oilseed rape MON 88302 x MS8 x RF3

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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

Onderzoek van Hoechst (dr. Arno Schulz) betreffende de substraten van Phosphinothricinacetyltransferase(PAT). _____ In herbicide (PPT)-resistente gewassen komt het gen-produkt, het PAT, voor.

Amsterdam, 7 november 1999.

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kunnen worden door geacetyleerd glutaminezuur aan de reactiemix toe te voegen in een hoeveelheid boven de detectiegrens en na te gaan of deze toegevoegde hoeveelheid bij de reactie verdwijnt. Op grond van de resultaten van het eerste onderzoek zal het verdwijnen zeker voorspelbaar plaatsvinden!! 3. Er is gewerkt met een reactiemix waarin een grote overmaat van een concurrerend substraat, het PPT, aanwezig was. Observaties met de zuivere aminozuren zijn niet gedaan. 4. Een bespreking van de uitkomsten van het eerste onderzoek in het bijzonder waarom deze anders uitvielen, ontbreekt geheel. 5. In wezen beschuldigen de auteurs van het tweede onderzoek de auteurs van het eerste onderzoek van duimzuigerij, van fraude (het eerste onderzoek bevat een schat van getalsmatige gegevens; in het tweede onderzoek ontbreken getallen). In het tweede onderzoek is dit aspect onvoldoende uitgewerkt. De achtergrond van de conclusie, dat PAT slechts één substraat - het PTT - zou hebben is het volgende: In herbicide (PPT)-resistente gewassen komt het gen-produkt, het PAT, voor. Voor een toelating tot de markt moet de giftigheid van dit gen-produkt worden bekeken. Zou dit gen-produkt kunnen reageren met onze DARMINHOUD b.v. met het -belangrijke- aminozuur L-glutaminezuur? Het zou handenvol onderzoeksgeld betekenen om het te bagatelliseren. Totaal ontkennen lijkt voor HOECHST een betere strategie! Wij geloven, dat de conclusie uit het tweede onerzoek totaal ongefundeerd is en dat het onderzoek niet de naam van "onderzoek" mag dragen. Het is een incompetent onderzoek, en de mensen, die dit citeren dienen op de incompetentie te worden aangesproken. J. van der Meulen, L. Eijsten. http://www.gentechvrij.nl/rvs9911.html

EU to restrict herbicide glufosinate

Category: Crop Protection Products Tags: EU , restrict , herbicide , glufosinate The European Commission has announced the restrictions for the use of the herbicide glufosinate, which will be effective from Nov 13, 2013.

The decision is based on the additional information provided by the notifier, the Commission considered that the further confirmatory information required had not been provided and that a high risk for mammals and non- target arthropods could not be excluded except by imposing further restrictions.

The active ingredient will only be authorised for band or spot application at rates not exceeding 750 g ai/ha (treated surface) per application, with a maximum of two applications per year.

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Glufosinate obtained EU approval for use in apple orchards in 2007. Source: EUR-Lex http://news.agropages.com/News/NewsDetail---9598.htm

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b. Food Safety Assessment:
Toxicology

http://www.boerenlandvogels.nl/sites/default/files/2017-04/srep39328%20%281%29.pdf
Non-alcoholic fatty liver disease in rats following chronic exposure to an ultra-low dose of Roundup herbicide

The impairment of liver function by low environmentally relevant doses of glyphosate-based herbicides (GBH) is still a debatable and unresolved matter. Previously we have shown that rats administered for 2 years with 0.1 ppb (50 ng/L glyphosate equivalent dilution; 4 ng/kg body weight/day daily intake) of a Roundup GBH formulation showed signs of enhanced liver injury as indicated by anatomorphological, blood/urine biochemical changes and transcriptome profiling. Here we present a multiomic study combining metabolome and proteome liver analyses to obtain further insight into the Roundup-induced pathology. Proteins significantly disturbed (214 out of 1906 detected, $q < 0.05$) were involved in organonitrogen metabolism and fatty acid β-oxidation. Proteome disturbances reflected peroxisomal proliferation, steatosis and necrosis. The metabolome analysis (55 metabolites altered out of 673 detected, $p < 0.05$) confirmed lipotoxic conditions and oxidative stress by showing an activation of glutathione and ascorbate free radical scavenger systems. Additionally, we found metabolite alterations associated with hallmarks of hepatotoxicity such as γ-glutamyl dipeptides, acylcarnitines, and proline derivatives. Overall, metabolome and proteome disturbances showed a substantial overlap with biomarkers of non-alcoholic fatty liver disease and its progression to steatohepatosis and thus confirm liver functional dysfunction resulting from chronic ultra-low dose GBH exposure. Source: Mesnage R et al. (2017) Scientific Reports 7, Article number: 39328 srep39328 (1).pdf

Court Rules Against Monsanto, Allows California To Put Cancer Warning On Roundup. January 27, 2017 3:27 PM http://sacramento.cbslocal.com/2017/01/27/court-rules-against-monsanto-allows-california-to-put-cancer-warning-on-roundup/

Allergenicity

Verklaringen van moeders in de USA waar GMO´s niet gelabeld zijn.

"When my son was born he fussed a lot, the whole day, wouldn't nap. I breast fed until he was three months old. And because his gut was not right, he fussed and I could never console him. I tried all the gassy meds, not sure they are considered meds. Once on formula the fussy continued, we switched to different formulas, but not until we switched to parents choice organic, Walmart, his fussy stopped, he began taking naps. As a toddler, I fed him cheerios, a main staple in our house. The tantrums began; two hours at a time couple times a day. This is with head banging or slamming his head into the wall repeatedly. He wouldn't let me hold him, not even touch him. Can you imagine not cuddling your baby? I cried everyday. I had watched the movie Food Inc. It touched on a subject I wasn't familiar with. After watching Genetic Roulette, I cleaned out the cupboards. After doing this, within two weeks my sons tantrums stopped completely, he started smiling, crawling into my lap for cuddles. I had no idea that was the issue. Even now when he gets something conventionally/ GMO poison, he'll have another tantrum like his past. So if there's a question as to where it's from-what kind of seed, I don't take it. So for me and my family, we bow out from being a guinea pig."- Stephanie Vanderyacht

"My husband was in the hospital 5 times last year. Doctors wanted to remove part of his intestine because it was so infected instead doctors pumped him full of antibotics for a week when he got out of hospital I changed his diet and all our family food choices to NON- GMO foods WOW what a diffrence he's doing great and food never tasted so good! I will march sign petitions anything to reclaim our healthy labeled food choices. God Speed JUST SAY NO TO GMO'S ….MAAM! " Rhonda Bryne, MAA

My 7 year old son was diagnosed with asthma and needed glasses inside of two weeks. I started learning about asthma and natural ways to control it. Then I found out about GMO. I removed my family from GMO foods/drinks. My 7 year old went from needing a nebulizer 3x's a day to not at all. His asthma disappeared. He also no longer had the stigmatism that required glasses. The eye Dr. said he must have had 'some sort of inflammation' that is now gone for whatever reason. The reason was removing GMO from our diets. He was recommended for retention last year. This year, he is at the top of his class. Karen L.~Moms Across America The above testimonials are a sampling of the hundreds of testimonials which Moms have sent to us. More see:
http://www.momsacrossamerica.com/zenhoneycutt/mom_s_testimonials

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Others

Persbericht Bart Staes

Terwijl Europese Commissie een agrochemische monsterfusie goedkeurt, stemt EP tegen goedkeuring nieuwe ggo's 2017-04-05 Voeding & landbouw Klimaat & energie Democratie & mensenrechten Gezondheid & consumenten Milieu & dierenwelzijn Geldzaken & handel Europa in de wereld Een ruime meerderheid van het Europees Parlement stemde vandaag (1) in met een door de groene fractie ingediende resolutie, die bezwaar aantekent tegen de goedkeuring van een hele reeks ggo's. Initiatiefnemer Bart Staes, Europees parlementslid voor Groen, reageert tevreden: "Dit is de zesde stemming op ruim een jaar waarin een meerderheid van het EP zich uitspreekt tegen het gebruik van ggo's in de landbouw en in de voedselketen. Ook een meerderheid van de experten van de lidstaten en Europese burgers is tegen. Als de Europese Commissie nog een greintje democratisch inzicht heeft, moet ze de vergunning voor deze ggo's niet afgeven." In een beroepscommissie van nationale experten (Standing Committee on Plants, Animals, Food and Feed) heeft een meerderheid het voorstel van de Europese Commissie om drie genetisch gewijzigde maïssoorten toe te laten voor de teelt op Europese akkers, op 27 maart ook al weggestemd (2). Liefst 16 lidstaten stemden toen tegen en slechts 6 voor. Staes: "Die allerlaatste stemmingen over ggo's op 27 maart in de beroepscommissie en vandaag in het EP zijn belangrijk, want het zou de eerste toestemming betekenen voor het telen van een nieuw ggo-gewas op Europese akkers in 18 jaar (3)." Drie genetisch gewijzigde maïssoorten lagen voor: Bt11 van Syngenta en 1507 van Dupont voor een eerste toelating, en de MON810 van Monsanto voor een hernieuwing van de toelating. Staes: "Er is een duidelijke en consistente oppositie in het EP tegen nieuwe ggo's, een onderwerp waar vele Europeanen bijzonder sceptisch tegenover staan (4). Het laatste voorstel van de Europese Commissie is om liefst 20 verschillende ggo-variëteiten toe te laten, waarvan verschillende nog niet eens op veiligheid zijn getest. Dat is in strijd met het huidige Europese beleid." De stemming vandaag valt samen met de goedkeuring door de Europese Commissie van een overname van het agrochemische bedrijf Syngenta door ChemChina. Staes: "Een

fusie tussen deze twee multinationals in een sector die al zeer geconcentreerd is, is zeer slecht nieuws voor boeren, het milieu en voedselveiligheid. Om verdere marktconcentratie en machtsconcentratie in de landbouw te voorkomen, kan de Europese Commissie niet anders dan de aangekondigde fusie tussen Bayer en Monsanto afwijzen."

(1) 426 parlementsleden stemden vandaag voor de resolutie, 230 tegen, bij 38 onthoudingen (2) De vergunningsvoorstellen van de Europese Commissie betreffen voor teelt : 3 maïssoorten ; voor gebruik in voeding of voeders (import) : 21 maïsvariëteiten; en een katoensoort. (3) Behalve de genetisch gewijzigde Amflora-aardappel die een heel kort leven beschoren was. (4) Volgens de Eurobarometer van 2010 is 61% van de Europeanen gekant tegen ggo's in het veld en in voeding.

Rising demand for organic and non-GMO grains outpaces U.S. production By Ken Roseboro Published: February 22, 2017 Issue: March Category: Organic/Sustainable Farming

Organic imports rise sharply as U.S. corn and soybean growers contemplate premiums, risk-reward scenarios Increasing consumer demand for organic and non-GMO foods led to a sharp rise in organic grain imports in 2016—prompting food manufacturers to explore new incentives for U.S. growers transitioning to organic production, according to a new report from CoBank. While U.S. production of non-GMO crops has risen, domestic production of organic corn and soybeans remains well short of demand. CUT http://non-gmoreport.com/articles/rising-demand-organic-non-gmo-grains-outpaces-u-s-production/

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4. Conclusions and recommendations

De Gentechvrije Burgers willen geen GMO´s op hun bord, noch als kleurstof, aroma of smaakstof o.i.d. noch als medicijn, biological of vaccin, ook geen gentech bloemen met een veranderde bloemkleur, noch als gewassen op het veld. En geen wasmiddelen met gentech enzymen.

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6. Labelling proposal

De labeling in Nederland is een farce. Als er gelabeld wordt doe het dan goed en controleer streng, vooral op gentechproducten die via paralelle import verkregen zijn. Daar kunnen mogelijk niet toegelaten GMO´s zoals bv. bepaalde gentech suikers in zitten. Label dan ook het zuivel van dieren die gentech voer kregen alsmede alle andere toepassingen die nu niet gelabeld zijn zoals vitamines, enzymen, kleurstoffen en smaakstoffen e.d. Lees wat de Gentechvrije Burgers uit Lelystad onderzocht hebben:

Alle Amerikaanse (gentech) producten bij Jumbo zijn foutief gelabeld. Jumbo zet op al haar producten uit het Amerikaanse assortiment standaard de waarschuwing "Amerikaanse producten kunnen genetisch gemodificeerde grondstoffen bevatten". Zelfs ook op de "GMO Free" producten. Voor de consument is het zo niet meer te bepalen of een product nu wel of niet genetisch gemodificeerde organismen (GGO/GMO) bevat. Dit tast basisprincipes van de

etiketteringsplicht voor gentech voedsel aan: • Consument heeft het recht om te weten wat hij eet • De keuzevrijheid van de consument om wel of niet voor genetisch gemanipuleerd voedsel te kiezen Bovendien kan het zijn dat deze producten ingredienten bevatten die niet toegelaten zijn in de EU. Het betreft alle Amerikaanse producten uit het assortiment van Jumbo (minimaal 36 producten). Jumbo overtreedt hiermee de Nederlandse wet en regelgeving met betrekking tot de verplichte GGO etikettering. Met name het Warenwetbesluit nieuwe voedingsmiddelen en EU verordening 1830/2003. In de EU geldt een etiketteringsplicht voor gentech producten. De te gebruiken teksten zijn letterlijk voorgeschreven. Hier mag niet van afgeweken worden. 5-7-2015 Verzoek aan de NVWA om over te gaan tot handhaving bij Jumbo. Daar deze actie van Jumbo de principes van keuzevrijheid en het recht van de consument om te weten wat hij eet aantasten, hebben we de NVWA (Nederlandse Voedsel- en Warenautoriteit) gevraagd in te grijpen. .(meer info>>)

1-9-2015 Uitspraak NVWA: Jumbo moet de etikettering van alle Amerikaanse producten aanpassen. Op verzoek van de Gentechvrije Burgers heeft de NVWA meteen een onderzoek in gesteld. Citaat uit de brief van de Nederlandse Voedsel- en Warenautoriteit (NVWA), 1 september 2015: "Er zijn door de NVWA en de verkooporganisatie passende maatregelen genomen om voortduring van de afwijking te stoppen. Per 14 augustus 2015 is de verkeerde informatie van de website verwijderd of aangepast. Tevens zijn op de genoemde datum de etiketten aangepast". (volledige tekst brief NVWA >>) Eind goed al goed? Helaas blijft Jumbo er een potje van maken..

Want we hebben inmiddels (2-9-2015) bij de nieuwe etiketten geconstateerd: • Producten die volgens het etiket genetisch gemodificeerde tarwe bevatten. GG-tarwe is in de EU niet toegestaan. • Producten met volgens het etiket genetisch gemodificeerde organismen (GGO) maar op verpakking staat GMO-Free. • Producten zonder enige labeling (geen Nederlandse declaratielijst). • We hebben er geen vertrouwen in dat Jumbo werkelijk checkt of de ingrediënten in deze Amerikaanse producten wel toegelaten zijn. Na twee ingrepen van de NVWA heeft Jumbo zijn zaakjes schijnbaar nog steeds niet op orde!! . Op 9 maart 2015 had de NVWA namelijk ook al op verzoek van De Gentechvrije Burgers ingegrepen bij Jumbo. Het betrof toentertijd plm. 30 geheel niet gelabelde Amerikaanse gentech producten. Citaat uitspraak NVWA op 9 maart 2015: Een inspecteur van de NVWA heeft monsters meegenomen voor onderzoek. Tijdens het onderzoek werd vastgesteld dat de etiketten niet aan de wettelijke eisen voldeed. Hiervoor heeft de NVWA een passende maatregel genomen. (meer info>>) 04-05-2016: Intussen worden dan eindelijk de eerste producten goed gelabeld door Jumbo na herhaaldelijke verzoeken van De Gentechvrije Burgers, Europees Consumentenplatform aan de NVWA. Maar wat gebeurt er als er weer een andere importeur wordt aangetrokken? En er staan nog steeds artikelen die niet goed gelabeld zijn in de schappen en die geen verplichte Nederlandse tekst op het label vermelden, die zegt dat het product genetisch gemodificeerde (= gemanipuleerde) organismen bevat. We houden de vinger aan de pols! 8 november 2016. Nu labels van Poptart ontdekt bij de Jumbo, die zeer onleesbaar zijn en het is er niet één maar meerdere pakken..

Via Facebook:

Miep Bos Jumbo Supermarkten 28 februari · Beste Jumbo, nu weer een USA product ontdekt met verkeerde labeling in één van uw winkels. Er zit GMO in of niet. "Bevat mogelijk GMO" is niet toegestaan volgens de EU richtlijn.

Jumbo Supermarkten Hallo Miep, dat is een goed punt. Dat is niet de bedoeling. We gaan dit navragen bij onze collega's hoe dit zit. Heb je wellicht ook een foto van de streepjescode voor ons? · 28 februari om 22:04

Jumbo Supermarkten Hallo Miep. Wij hebben hierover contact opgenomen met de ondernemer en het product is uit het assortiment gehaald. Bedankt voor het attenderen. 20 maart om 10:14
https://www.facebook.com/photo.php?fbid=324595777937632&set=o.156928557716372&type=3&theater¬if_t=photo_comment¬if_id=1488315874763235 24 maart 2017 Frisdranken Coca Cola Vanilla en A&W en Cheetos (zoutjes, doosje) bij Jumbo hebben geen vermelding dat ze geproduceerd zijn met gentech, Cheetos heeft zelfs geen Nederlands label. Deze producten zijn geproduceerd in de USA en via parallelle import verkregen. Jumbo zou een onderzoek instellen..

Maart-april 2017: Verkeerd Nederlands label, geen Nederlands label (Duncan Hines) en in één geval wel een Engelse waarschuwing maar geen Nederlands label (Frito Lay). "Bevat mogelijk GMO". Foutieve tekst. Pakken werden verwijderd na een klacht op internet, enkele dagen later stonden er weer pakken maar alleen de Blue Velvet variant en dan zonder Nederlands etiket of wel een etiket maar met een foutieve tekst. Engelse waarschuwing maar geen Nederlands etiket. Weer geklaagd via Facebook.

Jumbo reageerde zo: "Vervelend om te horen dat er nu helemaal geen label op de verpakking zat. We zullen jouw melding doorzetten naar de ondernemer. Je mag dit ook altijd direct aangeven in de winkel, zodat de verpakkingen van een label voorzien kunnen worden. Bedankt voor het attenderen."

Ons commentaar: Jumbo is en blijft verantwoordelijk en moet in alle gevallen de wet naleven. De labels zijn niet alleen verkeerd of ontbreken geheel in deze ene Jumbo maar in alle Jumbo's die deze gentechproducten van deze importeur voeren. En dus moet Jumbo er voor zorgen dat die gewoon zijn zaakjes op orde heeft en dat in alle supermarkten! Nog steeds wordt niet nagegaan waar er nog meer foute labels opzitten en die zijn we vandaag, 11 april 2017, zelfs weer tegengekomen! Een kwalijke zaak!

Voor verdere ontwikkelingen zie onze start pagina>> of volg ons via Facebook of twitter.

Verzoek aan de NVWA om over te gaan tot handhaving bij Jumbo>> Antwoord NVWA (volledige tekst)>> Inventarisatie gentech producten bij Jumbo>>

http://www.gentechvrij.nl/DossierJumbo_2.html

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b. Food Safety Assessment:
Toxicology

http://www.boerenlandvogels.nl/sites/default/files/2017-04/srep39328%20%281%29.pdf Non-alcoholic fatty liver disease in rats following chronic exposure to an ultra-low dose of Roundup herbicide

The impairment of liver function by low environmentally relevant doses of glyphosate-based herbicides (GBH) is still a debatable and unresolved matter. Previously we have shown that rats administered for 2 years with 0.1 ppb (50 ng/L glyphosate equivalent dilution; 4 ng/kg body weight/day daily intake) of a Roundup GBH formulation showed signs of enhanced liver injury as indicated by anatomorphological, blood/urine biochemical changes and transcriptome profiling. Here we present a multiomic study combining metabolome and proteome liver analyses to obtain further insight into the Roundup-induced pathology.

Proteins significantly disturbed (214 out of 1906 detected, $q < 0.05$) were involved in organonitrogen metabolism and fatty acid β-oxidation. Proteome disturbances reflected peroxisomal proliferation, steatosis and necrosis. The metabolome analysis (55 metabolites altered out of 673 detected, $p < 0.05$) confirmed lipotoxic conditions and oxidative stress by showing an activation of glutathione and ascorbate free radical scavenger systems. Additionally, we found metabolite alterations associated with hallmarks of hepatotoxicity such as γ-glutamyl dipeptides, acylcarnitines, and proline derivatives. Overall, metabolome and proteome disturbances showed a substantial overlap with biomarkers of non-alcoholic fatty liver disease and its progression to steatohepatosis and thus confirm liver functional dysfunction resulting from chronic ultra-low dose GBH exposure. Source: Mesnage R et al. (2017) Scientific Reports 7, Article number: 39328 srep39328 (1).pdf

Court Rules Against Monsanto, Allows California To Put Cancer Warning On Roundup. January 27, 2017 3:27 PM http://sacramento.cbslocal.com/2017/01/27/court-rules-against-monsanto-allows-california-to-put-cancer-warning-on-roundup/

Allergenicity

Verklaringen van moeders in de USA waar GMO´s niet gelabeld zijn.

"When my son was born he fussed a lot, the whole day, wouldn't nap. I breast fed until he was three months old. And because his gut was not right, he fussed and I could never console him. I tried all the gassy meds, not sure they are considered meds. Once on formula the fussy continued, we switched to different formulas, but not until we switched to parents choice organic, Walmart, his fussy stopped, he began taking naps. As a toddler, I fed him cheerios, a main staple in our house. The tantrums began; two hours at a time couple times a day. This is with head banging or slamming his head into the wall repeatedly. He wouldn't let me hold him, not even touch him. Can you imagine not cuddling your baby? I cried everyday. I had watched the movie Food Inc. It touched on a subject I wasn't familiar with. After watching Genetic Roulette, I cleaned out the cupboards. After doing this, within two weeks my sons tantrums stopped completely, he started smiling, crawling into my lap for cuddles. I had no idea that was the issue. Even now when he gets something conventionally/ GMO poison, he'll have another tantrum like his past. So if there's a question as to where it's from-what kind of seed, I don't take it. So for me and my family, we bow out from being a guinea pig."- Stephanie Vanderyacht

"My husband was in the hospital 5 times last year. Doctors wanted to remove part of his intestine because it was so infected instead doctors pumped him full of antibotics for a week when he got out of hospital I changed his diet and all our family food choices to NON- GMO foods WOW what a diffrence he’s doing great and food never tasted so good! I will march sign petitions anything to reclaim our healthy labeled food choices. God Speed JUST SAY NO TO GMO’S ….MAAM! " Rhonda Bryne, MAA

My 7 year old son was diagnosed with asthma and needed glasses inside of two weeks. I started learning about asthma and natural ways to control it. Then I found out about GMO. I removed my family from GMO foods/drinks. My 7 year old went from needing a nebulizer 3x’s a day to not at all. His asthma disappeared. He also no longer had the stigmatism that

required glasses. The eye Dr. said he must have had ‘some sort of inflammation’ that is now gone for whatever reason. The reason was removing GMO from our diets. He was recommended for retention last year. This year, he is at the top of his class. Karen L.~Moms Across America The above testimonials are a sampling of the hundreds of testimonials which Moms have sent to us. More see:
http://www.momsacrossamerica.com/zenhoneycutt/mom_s_testimonials

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Others

Persbericht Bart Staes

Terwijl Europese Commissie een agrochemische monsterfusie goedkeurt, stemt EP tegen goedkeuring nieuwe ggo’s 2017-04-05 Voeding & landbouw Klimaat & energie Democratie & mensenrechten Gezondheid & consumenten Milieu & dierenwelzijn Geldzaken & handel Europa in de wereld Een ruime meerderheid van het Europees Parlement stemde vandaag (1) in met een door de groene fractie ingediende resolutie, die bezwaar aantekent tegen de goedkeuring van een hele reeks ggo’s. Initiatiefnemer Bart Staes, Europees parlementslid voor Groen, reageert tevreden: “Dit is de zesde stemming op ruim een jaar waarin een meerderheid van het EP zich uitspreekt tegen het gebruik van ggo’s in de landbouw en in de voedselketen. Ook een meerderheid van de experten van de lidstaten en Europese burgers is tegen. Als de Europese Commissie nog een greintje democratisch inzicht heeft, moet ze de vergunning voor deze ggo’s niet afgeven.” In een beroepscommissie van nationale experten (Standing Committee on Plants, Animals, Food and Feed) heeft een meerderheid het voorstel van de Europese Commissie om drie genetisch gewijzigde maïssoorten toe te laten voor de teelt op Europese akkers, op 27 maart ook al weggestemd (2). Liefst 16 lidstaten stemden toen tegen en slechts 6 voor. Staes: “Die allerlaatste stemmingen over ggo’s op 27 maart in de beroepscommissie en vandaag in het EP zijn belangrijk, want het zou de eerste toestemming betekenen voor het telen van een nieuw ggo-gewas op Europese akkers in 18 jaar (3).” Drie genetisch gewijzigde maïssoorten lagen voor: Bt11 van Syngenta en 1507 van Dupont voor een eerste toelating, en de MON810 van Monsanto voor een hernieuwing van de toelating. Staes: “Er is een duidelijke en consistente oppositie in het EP tegen nieuwe ggo’s, een onderwerp waar vele Europeanen bijzonder sceptisch tegenover staan (4). Het laatste voorstel van de Europese Commissie is om liefst 20 verschillende ggo-variëteiten toe te laten, waarvan verschillende nog niet eens op veiligheid zijn getest. Dat is in strijd met het huidige Europese beleid.” De stemming vandaag valt samen met de goedkeuring door de Europese Commissie van een overname van het agrochemische bedrijf Syngenta door ChemChina. Staes: “Een fusie tussen deze twee multinationals in een sector die al zeer geconcentreerd is, is zeer slecht nieuws voor boeren, het milieu en voedselveiligheid. Om verdere marktconcentratie en machtsconcentratie in de landbouw te voorkomen, kan de Europese Commissie niet anders dan de aangekondigde fusie tussen Bayer en Monsanto afwijzen.”

(1) 426 parlementsleden stemden vandaag voor de resolutie, 230 tegen, bij 38 onthoudingen (2) De vergunningsvoorstellen van de Europese Commissie betreffen voor teelt : 3 maïssoorten ; voor gebruik in voeding of voeders (import) : 21 maïsvariëteiten; en een katoensoort. (3) Behalve de genetisch gewijzigde Amflora-aardappel die een heel kort leven beschoren was. (4) Volgens de Eurobarometer van 2010 is 61% van de Europeanen gekant tegen ggo’s in het veld en in voeding.

Rising demand for organic and non-GMO grains outpaces U.S. production By Ken Roseboro Published: February 22, 2017 Issue: March Category: Organic/Sustainable Farming

Organic imports rise sharply as U.S. corn and soybean growers contemplate premiums, risk-reward scenarios Increasing consumer demand for organic and non-GMO foods led to a sharp rise in organic grain imports in 2016—prompting food manufacturers to explore new incentives for U.S. growers transitioning to organic production, according to a new report from CoBank. While U.S. production of non-GMO crops has risen, domestic production of organic corn and soybeans remains well short of demand. CUT http://non-gmoreport.com/articles/rising-demand-organic-non-gmo-grains-outpaces-u-s-production/

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4. Conclusions and recommendations

De Gentechvrije Burgers willen geen GMO´s op hun bord, noch als kleurstof, aroma of smaakstof o.i.d. noch als medicijn, biological of vaccin, ook geen gentech bloemen met een veranderde bloemkleur, noch als gewassen op het veld. En geen wasmiddelen met gentech enzymen.

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5. Others

Ik sluit me volledig aan bij de uitspraken van Miep Bos, woordvoerster van De Gentechvrije Burgers, die al eerder een commentaar over GM oilseed rape MON 88302 x MS8 x RF3 aan u heeft gestuurd. Alle uitspraken i.o. van Wieteke van Dort opgetekend door Miep Bos, woordvoerster van De Gentechvrije Burgers. Lelystad. www.gentechvrij.nl

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6. Labelling proposal

De labeling in Nederland is een farce. Als er gelabeld wordt doe het dan goed en controleer streng, vooral op gentechproducten die via paralelle import verkregen zijn. Daar kunnen mogelijk niet toegelaten GMO´s zoals bv. bepaalde gentech suikers in zitten. Label dan ook het zuivel van dieren die gentech voer kregen alsmede alle andere toepassingen die nu niet gelabeld zijn zoals vitamines, enzymen, kleurstoffen en smaakstoffen e.d. Lees wat de Gentechvrije Burgers uit Lelystad onderzocht hebben:

Alle Amerikaanse (gentech) producten bij Jumbo zijn foutief gelabeld. Jumbo zet op al haar producten uit het Amerikaanse assortiment standaard de waarschuwing "Amerikaanse producten kunnen genetisch gemodificeerde grondstoffen bevatten". Zelfs ook op de "GMO Free" producten. Voor de consument is het zo niet meer te bepalen of een product nu wel of niet genetisch gemodificeerde organismen (GGO/GMO) bevat. Dit tast basisprincipes van de etiketteringsplicht voor gentech voedsel aan: • Consument heeft het recht om te weten wat hij eet • De keuzevrijheid van de consument om wel of niet voor genetisch gemanipuleerd voedsel te kiezen Bovendien kan het zijn dat deze producten ingredienten bevatten die niet

toegelaten zijn in de EU. Het betreft alle Amerikaanse producten uit het assortiment van Jumbo (minimaal 36 producten). Jumbo overtreedt hiermee de Nederlandse wet en regelgeving met betrekking tot de verplichte GGO etikettering. Met name het Warenwetbesluit nieuwe voedingsmiddelen en EU verordening 1830/2003. In de EU geldt een etiketteringsplicht voor gentech producten. De te gebruiken teksten zijn letterlijk voorgeschreven. Hier mag niet van afgeweken worden. 5-7-2015 Verzoek aan de NVWA om over te gaan tot handhaving bij Jumbo. Daar deze actie van Jumbo de principes van keuzevrijheid en het recht van de consument om te weten wat hij eet aantasten, hebben we de NVWA (Nederlandse Voedsel- en Warenautoriteit) gevraagd in te grijpen. .(meer info>>)

1-9-2015 Uitspraak NVWA: Jumbo moet de etikettering van alle Amerikaanse producten aanpassen. Op verzoek van de Gentechvrije Burgers heeft de NVWA meteen een onderzoek in gesteld. Citaat uit de brief van de Nederlandse Voedsel- en Warenautoriteit (NVWA), 1 september 2015: "Er zijn door de NVWA en de verkooporganisatie passende maatregelen genomen om voortduring van de afwijking te stoppen. Per 14 augustus 2015 is de verkeerde informatie van de website verwijderd of aangepast. Tevens zijn op de genoemde datum de etiketten aangepast". (volledige tekst brief NVWA >>) Eind goed al goed? Helaas blijft Jumbo er een potje van maken..

Want we hebben inmiddels (2-9-2015) bij de nieuwe etiketten geconstateerd: • Producten die volgens het etiket genetisch gemodificeerde tarwe bevatten. GG-tarwe is in de EU niet toegestaan. • Producten met volgens het etiket genetisch gemodificeerde organismen (GGO) maar op verpakking staat GMO-Free. • Producten zonder enige labeling (geen Nederlandse declaratielijst). • We hebben er geen vertrouwen in dat Jumbo werkelijk checkt of de ingrediënten in deze Amerikaanse producten wel toegelaten zijn. Na twee ingrepen van de NVWA heeft Jumbo zijn zaakjes schijnbaar nog steeds niet op orde!! . Op 9 maart 2015 had de NVWA namelijk ook al op verzoek van De Gentechvrije Burgers ingegrepen bij Jumbo. Het betrof toentertijd plm. 30 geheel niet gelabelde Amerikaanse gentech producten. Citaat uitspraak NVWA op 9 maart 2015: Een inspecteur van de NVWA heeft monsters meegenomen voor onderzoek. Tijdens het onderzoek werd vastgesteld dat de etiketten niet aan de wettelijke eisen voldeed. Hiervoor heeft de NVWA een passende maatregel genomen. (meer info>>) 04-05-2016: Intussen worden dan eindelijk de eerste producten goed gelabeld door Jumbo na herhaaldelijke verzoeken van De Gentechvrije Burgers, Europees Consumentenplatform aan de NVWA. Maar wat gebeurt er als er weer een andere importeur wordt aangetrokken? En er staan nog steeds artikelen die niet goed gelabeld zijn in de schappen en die geen verplichte Nederlandse tekst op het label vermelden, die zegt dat het product genetisch gemodificeerde (= gemanipuleerde) organismen bevat. We houden de vinger aan de pols! 8 november 2016. Nu labels van Poptart ontdekt bij de Jumbo, die zeer onleesbaar zijn en het is er niet één maar meerdere pakken..

Via Facebook:

Miep Bos Jumbo Supermarkten 28 februari · Beste Jumbo, nu weer een USA product ontdekt met verkeerde labeling in één van uw winkels. Er zit GMO in of niet. "Bevat mogelijk GMO" is niet toegestaan volgens de EU richtlijn.

Jumbo Supermarkten Hallo Miep, dat is een goed punt. Dat is niet de bedoeling. We gaan dit navragen bij onze collega's hoe dit zit. Heb je wellicht ook een foto van de streepjescode voor ons? · 28 februari om 22:04

Jumbo Supermarkten Hallo Miep. Wij hebben hierover contact opgenomen met de ondernemer en het product is uit het assortiment gehaald. Bedankt voor het attenderen. 20 maart om 10:14
https://www.facebook.com/photo.php?fbid=324595777937632&set=o.156928557716372&type=3&theater¬if_t=photo_comment¬if_id=1488315874763235 24 maart 2017 Frisdranken Coca Cola Vanilla en A&W en Cheetos (zoutjes, doosje) bij Jumbo hebben geen vermelding dat ze geproduceerd zijn met gentech, Cheetos heeft zelfs geen Nederlands label. Deze producten zijn geproduceerd in de USA en via parallelle import verkregen. Jumbo zou een onderzoek instellen..

Maart-april 2017: Verkeerd Nederlands label, geen Nederlands label (Duncan Hines) en in één geval wel een Engelse waarschuwing maar geen Nederlands label (Frito Lay). "Bevat mogelijk GMO". Foutieve tekst. Pakken werden verwijderd na een klacht op internet, enkele dagen later stonden er weer pakken maar alleen de Blue Velvet variant en dan zonder Nederlands etiket of wel een etiket maar met een foutieve tekst. Engelse waarschuwing maar geen Nederlands etiket. Weer geklaagd via Facebook.

Jumbo reageerde zo: "Vervelend om te horen dat er nu helemaal geen label op de verpakking zat. We zullen jouw melding doorzetten naar de ondernemer. Je mag dit ook altijd direct aangeven in de winkel, zodat de verpakkingen van een label voorzien kunnen worden. Bedankt voor het attenderen."

Ons commentaar: Jumbo is en blijft verantwoordelijk en moet in alle gevallen de wet naleven. De labels zijn niet alleen verkeerd of ontbreken geheel in deze ene Jumbo maar in alle Jumbo's die deze gentechproducten van deze importeur voeren. En dus moet Jumbo er voor zorgen dat die gewoon zijn zaakjes op orde heeft en dat in alle supermarkten! Nog steeds wordt niet nagegaan waar er nog meer foute labels opzitten en die zijn we vandaag, 11 april 2017, zelfs weer tegengekomen! Een kwalijke zaak!

Voor verdere ontwikkelingen zie onze start pagina>> of volg ons via Facebook of twitter.

Verzoek aan de NVWA om over te gaan tot handhaving bij Jumbo>> Antwoord NVWA (volledige tekst)>> Inventarisatie gentech producten bij Jumbo>>

http://www.gentechvrij.nl/DossierJumbo_2.html

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
Others

Summary of the advisory opinion of the International Monsanto Tribunal Delivered on the 18th of April 2017 in The Hague, Netherlands The International Monsanto Tribunal is a unique "Opinion Tribunal" convened by civil society to clarify the legal obligations and consequences of some of the activities of the Monsanto Company. During the hearings that took place on October 15th and 16th in The Hague, judges heard testimonies related to the six questions posed to the Tribunal1. The ensuing legal opinion delivered by the Tribunal includes a legal analysis of the questions asked, with respect to both existing international law, and to prospective law in order to improve international human rights and environmental law. The advisory opinion is structured in three parts. The introductory section details the conditions within which the Tribunal was initiated. The middle section examines the six questions posed to the Tribunal. Looking at the broader picture, the final section tackles the growing asymmetry between the rights conceded to corporations and the constraints imposed upon them to protect local communities and/or future generations, wherever corporations operate. Question 1, as posed to the Tribunal, related to alleged infringement on the right to a healthy environment. In other words, did the Monsanto firm, by its activities, act in conformity with the right to a safe, clean, healthy and sustainable environment, as recognized in international human rights law (Resolution 25/21 of the Human Rights Council, of 15 April 2014), taking into account the responsibilities imposed on corporations by the Guiding Principles on Business and Human Rights, as endorsed by the Human Rights Council in Resolution 17/4 of 16 June 2011? The Tribunal recalls that “the right to a healthy environment” concept can be traced to the UN Conference on the Human Environment in Stockholm, 1972. With the notion that the environment is a precondition for the enjoyment of human rights, this marked the dawn of a new era in international law. Today, no less than 140 states have incorporated the right to a healthy environment into their constitutions, making it a norm of international customary law. The Special Rapporteur on Human Rights and Environment, John Knox, has identified threats on the right to a healthy environment, and established a set of requirements to protect it. The UN Human Rights Council has concluded that human rights law sets certain obligations on States to guarantee that the right to enjoy a healthy environment is respected. The Monsanto Tribunal hearings allowed for the gathering of testimonies related to various impacts on human health (especially on farmers), soils, plants, aquatic organisms, animal health and biodiversity. These testimonies also included the impacts of spraying crop protection products (herbicides, pesticides). In addition, the information collected also shed light on the impacts on indigenous communities and peoples in many countries, and on the absence of adequate information given to those concerned. Based on the above findings and to answer Question 1, the Tribunal concludes that Monsanto has engaged in practices which have negatively impacted the right to a healthy environment. 1 See terms of reference. Question 2 concerned the alleged infringement on the right to food as recognized in Article 11 of the International Covenant on Economic, Social and Cultural Rights, in Articles 24.2(c) and (e) and 27.3 of the Convention on the Rights of the Child, and in Articles 25(f) and 28.1 of the Convention on the Elimination of All Forms of Discrimination against Women. According to the UN Committee on Economic, Social and Cultural Rights, “The right to adequate food is realized when every man, woman and child, alone or in community with others, has physical and economic access at all times to adequate food or means for its procurement”. According to the Tribunal, business entities are also responsible to respect this right by applying the Guidelines for Multinational Enterprises of the OECD and the UN Guiding Principles on Business and Human Rights. The hearings accounted for negative impacts on production systems and ecosystems, the appearance of invasive species and the loss of efficiency of Roundup over time. Some farmers were sentenced to pay royalties after their fields were contaminated by genetically modified organisms (GMOs), while others stated that the corporation is taking over the seed market,

even though Monsanto's products are not as productive as promised. In response to Question 2, the Tribunal concludes that Monsanto has engaged in practices that have negatively impacted the right to food. Monsanto's activities affect food availability for individuals and communities and interfere with the ability of individuals and communities to feed themselves directly or to choose non-genetically modified seeds. In addition, genetically modified seeds are not always affordable for farmers and threaten biodiversity. Monsanto's activities and products cause damage to soil, water and to the environment more generally. The Tribunal concludes that food sovereignty is also affected and underlines the cases in which genetic contamination of fields forced farmers to pay royalties to Monsanto or even to abandon their non-GMO crops due to this contamination. There is indeed an infringement on the right to food because of aggressive marketing on GMOs which can force farmers to buy new seeds every year. The dominant agro-industrial model can be criticized even more strongly because other models - such as agroecology - exist that respect the right to food. Question 3 concerned the alleged infringement on the right to the highest attainable standard of health of everyone can reach, as recognized in Article 12 of the International Covenant on Economic, Social and Cultural Rights, or the right of child to the enjoyment of the highest attainable standard of health, as recognized by Article 24 of the Convention on the Rights of the Child. The right to health is intertwined with the rights to food, water and sanitation, and to a healthy environment. The right to health is also recognized in many regional human rights protection instruments. It encompasses physical, mental and/or social health. The Tribunal heard witnesses' accounts of severe congenital diseases, development of non-Hodgkin lymphomas, chronic diseases, Lasso poisoning or even death occurring after direct or indirect environmental exposure to products manufactured by Monsanto. The Tribunal recalls that this company has manufactured and distributed many dangerous substances. First were PCBs, persistent organic pollutants exclusively commercialized by Monsanto between 1935 and 1979 despite the fact that the company knew about their deleterious health impacts. PCBs are now forbidden by the 2001 Stockholm Convention on Persistent Organic Pollutants. This carcinogenic product also causes problems with fertility and child development, and disrupts the immune system. Secondly, glyphosate (ingredient in Roundup) is considered in some studies as a carcinogenic product while other reports, such as the one from the European Food Safety Authority (EFSA), conclude the opposite. In an opinion issued on the 15th of March 2017 and related to the classification of glyphosate, the European Chemicals Agency (ECHA) indeed estimated that this product could not be classified as a carcinogen, as a mutagen or as toxic for reproduction. The Tribunal however stresses that this classification does not take into account the risks of exposure, with residues found in food, drinking water and even in human urine. The commercialization of Roundup-resistant GMO crop seed has resulted in widespread distribution and use of this product. It is classified as "probably carcinogenic to humans" by the World Health Organisation's (WHO) International Agency for Research on Cancer. Other reports assert the genotoxicity of glyphosate on humans and animals. Last but not least, internal Monsanto documents released in March 2017 as a result of a court order of the U.S. District Court, Northern District of California (San Francisco) show that Monsanto has manipulated science. This makes hollow the so-called scientific controversy about the risks glyphosate pose on health. Thirdly, the use of GMO seed raises multiple questions. There is a distinct lack of scientific consensus about the impacts of GMOs on human health. The controversy is embedded in a context of opacity on GMO studies, and even on the inability of researchers to conduct independent research. The "Monsanto Papers" cast light on practices of systematic manipulation of scientific studies, and on the influence exerted on experts by Monsanto. There is no political consensus on the cultivation of GMOs either. The UN Special Rapporteur on the Right to Food, an independent expert, calls for the need to follow the precautionary principle at the global level. The Tribunal concludes that Monsanto

has engaged in practices that negatively impacted the right to health. Question 4 concerned the alleged infringement on the freedom indispensable for scientific research, as guaranteed by Article 15(3) of the International Covenant on Economic, Social and Cultural Rights, as well as the freedoms of thought and expression guaranteed in Article 19 of the International Covenant on Civil and Political Rights. The "freedom indispensable for scientific research" closely relates to freedom of thought and expression, as well as the right to information. It is therefore key to safeguarding other fundamental rights, such as the right to health, food, water and a healthy environment. This freedom engenders the requirement to ensure that scientific researchers are able to express themselves freely and are protected when acting as whistle-blowers. Some of Monsanto's practices mentioned in the testimonies of agronomists and molecular biologists have resulted in court convictions for the company. Among those practices are: illegal GMO plantations; resorting to studies misrepresenting the negative impacts of Roundup by limiting the analysis to glyphosate only while the product is a combination of substances; massive campaigns aiming at discrediting the results of independent scientific studies. These strategies led, for example, to the withdrawal of a study published in an international journal and to the loss of a job for a scientist working in a governmental health agency. In response to Question 4, the Tribunal concludes that Monsanto's conduct is negatively affecting the right to freedom indispensable for scientific research. Conduct such as intimidation, discrediting independent scientific research when it raises serious questions about the protection of the environment and public health, suborning false research reports, putting pressure on governments are transgressing the freedom indispensable for scientific research. This abuse is exacerbated by exposure to health and accompanying environmental risks, which deprive society the possibility to safeguard fundamental rights. Taking direct measures to silence scientists or attempting to discredit their work constitutes conduct that abuses the right to freedom indispensable for scientific research and the right to freedom of expression. This negatively affects the right to information. Question 5 concerned the alleged complicity in war crimes as defined in Article 8(2) of the Statute of the International Criminal Court (ICC), by providing Agent Orange. Between 1962 and 1973, more than 70 million liters of Agent Orange (containing dioxin) were sprayed on approximately 2.6 million hectares of land. This defoliating chemical has caused serious harm to health in the Vietnamese civilian population. And the harm caused to American, New Zealand, Australian and Korean veterans has lead to court cases and to the recognition of Monsanto's responsibility, among others. Because of the current state of international law and the absence of specific evidence, the Tribunal cannot give any definitive answer to the question it was asked. Nevertheless, it seems that Monsanto knew how its products would be used and had information on the consequences for human health and the environment. The Tribunal is of the view that, would the crime of Ecocide be added in International law, the reported facts could fall within the jurisdiction of the International Criminal Court (ICC). Question 6 asked the Tribunal if the activities of Monsanto could constitute a crime of ecocide, understood as causing serious damage or destroying the environment, so as to significantly and durably alter the global commons or ecosystem services upon which certain human groups rely. Developments in international environmental law confirms the increased awareness of how environmental harm negatively affects the fundamental values of society. Preserving dignity for present and future generations and the integrity of ecosystems is an idea that has gained traction in the international community. As an evidence of these developments, and according to the Policy Paper on Case Selection and Prioritisation from September 2016, the Prosecutor of the ICC wants to give particular consideration to Rome Statute crimes involving the illegal dispossession of land or the destruction of the environment. However, despite the development of many instruments to protect the environment, a gap remains between legal commitments and the reality of environmental

protection. The Tribunal assesses that international law should now precisely and clearly assert the protection of the environment and the crime of ecocide. The Tribunal concludes that if such a crime of ecocide were recognized in international criminal law, the activities of Monsanto could possibly constitute a crime of ecocide. Several of the company's activities may fall within this infraction, such as the manufacture and supply of glyphosate-based herbicides to Colombia in the context of its plan for aerial application on coca crops, which negatively impacted the environment and the health of local populations; the large-scale use of dangerous agrochemicals in industrial agriculture; and the engineering, production, introduction and release of genetically engineered crops. Severe contamination of plant diversity, soils and waters would also fall within the qualification of ecocide. Finally, the introduction of persistent organic pollutants such as PCB into the environment causing widespread, long-lasting and severe environmental harm and affecting the right of the future generations could fall within the qualification of ecocide as well. In the third part of the advisory opinion, the Tribunal insists on the widening gap between international human rights law and corporate accountability. It calls for two urgent actions. First is the need to assert the primacy of international human and environmental rights law. Indeed, a whole set of legal rules are in place to protect investors' rights in the frame of the World Trade Organization, as well as in bilateral investment treaties or in the investment-related clauses of free-trade agreements. These provisions tend to undermine the capacity of nations to maintain policies, laws and practices protecting human and environmental rights. According to the Tribunal, there is an important risk of a widening gap between international human rights and environmental law and international trade and investment law. UN bodies urgently need to take action; otherwise key questions will be resolved by private tribunals operating entirely outside the UN framework. The second call concerns the need to hold non-state actors responsible within international human rights law. The Tribunal is of the view that the time is ripe to consider multinational enterprises as subjects of law that could be sued in the case of infringement of fundamental rights. The Tribunal clearly identifies and denounces a severe disparity between the rights of multinational corporations and their obligations. Therefore, the advisory opinion encourages authoritative bodies to protect the effectiveness of international human rights and environmental law against the conduct of multinational corporations. Appendices: letter sent by the Tribunal to invite Monsanto to participate in the hearings in The Hague on 15-16 October 2016, list of witnesses in alphabetical order and list of legal experts. Appendix 1: letter sent by the Tribunal to invite Monsanto to participate in the hearings in The Hague on 15-16 October 2016

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in alphabetical order William Bourdon Claudia Gómez Godoy Maogato Jackson Gwynn McCarrick (represented by Maogato Jackson) and Koffi Dogbevi http://en.monsantotribunal.org/upload/asset_cache/1016160509.pdf

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3. Environmental risk assessment

Aanvulling op onze eerdere bezwaren. Summary of the advisory opinion of the International Monsanto Tribunal Delivered on the 18th of April 2017 in The Hague, Netherlands zie "Others".

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
Others

Summary of the advisory opinion of the International Monsanto Tribunal Delivered on the 18th of April 2017 in The Hague, Netherlands The International Monsanto Tribunal is a unique "Opinion Tribunal" convened by civil society to clarify the legal obligations and consequences of some of the activities of the Monsanto Company. During the hearings that took place on October 15th and 16th in The Hague, judges heard testimonies related to the six questions posed to the Tribunal1. The ensuing legal opinion delivered by the Tribunal includes a legal analysis of the questions asked, with respect to both existing international law, and to prospective law in order to improve international human rights and environmental law. The advisory opinion is structured in three parts. The introductory section details the conditions within which the Tribunal was initiated. The middle section examines the six questions posed to the Tribunal. Looking at the broader picture, the final section tackles the growing asymmetry between the rights conceded to corporations and the constraints imposed upon them to protect local communities and/or future generations, wherever corporations operate. Question 1, as posed to the Tribunal, related to alleged infringement on the right to a healthy environment. In other words, did the Monsanto firm, by its activities, act in conformity with the right to a safe, clean, healthy and sustainable environment, as recognized in international human rights law (Resolution 25/21 of the Human Rights Council, of 15 April 2014), taking into account the responsibilities imposed on corporations by the Guiding Principles on Business and Human Rights, as endorsed by the Human Rights Council in Resolution 17/4 of 16 June 2011? The Tribunal recalls that “the right to a healthy environment” concept can be traced to the UN Conference on the Human Environment in Stockholm, 1972. With the notion that the environment is a precondition for the enjoyment of human rights, this marked the dawn of a new era in international law. Today, no less than 140 states have incorporated the right to a healthy environment into their constitutions, making it a norm of international customary law. The Special Rapporteur on Human Rights and Environment, John Knox, has identified threats on the right to a healthy environment, and established a set of requirements to protect it. The UN Human Rights Council has concluded that human rights law sets certain obligations on States to guarantee that the right to enjoy a

healthy environment is respected. The Monsanto Tribunal hearings allowed for the gathering of testimonies related to various impacts on human health (especially on farmers), soils, plants, aquatic organisms, animal health and biodiversity. These testimonies also included the impacts of spraying crop protection products (herbicides, pesticides). In addition, the information collected also shed light on the impacts on indigenous communities and peoples in many countries, and on the absence of adequate information given to those concerned. Based on the above findings and to answer Question 1, the Tribunal concludes that Monsanto has engaged in practices which have negatively impacted the right to a healthy environment. 1 See terms of reference. Question 2 concerned the alleged infringement on the right to food as recognized in Article 11 of the International Covenant on Economic, Social and Cultural Rights, in Articles 24.2(c) and (e) and 27.3 of the Convention on the Rights of the Child, and in Articles 25(f) and 28.1 of the Convention on the Elimination of All Forms of Discrimination against Women. According to the UN Committee on Economic, Social and Cultural Rights, "The right to adequate food is realized when every man, woman and child, alone or in community with others, has physical and economic access at all times to adequate food or means for its procurement". According to the Tribunal, business entities are also responsible to respect this right by applying the Guidelines for Multinational Enterprises of the OECD and the UN Guiding Principles on Business and Human Rights. The hearings accounted for negative impacts on production systems and ecosystems, the appearance of invasive species and the loss of efficiency of Roundup over time. Some farmers were sentenced to pay royalties after their fields were contaminated by genetically modified organisms (GMOs), while others stated that the corporation is taking over the seed market, even though Monsanto's products are not as productive as promised. In response to Question 2, the Tribunal concludes that Monsanto has engaged in practices that have negatively impacted the right to food. Monsanto's activities affect food availability for individuals and communities and interfere with the ability of individuals and communities to feed themselves directly or to choose non-genetically modified seeds. In addition, genetically modified seeds are not always affordable for farmers and threaten biodiversity. Monsanto's activities and products cause damage to soil, water and to the environment more generally. The Tribunal concludes that food sovereignty is also affected and underlines the cases in which genetic contamination of fields forced farmers to pay royalties to Monsanto or even to abandon their non-GMO crops due to this contamination. There is indeed an infringement on the right to food because of aggressive marketing on GMOs which can force farmers to buy new seeds every year. The dominant agro-industrial model can be criticized even more strongly because other models - such as agroecology - exist that respect the right to food. Question 3 concerned the alleged infringement on the right to the highest attainable standard of health of everyone can reach, as recognized in Article 12 of the International Covenant on Economic, Social and Cultural Rights, or the right of child to the enjoyment of the highest attainable standard of health, as recognized by Article 24 of the Convention on the Rights of the Child. The right to health is intertwined with the rights to food, water and sanitation, and to a healthy environment. The right to health is also recognized in many regional human rights protection instruments. It encompasses physical, mental and/or social health. The Tribunal heard witnesses' accounts of severe congenital diseases, development of non-Hodgkin lymphomas, chronic diseases, Lasso poisoning or even death occurring after direct or indirect environmental exposure to products manufactured by Monsanto. The Tribunal recalls that this company has manufactured and distributed many dangerous substances. First were PCBs, persistent organic pollutants exclusively commercialized by Monsanto between 1935 and 1979 despite the fact that the company knew about their deleterious health impacts. PCBs are now forbidden by the 2001 Stockholm Convention on Persistent Organic Pollutants. This carcinogenic product also causes problems with fertility and child development, and disrupts

the immune system. Secondly, glyphosate (ingredient in Roundup) is considered in some studies as a carcinogenic product while other reports, such as the one from the European Food Safety Authority (EFSA), conclude the opposite. In an opinion issued on the 15th of March 2017 and related to the classification of glyphosate, the European Chemicals Agency (ECHA) indeed estimated that this product could not be classified as a carcinogen, as a mutagen or as toxic for reproduction. The Tribunal however stresses that this classification does not take into account the risks of exposure, with residues found in food, drinking water and even in human urine. The commercialization of Roundup-resistant GMO crop seed has resulted in widespread distribution and use of this product. It is classified as "probably carcinogenic to humans" by the World Health Organisation's (WHO) International Agency for Research on Cancer. Other reports assert the genotoxicity of glyphosate on humans and animals. Last but not least, internal Monsanto documents released in March 2017 as a result of a court order of the U.S. District Court, Northern District of California (San Francisco) show that Monsanto has manipulated science. This makes hollow the so-called scientific controversy about the risks glyphosate pose on health. Thirdly, the use of GMO seed raises multiple questions. There is a distinct lack of scientific consensus about the impacts of GMOs on human health. The controversy is embedded in a context of opacity on GMO studies, and even on the inability of researchers to conduct independent research. The "Monsanto Papers" cast light on practices of systematic manipulation of scientific studies, and on the influence exerted on experts by Monsanto. There is no political consensus on the cultivation of GMOs either. The UN Special Rapporteur on the Right to Food, an independent expert, calls for the need to follow the precautionary principle at the global level. The Tribunal concludes that Monsanto has engaged in practices that negatively impacted the right to health. Question 4 concerned the alleged infringement on the freedom indispensable for scientific research, as guaranteed by Article 15(3) of the International Covenant on Economic, Social and Cultural Rights, as well as the freedoms of thought and expression guaranteed in Article 19 of the International Covenant on Civil and Political Rights. The "freedom indispensable for scientific research" closely relates to freedom of thought and expression, as well as the right to information. It is therefore key to safeguarding other fundamental rights, such as the right to health, food, water and a healthy environment. This freedom engenders the requirement to ensure that scientific researchers are able to express themselves freely and are protected when acting as whistle-blowers. Some of Monsanto's practices mentioned in the testimonies of agronomists and molecular biologists have resulted in court convictions for the company. Among those practices are: illegal GMO plantations; resorting to studies misrepresenting the negative impacts of Roundup by limiting the analysis to glyphosate only while the product is a combination of substances; massive campaigns aiming at discrediting the results of independent scientific studies. These strategies led, for example, to the withdrawal of a study published in an international journal and to the loss of a job for a scientist working in a governmental health agency. In response to Question 4, the Tribunal concludes that Monsanto's conduct is negatively affecting the right to freedom indispensable for scientific research. Conduct such as intimidation, discrediting independent scientific research when it raises serious questions about the protection of the environment and public health, suborning false research reports, putting pressure on governments are transgressing the freedom indispensable for scientific research. This abuse is exacerbated by exposure to health and accompanying environmental risks, which deprive society the possibility to safeguard fundamental rights. Taking direct measures to silence scientists or attempting to discredit their work constitutes conduct that abuses the right to freedom indispensable for scientific research and the right to freedom of expression. This negatively affects the right to information. Question 5 concerned the alleged complicity in war crimes as defined in Article 8(2) of the Statute of the International Criminal Court (ICC), by providing Agent Orange. Between 1962

and 1973, more than 70 million liters of Agent Orange (containing dioxin) were sprayed on approximately 2.6 million hectares of land. This defoliating chemical has caused serious harm to health in the Vietnamese civilian population. And the harm caused to American, New Zealand, Australian and Korean veterans has lead to court cases and to the recognition of Monsanto's responsibility, among others. Because of the current state of international law and the absence of specific evidence, the Tribunal cannot give any definitive answer to the question it was asked. Nevertheless, it seems that Monsanto knew how its products would be used and had information on the consequences for human health and the environment. The Tribunal is of the view that, would the crime of Ecocide be added in International law, the reported facts could fall within the jurisdiction of the International Criminal Court (ICC). Question 6 asked the Tribunal if the activities of Monsanto could constitute a crime of ecocide, understood as causing serious damage or destroying the environment, so as to significantly and durably alter the global commons or ecosystem services upon which certain human groups rely. Developments in international environmental law confirms the increased awareness of how environmental harm negatively affects the fundamental values of society. Preserving dignity for present and future generations and the integrity of ecosystems is an idea that has gained traction in the international community. As an evidence of these developments, and according to the Policy Paper on Case Selection and Prioritisation from September 2016, the Prosecutor of the ICC wants to give particular consideration to Rome Statute crimes involving the illegal dispossession of land or the destruction of the environment. However, despite the development of many instruments to protect the environment, a gap remains between legal commitments and the reality of environmental protection. The Tribunal assesses that international law should now precisely and clearly assert the protection of the environment and the crime of ecocide. The Tribunal concludes that if such a crime of ecocide were recognized in international criminal law, the activities of Monsanto could possibly constitute a crime of ecocide. Several of the company's activities may fall within this infraction, such as the manufacture and supply of glyphosate-based herbicides to Colombia in the context of its plan for aerial application on coca crops, which negatively impacted the environment and the health of local populations; the large-scale use of dangerous agrochemicals in industrial agriculture; and the engineering, production, introduction and release of genetically engineered crops. Severe contamination of plant diversity, soils and waters would also fall within the qualification of ecocide. Finally, the introduction of persistent organic pollutants such as PCB into the environment causing widespread, long-lasting and severe environmental harm and affecting the right of the future generations could fall within the qualification of ecocide as well. In the third part of the advisory opinion, the Tribunal insists on the widening gap between international human rights law and corporate accountability. It calls for two urgent actions. First is the need to assert the primacy of international human and environmental rights law. Indeed, a whole set of legal rules are in place to protect investors' rights in the frame of the World Trade Organization, as well as in bilateral investment treaties or in the investment-related clauses of free-trade agreements. These provisions tend to undermine the capacity of nations to maintain policies, laws and practices protecting human and environmental rights. According to the Tribunal, there is an important risk of a widening gap between international human rights and environmental law and international trade and investment law. UN bodies urgently need to take action; otherwise key questions will be resolved by private tribunals operating entirely outside the UN framework. The second call concerns the need to hold non-state actors responsible within international human rights law. The Tribunal is of the view that the time is ripe to consider multinational enterprises as subjects of law that could be sued in the case of infringement of fundamental rights. The Tribunal clearly identifies and denounces a severe disparity between the rights of multinational corporations and their obligations. Therefore, the

advisory opinion encourages authoritative bodies to protect the effectiveness of international human rights and environmental law against the conduct of multinational corporations. Appendices: letter sent by the Tribunal to invite Monsanto to participate in the hearings in The Hague on 15-16 October 2016, list of witnesses in alphabetical order and list of legal experts. Appendix 1: letter sent by the Tribunal to invite Monsanto to participate in the hearings in The Hague on 15-16 October 2016

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3. Environmental risk assessment

Aanvulling op onze eerdere bezwaren. Summary of the advisory opinion of the International Monsanto Tribunal Delivered on the 18th of April 2017 in The Hague, Netherlands zie "Others". In opdracht van Mevr. Wieteke van Dort. Opgetekend door Mevr. Miep Bos, woordvoerster van de Gentechvrije Burgers. (The European GMO-free Citizens.)

Organisation: Individual
Country: France
Type: Individual

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a. Assessment:
b. Food Safety Assessment:
Toxicology

Il est toujours aussi étonnant de voir que des institutions d'autorisation se pose encore la question suivante : "Y a t'il un problème à autoriser un aliment dont les tissus sont imbibé d'herbicide(s) ?" Bien sûr qu'il y a des problèmes sinon ces produits ne s’appelleraient pas "pesticides" qui sont donc tous des "biocides" !

Allergenicity

Idem au dessus. L’absence de preuve de danger n'est pas la preuve de l’absence de danger. Surtout quand les tests dit scientifiques sont fournis par... les fabricants des produits et qu'en plus la société civile a le plus grand mal à obtenir les données brutes au nom du secret industriel !!!!! Quand l'entendrez vous enfin ?

Others

Quid des risques de pollinisation et des brevets attenants ? Est ce juste que les agriculteurs génétiquement contaminés ai a payer des royalties alors que ces contaminations inévitables ne sont pas de leurs faits ? Alors même qu'ils n'ont pas le droit aux OGM ou tout simplement parce qu'ils ont fait le choix de ne pas en utiliser/cultiver ? À moins que les autorités régulatrices nous expliquent comment contrôler les oiseaux, les rongeurs, le vent, tous facteurs de contaminations inévitables... Messieurs les élus, commissaires et membres des autorités de régulation, les lois et règlements ne sont ils pas censés protégés "les faibles" ?

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3. Environmental risk assessment

Les contaminations génétiques de la biodiversité naturelle sont I-NÉ-VI-TABLES !!!! Voir ci-dessus...

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4. Conclusions and recommendations

Il est donc important qu'enfin, ce genre de produits ne soient plus autorisés quelles que soient leurs finalités : alimentation humaine ou animale, et ce, qu'ils soient issus d'Europe ou importer principalement d'outre-Atlantique.

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The data presented in the assessment are not conclusive.

The expression of the additional DNA constructs showed significant combinatorial effects compared to the parental plants, but no further investigations were carried out. The

assessment was made without any systematic investigation of the impact of stressful environmental conditions that may impact gene expression.

Further, there were several so-called open reading frames (ORF) identified in the parental plants; they were found at the site of insertion and can give rise to various new gene products. Nevertheless, the relevant DNA sequences were only assessed for potential new proteins and not in regard to other biologically active DNA products, such as micro-RNA. These small RNA parts are likely to emerge from the open reading frames and interact with gene regulation without being translated into proteins. There are publications showing miRNA might pass from plants to animals and humans (Zhang et al., 2011, Lukasik & Zielenkiewicz, 2014). Their effects on health and the environment are uncertain. In its opinion, EFSA completely ignored this issue.

References:

Lukasik, A, & Zielenkiewicz, P. (2014) In Silico Identification of Plant miRNAs in Mammalian Breast Milk Exosomes – A Small Step Forward? PLoS ONE 9(6): e99963.

Zhang, L., Hou, D., Chen, X., Li, D., Zhu, L., Zhang, Y., Li, J., Bian, Z., Liang, X., Cai, X., Yin, Y., Wang, C., Zhang, T., Zhu, D., Zhang, D., Xu, J., Chen, Qu., Ba, Y., Liu, J., Wang, Q., Chen, J., Wang, J., Wang, M., Zhang, Q., Zhang, J., Zen, K., Zhang, C.Y. (2011) Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. Cell Research, 22(1): 107-126.

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

Agronomic and phenotypic characteristics

Data that are crucial for the assessment of persistence and invasiveness, such as data on the duration of flowering, pollen production, pollen viability, as well as seed dormancy were not investigated. Thus, as also stated by experts from Member States (EFSA 2017b), the selected agronomic characteristics cannot sufficiently indicate differences in reproduction, dissemination and survivability of MON 88302 x MS8 x RF3 oilseed rape compared to conventional oilseed rape.

Several significant findings were observed on plant height, pod shattering, seed moisture and final stand count, as well as on yield. These differences should have been investigated in more detail under various defined stress conditions and after introgression into other genetic backgrounds.

In addition, observations made on the parental plants, such as a delay in the first day flowering of MON88302, were not reported in the stacked event.

Compositional analysis 59 endpoints were used for comparison. According to EFSA, for oilseed rape MON 88302 x MS8 x RF3 (not treated) statistically significant differences with the conventional counterpart were identified for 28 endpoints. For oilseed rape MON 88302 x MS8 x RF3 (treated), statistically significant differences with the conventional counterpart

were identified for 13 endpoints. These differences, despite their high number, were not investigated further.

The complementary herbicides were not applied in high dosages as might be expected in fields under pressure from herbicide resistant weeds. Furthermore, the herbicides were only applied in combination, but not separately. Consequently, many of the potential effects that might have occurred under real conditions in the fields were not assessed by EFSA.

EFSA failed to require further studies e.g. - A detailed comparison of the observations made on the single parental plants compared to the stacked events. - Omics studies (proteomics, transcriptomics, metabolomics) to assist the compositional analysis and the assessment of the phenotypical changes. - Investigations of changes in content of miRNA which can be taken up at from the gut and render biological effects across border of life domains. - Exposing the plants to a wide range of defined biotic or abiotic stressors to assess the true range of possible changes in the plants´ composition. - More varieties inheriting the trait should have been included to investigate how the gene constructs interact with the genetic background of the plants. - Several dosages and formulations of the complementary herbicide should have been applied to the plants.

References: EFSA (2017b) Application EFSA-GMO-NL-2013-119 by Monsanto Company and Bayer CropScience, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL

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b. Food Safety Assessment:
Toxicology

No feeding studies with the whole food and feed derived from parental plants were presented, nor from the stacked events. This is surprising because since 2014, 90-day feeding studies are requested at least for the assessment of the single plants (Commission Implementing Regulation (EU) No 503/2013). While there might be formal reasons not to apply this request for a specific notification, from the point of view of food and feed safety such deficiencies cannot be justified.

The lack of detailed toxicological investigation is highly relevant in this case. Testing of whole food and feed is especially relevant for assessing potential effects on health from the combination of the residues from spraying with high dosages of glyphosate and glufosinate.

The application of the complementary herbicide is part of regular agricultural practice in the cultivation of herbicide resistant plants. Therefore, it can be expected that residues from spraying are always present in the harvest and could be seen as inevitable “constituents”.

In general, EFSA considers residues from spraying with the complementary herbicide to be outside the remit of the GMO panel. However, clearly from a scientific and regulatory point of view, there is no justification for carrying out an assessment of herbicide-resistant genetically engineered plants for health risks and leaving out the residues from spraying with complementary herbicides. Health risk assessment cannot be reduced to what is required

under Regulation 396/ 2005 (Pesticide Regulation) since this assessment does not take the specific pattern of exposure and relevant cumulative effects into account.

Due to the specific agricultural practices in the cultivation of herbicide-resistant plants, there are specific patterns of applications, exposure and occurrence of specific metabolites and an emergence of combinatorial effects that require special attention. For example, large-scale commercial cultivation of these plants results in a strong selective pressure on weeds to develop resistance to the herbicides (Sammons et al., 2014). This problem is also relevant for health risk assessment since it has led to increasing amounts of glyphosate being sprayed (Benbrook, 2016) and subsequently more residues in the harvest (Cuhra, 2015). Herbicide-resistant plants are meant to survive the application of the complementary herbicide while most other plants will die after short time. Thus, residues of glufosinate and glyphosate, their metabolites and additives to the formulated product might accumulate and interact in the plants.

As a publication by Kleter et al. (2011) shows, using herbicides to spray genetically engineered herbicide-resistant plants does indeed lead to patterns of residues and exposure that are not taken into account in regular pesticide registration. Further, according to a reasoned legal opinion drawn up by Kraemer (2012), from a regulatory point of view, residues from spraying with complementary herbicides have to be taken into account in the risk assessment of genetically engineered plants.

In regard to the pending application, there are specific reasons for concern. At present, there are continuing discussions about glyphosate being "probably carcinogenic" (IARC, 2015). Furthermore, in 2015, EFSA presented the result of the risk assessment of glyphosate. In its opinion, EFSA (EFSA 2015a) stated that not enough data were available on the applications of glyphosate to genetically engineered plants resistant to the herbicide. As a result, EFSA was unable to deliver a conclusive risk assessment on the actual risks of residues from spraying with glyphosate and the various glyphosate formulations (see also EFSA, 2015b). In addition, glufosinate is about to be phased out in the EU due to negative health impacts (see Annex I of Commission Implementation Regulation (EU) No 540/2011). Glufosinate-induced severe reproductive and developmental toxicity has been described (EFSA, 2005).

Therefore, the safety of the genetically engineered oilseed rape sprayed with glyphosate and glufosinate cannot be proven by EFSA´s assessment.

In addition, there are many other substances such as oestrogens, allergens, antinutritional compounds present in the plants that in interaction with trait-related characteristics might act as stressors: There is a considerable amount of literature indicating that glyphosate formulations can act as so-called endocrine disruptors (see, for example, Thongprakaisang et al., 2013; Çağlar & Kolankaya, 2008; de Liz Oliveira Cavalli et al., 2013; Omran & Salama, 2013). Endocrine effects were found when young rats were exposed to soy milk in combination with glyphosate (Nardi et al., 2016). There may be synergistic or additive interactions of plant components (see for example de Lemos, 2001) with the residues from spraying with glyphosate formulations.

There are other relevant issues: For example, the potential impact on the intestinal microbiome also has to be considered. Such effects might be caused by the residues from spraying since glyphosate was shown to have negative effects on the composition of the intestinal flora of cattle (Reuter et al., 2007) and poultry (Shehata et al., 2013). Further,

Bremmer and Leist (1997) examined the possible conversion of NAG to glufosinate in rats. Up to 10% deacetylation occurred at a low dose of 3 mg/kg bw as shown by the occurrence of glufosinate in the faeces. The authors concluded, however, that most of the conversion was caused by bacteria in the colon and rectum although toxicity findings indicate partial bioavailability.

As a result, there is a huge gap in the safety assessment of the genetically engineered plants that cannot be filled by adjustments to the MRLs applicable under the Pesticide Regulation. Consequently, the impact of residues in the plants from spraying with the herbicides must be assessed before the plants can be declared safe. The failure to do so poses real safety risks to humans, animals and the environment generally.

In any case, both the EU pesticide regulation and the GMO regulation require a high level of protection of health and the environment. Thus, in regard to herbicide-resistant plants, specific assessment of residues from spraying with complementary herbicides must be considered to be a prerequisite for granting authorisation. In addition, cumulative effects have to be investigated if a plant contains or produces other compounds of potential toxicity.

It should be acknowledged, that no new methodology is needed to assess the health risks emerging from the combinatorial application of the herbicides and their potential interaction with the other plant constituents. There is, for example, no need to apply methods such as the Monte Carlo Risk Assessment (MCRA) because the majority of potential stressors can be expected to occur in a fixed combination and follow a specific pattern of exposure. Rather, the methods currently available (in vivo and / or in vitro) are sufficient to assess the health effects. Regulation (EC) No 1907/2006 (REACH), for instance, provides guidance on how substances that are in fact mixtures (isomeric mixtures, MCS (multi-constituent substance) and UVCB (substances of unknown or variable composition, complex reaction products or biological materials) should be assessed for their PBT/vPvB (persistent, bioaccumulative and toxic) properties. In general, due to the nature of "substances of unknown or variable composition, complex reaction products or biological materials" it is not possible to make reliable predictions about additive, or synergistic, or antagonistic modes of effects. Therefore, such substances have to be tested as a mixture, not as single compounds. For example, chronic feeding studies are a well-established method of generating the relevant data.

Benbrook, C.M. (2016) Trends in glyphosate herbicide use in the United States and globally. Environmental Sciences Europe, 28(1): 3.

Bremmer, J.N. and Leist, K.-H. (1997) Disodium-N-acetyl-L-glufosinate; AE F099730 - Hazard evaluation of Lglufosinate produced intestinally from N-acetyl-L-glufosinate. Hoechst Schering AgrEvo GmbH, Safety Evaluation Frankfurt. TOX97/014. A58659. Unpublished. (see FAO publication on https://web.archive.org/web/20060101000000*/http://www.fao.org/ag/agp/agpp/pesticid/jmpr/Download/98/glufosi3.pdf)

Çağlar, S., & Kolankaya, D. (2008) The effect of sub-acute and sub-chronic exposure of rats to the glyphosate-based herbicide Roundup. Environmental toxicology and pharmacology, 25(1): 57-62.

Cuhra, M. (2015) Review of GMO safety assessment studies: glyphosate residues in Roundup Ready crops is an ignored issue. Environmental Sciences Europe 27(1): 1-14.

EFSA (2015a) Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal, 13 (11):4302.

EFSA (2015b) Statement of EFSA on the request for the evaluation of the toxicological assessment of the coformulant POE-tallowamine. EFSA Journal, 13(11):4303.

EFSA (2005) Conclusion regarding the peer review of the pesticide risk assessment of the active substance glufosinate. EFSA Journal 2005;3(4):RN-27, 81 pp. doi:10.2903/j.efsa.2005.27r

IARC (2015) Glyphosate Monograph. http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf

Kleter, G.A., Unsworth, J.B., Harris, C.A. (2011) The impact of altered herbicide residues in transgenic herbicide-resistant crops on standard setting for herbicide residues. Pest Managment Science, 67(10): 1193-1210.

Kraemer, L. (2012) The consumption of genetically modified plants and the potential presence of herbicide residues, legal dossier compiled on behalf of Testbiotech, http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

de Lemos, M.L. (2001) Effects of soy phytoestrogens genistein and daidzein on breast cancer growth. Annals of Pharmacotherapy, 35(9): 1118-1121.

de Liz Oliveira Cavalli, V.L., Cattani, D., Elise Heinz Rieg, C., Pierozan, P., Zanatta, L., Benedetti Parisotto, E., ... & Zamoner, A. (2013) Roundup disrupted male Reproductive Functions By Triggering Calcium-Mediated Cell Death In Rat Testis And Sertoli Cells. Free Radical Biology and Medicine, 65: 335-346.

Nardi, J., Moras, P. B., Koeppe, C., Dallegrave, E., Leal, M. B., Rossato-Grando, L. G. (2016) Prepubertal subchronic exposure to soy milk and glyphosate leads to endocrine disruption. Food and Chemical Toxicology. http://www.sciencedirect.com/science/article/pii/S0278691516304896

Omran, N.E., & Salama, W.M. (2013) The endocrine disrupter effect of atrazine and glyphosate on Biomphalaria alexandrina snails. Toxicology and industrial health, 0748233713506959.

Reuter T., Alexander T.W., Martinez T.F., McAllister T.A. (2007) The effect of glyphosate on digestion and horizontal gene transfer during in vitro ruminal fermentation of genetically modified canola. J Sci Food Agr 87:2837-2843.

Sammons R.D., Gaines T.A. (2014) Glyphosate resistance: State of knowledge. Pest Manag Sci 70(9):1367-1377.

Shehata, A.A., Schrödl, W., Aldin, A.A., Hafez, H.M., Krüger, M. (2013) The effect of glyphosate on potential pathogens and beneficial members of poultry microbiota in vitro. Current microbiology, 66(4): 350-358.

Thongprakaisang, S., Thiantanawat, A., Rangkadilok, N., Suriyo, T., Satayavivad, J. (2013) Glyphosate induces human breast cancer cells growth via estrogen receptors. Food and Chemical Toxicology, 59: 129-136.

Others

EFSA agrees with the notifier that no targeted case-specific monitoring of the uncontrolled spread of the transgenic and related gene flow is necessary if import is allowed. It would be up to the notifier and other members of the industry lobby organisation EuropaBio to oversee the import and report potential unanticipated adverse effects.

Several experts from EU Member States, such as those from Germany (BfN) (EFSA, 2017b), voiced concerns that this is not a sufficiently robust approach. They believe there is a need for much more targeted case-specific monitoring of factual gene flow. Thus, case-specific monitoring should be run in regions where MON 88302 x MS8 x RF3 oilseed rape will be transported, stored, packaged, processed or used. In case of substantial losses and spread of MON 88302 x MS8 x RF3 oilseed rape, all receiving environments need to be monitored.

Recently, also in Europe studies on feral oilseed rape stemming from imports were conducted in vicinity of "hot spots" like oil mills and along transportation roads. Fertile engineered oilseed rape was found in Switzerland (Hecht et al., 2012, Schoenenberger & D'Andrea, 2012, Schulze et al., 2014). In Germany, large amounts of feral oilseed rape were found in the vicinity of oils mills and seed processing industries at the harbours along the river Rhine (Franzaring et al., 2016). Only one of the plants proved to be transgenic. Nevertheless, the findings indicate an urgent need for monitoring efforts.

Monitoring for genetically engineered oilseed rape should also be extended to other plant species when imports enter the EU: A study by Schulze et al. (2015) investigated the possible sources of herbicide tolerant oilseed rape along transportation routes in Switzerland. Analyses revealed that low level impurities of genetically engineered oilseed rape in imports of Canadian durum wheat is one source of feral genetically engineered oilseed rape in Switzerland. The researchers found traces of oilseed rape events GT73, MS8×RF3, MS8 and RF3 in imports of durum wheat from Canada. The reported results should be considered carefully as they may have far-reaching consequences for the regulation of genetically engineered crops.

In the light of the potential environmental risks, the monitoring plan as presented cannot be accepted.

EFSA (2017b) Application EFSA-GMO-NL-2013-119 by Monsanto Company and Bayer CropScience, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL

Franzaring, J., Wedlich, K., Fangmeier, A., Eckert, S., Zipperle, J., Krah-Jentgens, I., ... & Züghart, W. (2016). Exploratory study on the presence of GM oilseed rape near German oil mills. Environmental Science and Pollution Research, 23(22), 23300-23307.

Hecht, M., Oehen, B., Schulze, J., Brodmann, P., Bagutti, C. (2013) Detection of feral GT73 transgenic oilseed rape (Brassica napus) along railway lines on entry routes to oilseed factories in Switzerland. Environmental Science and Pollution Research, 21(2): 1455-1465.

Schoenenberger, N., & D'Andrea, L. (2012) Surveying the occurrence of subspontaneous glyphosate-tolerant genetically engineered Brassica napus L.(Brassicaceae) along Swiss railways. Environmental Sciences Europe, 24(1): 1-8.
http://link.springer.com/article/10.1186/2190-4715-24-23

Schulze, J., Frauenknecht, T., Brodmann, P., Bagutti, C. (2014) Unexpected Diversity of Feral Genetically Modified Oilseed Rape (Brassica napus L.) Despite a Cultivation and Import Ban in Switzerland. PLoS ONE 9(12): e114477.
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0114477

Schulze, J., Brodmann, P., Oehen, B., & Bagutti, C. (2015) Low level impurities in imported wheat are a likely source of feral transgenic oilseed rape (Brassica napus L.) in Switzerland. Environmental Science and Pollution Research, 1-7.
http://link.springer.com/article/10.1007/s11356-015-4903-y

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3. Environmental risk assessment

Europe is the centre of origin and genetic diversity for the group of Brassica plants to which oilseed rape belongs. Thus, there are several wild relatives that can interbreed with Brassicus napus. Oilseed rape (Brassica napus) can spread via pollen and seeds. Further, the seed remains viable in the soil for more than ten years (Lutman et al., 2003). Consequently, oilseed rape has a high potential for establishing volunteer plants even many years after the first sowing. The plants are mostly pollinated by insects such as flies, honey bees and butterflies, which can also carry the pollen over many kilometres. Wind is also relevant for pollen drift: The farthest pollen-mediated outcrossing distance measured to date is 26 kilometres, recorded in a field trial with sterile male plants (Ramsay et al., 2003). Oilseed rape can appear in ruderal populations along field edges and roadsides. Pivard et al. (2008) found that ruderal populations are self-sustaining in a semi-permanent form. According to Munier et al. (2012), herbicide tolerant oilseed rape is a weed. There are weedy forms of B. rapa and B. olereracea. The wild relative species Sinapis arvensis, Raphanus raphanistrum and Hirschfeldia incana are also considered to be weeds (OECD, 2012).

The EFSA (EFSA 2014) opinion on the assessment of the parental plant MON88302 states that the import and transport of MON88302 (which they summarise as genetically modified herbicide tolerant – GMHT - oilseed rape), is likely to establish volunteer plants alongside transport routes and processing facilities. However, EFSA does not consider this to be a problem: "The EFSA GMO Panel confirms that feral GMHT oilseed rape plants are likely to occur wherever GMHT oilseed rape is transported. However, there is no evidence that the herbicide tolerance trait results in enhanced fitness, persistence or invasiveness of oilseed rape MON 88302, or hybridising wild relatives, unless these plants are exposed to glyphosate-based herbicides. Escaped oilseed rape plants and genes introgressed into other cross-compatible plants would therefore not create any additional agronomic or environmental impacts."

As reasoned in EFSA´s current opinion, the GMO panel is of the opinion that the occurrence of feral MON88302 oilseed rape resulting from seed import spills is likely to be low, as is the likelihood of gene flow to wild relatives.

However, these assumptions are questionable. In general, the amount of spillage will be largely dependent on the amount of imports, the transport routes and the transport vehicles. The frequency of spillage is likely to increase with a higher volume of imports. Demands for import might vary over the years and will be driven by various markets, not only for usage in food and feed but also for energy production.

Several publications show that spillage from transport can occur in amounts that give rise to populations that can persist in the environment over several years; gene flow will also occur between these populations and wild relatives. Studies have shown that oilseed rape seed can produce progeny in semi-natural habitats. Feral oilseed rape populations can persist for several years (Pessel et al., 2001; Schafer et al., 2011). While they persist mainly through the soil seed bank (Pivard et al., 2008a; Pivard et al., 2008b), they can in fact constitute transgene reservoirs. Knispel & Lachlan (2010) have found that feral herbicide-resistant populations have now become a permanent feature of agricultural landscapes in western Canada (Knispel and McLachlan, 2010). Under selection pressure (for example, glyphosate treatment for glyphosate-tolerant oilseed rape), these populations can grow in number and contribute to gene flow in neighbouring fields (Squire et al., 2011).

As seen in Japan, import can also lead to the emergence of self-sustaining populations. Japan is especially relevant in this context because even though transgenic oilseed rape is not commercially cultivated in this country, genetically engineered oilseed rape has been found growing and attributed to imports. The first studies on the presence of transgenic oilseed rape in Japan were published in 2005 (Saji et al., 2005). Plants that proved to be resistant to glyphosate or glufosinate were found in the proximity of ports like Kashima, Chiba, Nagoya and Kobe, as well as along transportation routes to industry plants where oilseed rape is processed. Follow-up studies found ruderal populations along further transportation routes (Nishizawa et al.,2009) and in areas close to all other major ports (such as Shimizu, Yokkaichi, Mizushima, Hakata, or Fukushima) (see for example Kawata et al., 2009; Mizuguti et al., 2011). Further, in their publication Mizuguti et al. (2011) came to the conclusion that oilseed rape populations are able to self-sustain over time. Obviously, the percentage of transgenic oilseed rape in ruderal populations is constantly growing. In 2008, 90 percent of all tested plants in the proximity of Yokkaichi port proved to be genetically engineered.

Together with feral oilseed rape populations, transgenic volunteers can open up many opportunities for genetic recombination, stacking of genes and the evolution of genotypes that could lead not only to an increase in the cost of weed control in the future, but also to phenotypes with new environmental risks, such as enhanced invasiveness. For example, new combinations of herbicide-resistant traits can emerge, such as crossings with Clearfield oilseed rape which is grown in the EU and was made resistant by mutagenesis to the ALS-inhibitor herbicide known as imazamox. Oilseed rape could become a multi-resistant weed with a much higher fitness (at least under current agricultural practices) compared to other oilseed rape plants.

There are several findings on crossings of wild and domesticated plants giving rise to transgenic offspring. The first transgenic hybrid plants between B. napus and B. rapa were

found in Yokkaichi (Aono et al., 2011). Aono et al. (2006) also detected herbicide-tolerant transgenic oilseed rape plants that had hybridised with each other and were thus tolerant to both glyphosate and glufosinate herbicides. Schafer et al. (2011) also reported crosses of transgenic plants giving rise to spontaneous stacked events.

Banks (2014), a researcher who led the first long-term study over a period of 11 years on feral oilseed rape populations, comes to the conclusion that feral oilseed rape populations: "can persist and flower outside the range of cropped oilseed rape plants. It has become part of the native weed and wildflower community, but to date has had no major ecological impact. The long term demographic changes in feral oilseed rape that were found in the 11 year study could not have been predicted from the initial early years when there were few populations or from prior estimates of risk carried out at small spatial scales."

EFSA did not assess Banks' (2014) actual findings in detail, such as new findings on invasiveness. Contrary to the opinion of EFSA, Banks (2014) points to the potential invasiveness of oilseed rape in ruderal areas of Scotland. While the number of feral oilseed rape populations has increased substantially over the years, the number of other ruderal brassica species has decreased: "By the end of the survey, however, feral oilseed rape had possibly become the most common crucifer in ruderal habitats. Its rise coincided with a widespread decline in wild crucifers such as Sinapis arvensis and Sisymbrium officinale that occupy similar habitats. Questions arise as to whether feral oilseed rape might be contributing to the decline of these crucifers or might be substituting for them in the ruderal food web. To date, no one has examined such interactions between feral oilseed rape and wild crucifers."

He discusses several causes, finding indications for invasiveness but no final evidence. He states that: "In total these are substantial changes that merit a re-assessment of feral oilseed rape as an invasive plant and of its role in the environmental risk assessment of GM crops."

According to Banks, several issues have to be taken into account in assessing the potential invasiveness of feral populations of oilseed rape in ruderal areas: - Feral populations can show significant changes in their biology, such as a change in the period of flowering. Consequently, feral populations can have a higher potential for invasiveness than the original varieties used for cultivation. - Feral populations might become perennial (see also Kawata et al., 2009), which is unlikely under cultivation conditions. Perennial plants have a higher probability of spreading their genes because they persist for a longer period. This is a factor supporting higher fitness, which can render higher invasiveness. - Comparisons with species that became weeds due to agricultural practices show that weedy characteristics can be acquired over a period of time even if they are not initially present. - He also mentions that climate conditions can have a substantial impact on the competitiveness of feral oilseed rape populations.

Consequently, if oilseed rape is enabled to become a feral population, this can be a starting point for the plants to become invasive and / or acquire weed characteristics at a later stage. Unlike crop plants under cultivation these plants can start to evolve and adapt over a longer period of time. As Banks states: "Nevertheless, the different behaviour of ferals in corridors and farmland demonstrate that the populations have to a degree arranged themselves in relation to local conditions beyond those just to do with transport. This is further evidence that ferals may be becoming established like weeds and other ruderals and finding preferred sub-habitats."

Further, in comparison to some other weeds, he showed that weediness of ruderal populations can be acquired over a longer period of time. As Banks states: “To illustrate this, feral oilseed rape is compared with several of the major agricultural weeds (...). None of these plants were ‘weeds’ originally, but all have become serious weeds because they fit into the various cycles of grassland and arable land. All began at some time in local or restricted habitats.”

The EFSA assessment, which is based on the biology of annual oilseed rape grown as crops in the fields, is not sufficient to assess the long-term dynamics of feral populations. As Banks shows, feral populations can show population dynamics that are largely distinct from those of cultivated crops. One of the relevant characteristics which can emerge in feral populations but is hardly likely in cultivation is perenniality. This has been reported by Kawata et al. (2009) as well as by Banks (2014): “Feral oilseed rape is mostly a spring annual germinating in spring or a winter annual germinating in autumn. However, a few individuals have been found to survive into a third summer in Tayside, following cutting and re-growth from the cut stumps (written records of the Tayside Study 1993-1995; G. R. Squire, personal communication). Whether perenniality would become more common in feral oilseed rape is uncertain at present.”

In addition, EFSA failed to make a detailed assessment of the specific invasiveness of the herbicide-resistant oilseed rape. Since ruderal areas are the most relevant ecological areas for oilseed rape to persist and spread, its resistance to glyphosate is highly relevant when it comes to competitiveness with other brassica populations that can be found in overlapping ecological niches. As Banks states by referring to relevant literature, this can become a decisive issue: “Under strong selection pressure, for instance if herbicide-tolerant feral genotypes were treated with the respective herbicide, evolved genotypes could increase rapidly, re-colonise fields and thereby join existing volunteer populations to increase the economic weed burden and the potential for impurity (Squire et al. 2011).”

In addition, according to Gressel (2015), “transgenic herbicide resistance poses a major risk if introgressed into weedy relatives.” Gene flow from oilseed rape to related species was recently discussed by Garnier et al. (2014) and Liu et al. (2013). Both studies highlight the aspect of uncertainty in the risk assessment of such events. According to Wang et al. (2013), EPSPS overexpression in oilseed crop plants may foster the fitness of glyphosate resistance in weeds and lead to fitness advantages.

Finally, the EFSA risk assessment did not sufficiently assess the invasiveness of the genetically engineered plants. Most of the relevant characteristics for assessing the specific invasiveness of MON88302, such as pollen, seed characteristics (secondary dormancy) and duration of flowering, were omitted.

Banks’ research (2014) has uncovered substantial new findings on the persistence of oilseed rape in the environment. Contrary to the opinion of EFSA, the actual area on which oilseed rape is grown in a region does not necessarily impact the dynamics of the feral populations. Within the region investigated in Scotland, the area on which oilseed rape was grown was decreasing, while the number of feral oilseed rape populations was strongly increasing. Banks comes to following conclusions: “The number of feral oilseed rape populations increased almost five-fold during a period when the number of fields and total area cropped with oilseed rape decreased. Ferals did not usually remain at the same location for more than one or two years, and did not spread by gradual movement out from the sites of initial colonization. They

persisted and spread in the region by occurring at different places each year, most likely through long range dispersal."

Banks also presented new findings on the pattern of distribution in the environment: "However, the demographic study reported here showed that feral populations increased in number, not just along transport routes but in farmland generally. The reason for the discrepancy between small-scale studies on risk assessment and the actual rise of ferals here is unclear."

Emergence of persistent feral populations of oilseed rape as described by Banks is in no way restricted to conditions under cultivation. In a publication by Mizuguti et al. (2011), it is concluded that populations of genetically engineered oilseed rape are able to self-sustain around Japanese harbours. These plants stem from spillage, since their cultivation is not allowed in Japan. Further, Katsuta (2015) found no clear tendency (decrease or increase) in populations of genetically engineered oilseed rape around Japanese harbours stemming from spillage between 2006 and 2011. At some sites, the populations of genetically engineered plants reported by Katsuta (2015) were found to remain stable for several years, even though there had been no further imports. Further, in the US and Canada, ferals occurred along routes that were sometimes distant from fields, and they increased in density towards storage depots and industrial sites (Knispel & McLachlan, 2010; Schafer et al. 2011).

There is sufficient evidence to show that spillage alone can give rise to persistent populations. As Banks (2014) shows, the number of feral populations was increasing while the cultivation sites were decreasing. Further, the examples from Japan and the US show that persistent feral populations emerged from import, and seem to be able to persist in some regions even if no further import and transport is taking place.

In general, according to Banks (2014) there are dynamics within the distribution of feral populations that cannot be predicted on the basis of currently available short-term investigations: "The long term demographic changes in feral oilseed rape that were found in the 11 year study could not have been predicted from the initial early years when there were few populations or from prior estimates of risk carried out at small spatial scales."

As mentioned, EFSA did not request any data on seed dormancy, duration of flowering, number of pollen, viability of pollen, nor on any other parameter crucial to judging whether the plants have enhanced fitness. Further, no assessment was made of the potential impact of gene flow from the single parental plants MS8 or RF3 to native populations.

Furthermore, EFSA only took the characteristics as observed in the original event into account. Indeed, EFSA assumed that offspring and hybrids would show the same characteristics as the original event. In making this assumption, EFSA overlooked publications, such as those by Kawata et al. (2009) or Aono et al. (2006), which indicate unexpected changes in the fitness of transgenic plants that are unrelated to the intended trait. No crossing experiments with the genetically engineered plants were performed to investigate the effects of the transgenes on plants with other genetic backgrounds. It is therefore not possible to predict fitness, persistence or the invasiveness of hybrids from crossing with the genetically engineered oilseed rape.

Further, genome x environmental interactions were also ignored. For example, outcrossing into wild species could be enhanced by climate or other environmental changes. A higher

amount of gene flow for oilseed rape under extreme climatic conditions has been reported (Franks & Weis, 2009). The study shows there was a change in the time for flowering resulting in matching of flowering between species.

In a worst case scenario, due to crossing with other transgenic oilseed rape of wild relatives, the resulting transgenic plants could become resistant to one or several herbicides. Further, the genetic background of the wild relatives is very different from that of the domesticated oilseed rape. Therefore, enhanced fitness in hybrids might emerge that was not observed in the original event. Once established in the environment, oilseed rape can persist over a long period of time and the transgenic plants can, for example, be exposed to climate change stress factors which might confer higher fitness than observed in the original events.

If such a worst case scenario, whether wholly or partially, became reality, teosinte plants might become a “superweed” with invasive characteristics that could endanger oilseed rape production in the EU and, if transgenic plants are established besides the fields, also impact the ecosystems.

In conclusion, EFSA´s risk assessment suffers from: - No investigation of enhanced fitness of the original events; and no assessment of the single parental plants MS8 or RF3. Underestimating the likelihood and consequences of spillage and gene flow - No assessment of the fitness in offspring and hybrids - No assessment of genome x environmental interactions. - No detailed assessment of whether applications of the complementary herbicide glyphosate might promote enhanced fitness of the transgenic oilseed rape.

Taking worst case scenarios into account, EFSA risk assessment is not sufficient to conclude on the risks associated with the import of viable kernels of oilseed rape MON88302 into the EU.

Aono, M., Wakiyama, S., Nagatsu, M., Nakajima, N., Tamaoki, M., Kubo, A., Saji, H. (2006) Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan. Environmental Biosafety Research, 5(2): 77-87.

Aono, M., Wakiyama, S., Nagatsu, M., Kaneko, Y., Nishizawa, T., Nakajima, N., Tamaoki, M., Kubo, A., Saji, H. (2011) Seeds of a possible natural hybrid between herbicide-resistant Brassica napus and Brassica rapa detected on a riverbank in Japan. GM Crops, 2(3): 201-10.

Banks, G. (2014) Feral oilseed rape populations within a Scottish landscape: implications for GM coexistence and environmental risk assessment (Doctoral dissertation, University of Dundee). http://ethos.bl.uk/OrderDetails.do?uin=uk.bl.ethos.613607?

EFSA (2014) Panel on Genetically Modified Organisms (GMO), Scientific Opinion on application (EFSAGMO-BE-2011-101) for the placing on the market of herbicide-tolerant genetically modified oilseed rape MON 88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2014;12(6):3701, 37 pp. doi:10.2903/j.efsa.2014.3701, Available online: www.efsa.europa.eu/efsajournal

Garnier, A., Darmency, H., Tricault, Y., Chèvre, A. M., & Lecomte, J. (2014) A stochastic cellular model with uncertainty analysis to assess the risk of transgene invasion after crop-wild hybridization: Oilseed rape and wild radish as a case study. Ecological Modelling, 276: 85-94. http://www.sciencedirect.com/science/article/pii/S0304380014000386

Gressel, J. (2015) Dealing with transgene flow of crop protection traits from crops to their relatives. Pest management science, 71(5): 658-667.

Katsuta K., Matsuo K., Yoshimura, Y., Ohsawa, R. (2015) Long-term monitoring of feral genetically modified herbicide-tolerant Brassica napus populations around unloading Japanese ports. Breeding Science 65:265-275.

Kawata, M., Murakami, K., Ishikawa, T. (2009) Dispersal and persistence of genetically modified oilseed rape around Japanese harbors. Environmental Science and Pollution Research, 16(2): 120-126.

Knispel, A.L., & McLachlan, S.M. (2010) Landscape-scale distribution and persistence of genetically modified oilseed rape (Brassica napus) in Manitoba, Canada. Environmental Science and Pollution Research, 17(1): 13-25.

Liu, Y., Wei, W., Ma, K., Li, J., Liang, Y., & Darmency, H. (2013) Consequences of gene flow between oilseed rape (Brassica napus) and its relatives. Plant Science, 211: 42-51.

Lutman, P.J.W., Freeman, S.E., Pekrun, C. (2003) The long-term persistence of seeds of oilseed rape (Brassica napus) in arable fields. The Journal of Agricultural Science, 141(2): 231-240.

Mizuguti, A., Yoshimura, Y., Shibaike, H., Matsuo, K. (2011) Persistence of feral populations of Brassica napus originated from spilled seeds around the Kashima seaport in Japan. Japanese Agricultural Research Quarterly, 45(2): 181-5.

Munier, D.J., Brittan, K.L., Lanini,W.T. (2012) Seed bank persistence of genetically modified canola in California. Environmental Science and Pollution Research, 19(6): 2281-2284.

Nishizawa, T., Nakajima, N., Aono, M., Tamaoki, M., Kubo, A., Saji, H. (2009) Monitoring the occurrence of genetically modified oilseed rape growing along a Japanese roadside: 3-year observations. Environmental Biosafety Research, 8(1): 33-44.

OECD (2012) Consensus Document on the Biology of Brassica crops (Brassica spp.). Organisation for Economic Co-operation and Development.

Pessel, F.D., Lecomte, J., Emeriau, V., Krouti, M., Messean, A., Gouyon, P.H. (2001) Persistence of oilseed rape (Brassica napus L.) outside of cultivated fields. Theor Appl Genet, 102: 841-846.

Pivard, S., Adamczyk, K., Lecomte, J., Lavigne, C., Bouvier, A., Deville, A., Gouyon, P.H., Huet, S. (2008a) Where do the feral oilseed rape populations come from? A large-scale study of their possible origin in a farmland area. J Appl Ecol, 45: 476-485.

Pivard, S., Demsar, D., Lecomte, J., Debeljak, M., Dzeroski, S. (2008b) Characterizing the presence of oilseed rape feral populations on field margins using machine learning. Ecol Model, 212: 147-154.

Ramsay, G., Thompson, C., Squire, G. (2003) Quantifying landscape-scale gene flow in oilseed rape. Final Report of DEFRA Project RG0216: An experimental and mathematical

study of the local and regional scale movement of an oilseed rape transgene. www.scri.ac.uk/scri/file/EPI/Agroecology/Landscape_scale_geneflow_in_oilseed_rape_rg0216.pdf

Saji, H., Nakajima, N., Aono, M., Tamaoki, M., Kubo, A., Wakiyama, S., Hatase, Y., Nagatsu, M., (2005) Monitoring the escape of transgenic oilseed rape around Japanese ports and roadsides. Environmental Biosafety Research, 4(4): 217-222.

Schafer, M.G., Ross, A.A., Londo, J.P., Burdick, C.A., Lee, E.H., Travers, S.E., Van de Water, P.K., Sagers, C.L. (2011) The Establishment of Genetically Engineered Canola Populations in the U.S.. PLoS ONE 6(10):e25736.

Squire, G.R., Breckling, B., Pfeilstetter, A.D., Jorgensen, R.B., Lecomte, J., Pivard, S., Reuter, H., Young, M.W. (2011). Status of feral oilseed rape in Europe: its minor role as a GM impurity and its potential as a reservoir of transgene persistence. Environmental Science and Pollution Research, 18: 111-115.

Wang, W., Xia H., Yang X., Xu T., Si, H.J., Cai X., X., Wang F., Su J., Snow A., Lu B-R., (2013) A novel 5-enolpyruvoylshikimate-3-phosphate (EPSP) synthase transgene for glyphosate resistance stimulates growth and fecundity in weedy rice (Oryza sativa) without herbicide. New Phytologist, 202(2), 679-688.

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4. Conclusions and recommendations

The import of viable whole kernels of the stacked event MON88302 x MS8 x RF3 cannot be allowed. The opinion of EFSA has to be rejected due to major flaws and substantial gaps.
