hold national referendums on the basis of the provisions of Directive 2001/18/EC on GMOs prior to each decision.

6. Labelling proposal

Chiudere le frontiere europee agli OGM in modo che gli altri Paesi produttori di OGM smettano di esportare nella EU Inserire l'etichettatura obbligatoria di ogni traccia di presenza di OGM negli alimenti convenzionali Tolleranza zero di OGM negli alimenti biologici con test di presenza/assenza Le tecnologie e i processi sociali per migliorare la qualità delle colture convenzionali a livello locale sono sempre più operativi e continuamente testati

Close Europe's borders to GMOs, so as to ensure that other countries which produce GMOs stop exporting to the EU. Introduce the compulsory labelling of all traces of GMOs in conventional foodstuffs. Zero tolerance towards GMOs in organic foodstuffs, including tests on whether they are present. The technologies and social processes for improving the quality of conventional crops at local level are becoming constantly more effective and are tested on an ongoing basis.

19/02/2008
