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NBT に関する USDA への相談一覧

（平成 27 年 5 月 22 日現在）

※赤字は前回の中間取りまとめ以降追記下内容を示す

１．ZFN による変異導入技術	（１）質問者：ダウ・アグロサイエンス（2010 年 3 月） （２）内容：ZFN の DNA（宿主ゲノムには組み込まれない）を導入し部位特異的欠失を生じさせる場合、規制対象か否か。ただし、植物ペストに該当する配列は一切使われない。 （３）USDA の回答（2010 年 5 月 26 日） 植物ペストに該当しないので規制対象外。 （４）USDA によるフォローアップ（2012 年 3 月 8 日） ZFN により、宿主ゲノムに部位特異的塩基置換または遺伝子挿入を生じさせる場合は、ケースバイケースで検討。
２．メガヌクレアーゼ（人工制限酵　素の一種）による変異導入技術	（１）質問者：セレクティス（の代理人）（2011 年 9 月 9 日） （２）内容：メガヌクレアーゼそのもの、あるいはその mRNA、またはその DNA（宿主ゲノムには組み込まれない）を導入し、①部位特異的欠失または②相同組換えにより部位特異的変異導入（鋳型 DNA を利用）を起こさせる場合、規制対象か否か。 （３）USDA の回答（2011 年 12 月 16 日） ①　部位特異的欠失 材料が植物ペスト由来でなければ、ほとんどの場合、規制対象外。 ②　相同組換えによる部位特異的変異導入（鋳型 DNA の活用） 植物ゲノムに多くの変化をもたらし得るのでケースバイケースで検討。
３．TALEN による変異導入技術	（１）質問者：セレクティス（2013 年 7 月 29 日） （２）内容：バレイショのプロトプラストに TALEN の DNA を含むプラスミドを導入し、部位特異的欠失を生じさせた後、細胞分裂を経て得た植物体に対し、PCR により導入遺伝子が残存していないことを確認する場合、当該植物体は規制対象か否か。 （３）USDA の回答（2014 年 8 月 28 日） 導入遺伝子には、*Xanthomonas* 及びアグロバクテリウムなどの植物ペスト由来の配列が含まれているが、申請者は、適切な分子生物学的分析により、最終産物であるバレイショには導入遺伝子が含まれていないことを示しており、規制対象にはあたらない。また、当該バレイショから野生型バレイショへのジーンフローの可能性は極めて低いと考えられる。さらに、導入された変異が野生型のバレイショの適応度に影響を与えることはないだろう。
	（１）質問者：セレクティス（2014 年 12 月 17 日） （２）内容：ダイズの子葉に TALEN をコードする遺伝子カセットを導入し、オレイン酸のリノール酸への生合成を触媒する FAD2-1A 及び FAD2-1B をコードする遺伝子に部位特異的欠失を生じさせた後、細胞分裂を経て得た植物体に対し、植物ペスト由来の導入遺伝子が残存していないことを確認する場合、当該植物体は規制対象か否か。 （３）USDA の回答（2015 年 5 月 5 日） 導入遺伝子には、*Xanthomonas* 及びアグロバクテリウムなどの植物ペスト由来の配列が含まれているが、最終産物であるダイズには導入した DNA が含まれておらず、植物ペストであるとは考えられない。そのため、本 FAD2KO ダイズは規制対象にはあたらない。

４．シスジェネシス	（１）質問者：ワーゲニンゲン大学（2012 年 2 月 23 日） （２）内容：リンゴ由来の黒星病耐性遺伝子をアグロバクテリウム法によりリンゴに導入する場合、規制対象か否か。 （３）USDA の回答（2012 年 4 月 2 日） 当該手法により作出された黒星病耐性リンゴは、植物ペストであるアグロバクテリウムが使われているので、規制対象となるかもしれない。このような植物については、USDA はケースバイケースで検討。
５．イントラジェネシス	（１）質問者：フロリダ大学（2012 年 2 月 8 日） （２）内容：ブドウ由来のアントシアニン制御遺伝子と 2s アルブミンプロモーター及びターミネーターとの融合遺伝子をブドウにプロトプラスト注入法またはパーティクルガン法により導入する場合、規制対象か否か。 （３）USDA の回答（2012 年 4 月 2 日） ブドウは植物ペストではなく、植物ペスト由来の材料も使われてないので規制対象外。
６．プラムの世代促進育種	（１）質問者：USDA・ARS ｱﾊﾟﾗﾁｱﾝ果樹研究所（2011 年 1 月 18 日） （２）内容：プラムの世代促進育種を行うため、ポプラ由来の早期開花遺伝子を導入するが、最終的には、分離により導入遺伝子を含まない個体を選抜、PCR 等により導入遺伝子が残存していないことを確認する場合、最終産物は規制対象か否か。 （３）USDA の回答（2011 年 10 月 27 日） 従来育種により作出されるものと区別がつかず、導入遺伝子及び植物ペスト由来配列を含まないので規制対象外。
７．タバコの世代促進育種	（１）質問者：ﾉｰｽｷｬﾛﾗｲﾅ州立大学（2011 年 1 月 22 日） （２）内容：有害性を減らしたタバコを早期に開発するため、シロイヌナズナ由来の早期開花遺伝子を導入するが、最終的には、分離により導入遺伝子を含まない個体を選抜、PCR により導入遺伝子が残存していないことを確認する場合、最終産物は規制対象か否か。 （３）USDA の回答（2011 年 10 月 27 日） 従来育種により作出されるものと区別がつかず、導入遺伝子及び植物ペスト由来配列を含まないので規制対象外。
８．ソルガムにおける変異体の獲得	（１）質問者：ネブラスカ大学（2011 年 12 月 20 日） （２）内容：ソルガム内在性遺伝子 *MSH1* (*MutS HOMOLOG1*; 植物特異的な核内遺伝子であり、ミトコンドリア及び色素体のゲノムの安定性に寄与するタンパク質をコードする。) の発現を RNAi 干渉により抑制するため、アグロバクテリウム法により該当遺伝子を導入後、遺伝的分離により導入遺伝子が残存していない個体を選抜した場合、その個体は規制対象か否か（RNAi 干渉により、矮性、開花時期の遅れ及び生育の遅れなどの形質変化が現れ、導入遺伝子が残存していない個体も同様の形質を示す。）。 （３）USDA の回答（2012 年 6 月 6 日） 導入遺伝子を含まない最終産物は規制対象外。最終産物に導入遺伝子が残存していないことを分子生物学的分析により確認することを奨励する。しかし、植物ペスト由来の配列を含むベクターが使用されているため、組換え親系統は規制対象。

除草剤耐性セイヨウナタネの事例

1. 概要

本セイヨウナタネは、イミダゾリノン耐性及びスルフォニル尿素耐性のナタネである。Cibus 社（米国）は、ODM（Oligo-directed Mutagenesis）を用いてセイヨウナタネに内在するアセト乳酸合成酵素遺伝子（*BnAHAS1C*、*BnAHAS3A*）に変異を誘発することにより、イミダゾリノン耐性及びスルフォニル尿素耐性のセイヨウナタネ（Canola Cibus Event 5715）を開発した。

具体的には、アセト乳酸合成酵素遺伝子のアミノ酸配列の 574 位のトリプトファンをロイシンに置換した変異型アセト乳酸合成酵素を発現させることによって除草剤イミダゾリノン及び除草剤スルフォニル尿素による阻害を受けない作物を作出した。

本セイヨウナタネは、米国では 2014 年から栽培されており、カナダにおいても 2017 年から栽培する見込み[1]。

2. 規制当局の対応

１）米国

USDA、EPA 及び FDA のウェブサイトにおいて認可品種を調べたが、該当するものは見当たらず。

２）カナダ

カナダ食品検査庁 (CFIA)においては、環境リスクや飼料としての安全性に関する懸念はないと判断し、本セイヨウナタネを非遺伝子組換え生物とみなす旨の判断（2013 年 12 月）[2]。

カナダ保健省（HC）においては、食品の安全に関する懸念はないと判断（2013 年 11 月）[3]。

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[1] www.cibus.com
[2] www.inspection.gc.ca
[3] www.hc-sc.gc.ca

バレイショのイントラジェネシスの事例

1. 概要

本バレイショは、熱調理時のアクリルアミドの生成の抑制や打撲による黒班化を防止することを目的として、米国のSimplot 社が開発。

本バレイショは、それら特性に関係する４つの遺伝子（下表）が逆位反復配列の形で導入されたイントラジェネシス。

当該２本鎖 RNA（dsRNA）を発現させ、dsRNA の働きによってそれぞれの内在性遺伝子の発現を抑制させることにより、アクリルアミドの生成に関わるアスパラギンや還元糖等の産生を抑制。

図．皮をむいて３０分後の写真[1]．Innate™ バレイショ（手前），従来品種（奥）

それら４つの遺伝子はアグロバクテリウム法により導入されているが、ベクターの T-DNA ボーダー配列をバレイショが有する相同的な DNA 配列に改変。

表．二本鎖 RNA の標的遺伝子[2)]

遺伝子名	機能等
Ppo5	ポリフェノール酸化酵素遺伝子、黒斑の生成に関与する
AsnI	アスパラギン合成酵素遺伝子、アスパラギンの生成に関与する
pR1	ジキナーゼ遺伝子プロモーター、デンプンのリン酸化に関与する
pPhL	ホスホリラーゼ遺伝子プロモーター、デンプン分解に関与する

2. 規制当局の対応

USDA においては、４つの遺伝子がアグロバクテリウム法によって導入されているが、挿入ベクターの T-DNA ボーダー配列がバレイショ由来の相同的な DNA 配列に改変されていることから、USDA では植物ペストによるリスクが生じる可能性は低く、規制の対象外と判断（2014 年 11 月）[3]。

FDA の任意コンサルテーションでは、同種のバレイショと構成成分及び安全性において差異はないと判断（2015 年 3 月）。

今後、米国において商業生産が開始される見込み[4]。

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[1] www.simplot.com
[2] Patent No. US8,889,964 B1
[3] www.aphis.usda.gov
[4] www.fda.gov

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0067]

J.R. Simplot Co.; Determination of Nonregulated Status of Potato Genetically Engineered for Low Acrylamide Potential and Reduced Black Spot Bruise

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that potatoes designated as Innate™ potatoes (events E12, E24, F10, F37, J3, J55, J78, G11, H37, and H50), which have been genetically engineered for low acrylamide potential (acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under certain cooking conditions) and reduced black spot bruise, are no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by J.R. Simplot Company in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: Effective November 10, 2014.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0067* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

Supporting documents are also available on the APHIS Web site at *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS Petition Number 13–022–01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: *john.t.turner@aphis.usda.gov*. To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851–3892, email: *cynthia.a.eck@aphis.usda.gov*.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 13–022–01p) from J.R. Simplot Company (Simplot) of Boise, ID, seeking a determination of nonregulated status of potatoes (*Solanum tuberosum*) designated as Innate™ potatoes (events E12, E24, F10, F37, J3, J55, J78, G11, H37, and H50), which have been genetically engineered for low acrylamide potential and reduced black spot bruise. Acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under certain cooking conditions. The petition states that these potatoes are unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process [1] for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice [2] published in the **Federal Register** on May 3, 2013 (78 FR 25942–25943, Docket No. APHIS–2012–0067), APHIS announced the availability of the Simplot petition for public comment. APHIS solicited comments on the petition for 60 days ending on July 2, 2013, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received 308 comments on the petition; one of these comments included electronic attachments consisting of a consolidated document of many identical or nearly identical letters, for a total of 41,475 comments. Issues raised during the comment period include concerns regarding potential effects on conventional potato production, export markets, and plant fitness. APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS first solicits written comments from the public on a draft environmental assessment (EA) and a plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a **Federal Register** notice. Then, after reviewing and evaluating the comments on the draft EA and the PPRA and other information, APHIS revises the PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the **Federal Register** announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and a PPRA from May 30, 2014, to June 30, 2014. APHIS solicited comments on the draft EA, the PPRA, and whether the subject potatoes are likely to pose a plant pest risk. APHIS received 60 comments during the comment period. The majority of comments expressed general opposition to APHIS making a determination of

[1] On March 6, 2012, APHIS published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129*.

[2] To view the notice, the petition, the comments we received, and other supporting documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0067*.

nonregulated status of GE organisms. Issues raised during the comment period included concerns regarding the potential transfer of genes from GE to non-GE potatoes and potential health and environmental impacts. APHIS has addressed the issues raised during the comment period and has provided responses to comments as an attachment to the FONSI.

APHIS received additional information from Simplot on the molecular characterization of one of the events, J3, after publication of the petition, PPRA, and draft EA. The new information indicates rearranged repeated sequences of the inserted genetic material at the right border. APHIS has reviewed the revised structure and concluded the revision does not change the analyses or conclusions in either the PPRA or the EA because there are no new sequences present that were not previously described, no new insertion site(s), and no expected change in functionality. The updated characterization of J3 has been appended to the petition as Appendix 11.

National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and PPRA and other information, APHIS has prepared a final EA. The EA has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Simplot's Innate™ potatoes. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of Innate™ potatoes).

Determination

Based on APHIS' analysis of field and laboratory data submitted by Simplot, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Simplot's Innate™ potatoes are unlikely to pose a plant pest risk and therefore are no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 3rd day of November 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–26593 Filed 11–7–14; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0076]

J.R. Simplot Co.; Availability of Petition for Determination of Nonregulated Status of Potato Genetically Engineered for Late Blight Resistance, Low Acrylamide Potential, Reduced Black Spot Bruising, and Lowered Reducing Sugars

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from the J.R. Simplot Company seeking a determination of nonregulated status for Innate™ Potato designated as Russet Burbank event W8, which has been genetically engineered for late blight resistance, low acrylamide potential, reduced black spot bruising, and lowered reducing sugars. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the J.R. Simplot Company petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that the Animal and Plant Health Inspection Service may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before January 9, 2015.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0076.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2014–0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0076* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming.

The petition is also available on the APHIS Web site at: *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS petition number 14–093–01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: *john.t.turner@aphis.usda.gov.* To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851–3892, email: *cynthia.a.eck@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Biotechnology Consultation Agency Response Letter BNF 000141

Return to inventory: **Completed Consultations on Foods from Genetically Engineered Plant Varieties (http://www.fda.gov/bioconinventory)**

See also **Biotechnology: Genetically Engineered Plants for Food and Feed (http://www.fda.gov/geplantfoods)** and **about Submissions on Bioengineered New Plant Varieties (/Food/FoodScienceResearch/Biotechnology/Submissions/default.htm)**

See FDA's memo on BNF No. 000141 (/Food/FoodScienceResearch/Biotechnology/Submissions/ucm436173.htm) for further details

March 20, 2015

Tracy Rood
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5369 West Irving Street
Boise, ID 83706

Dear Ms. Rood:

This letter addresses J.R. Simplot Company's (Simplot) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered potatoes, events F10, E12, J3, J55, G11, and H50. According to information Simplot has provided, F10, E12, J3, J55, G11, and H50 potatoes are genetically engineered to lower the levels of asparagine and reducing-sugars, thus lowering the potential for acrylamide formation upon heating, and to lower the potential for black spot bruising, by lowering the levels of endogenous enzymes in the potato. All materials relevant to this consultation have been placed in a file designated BNF 000141. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Simplot submitted a summary of its safety and nutritional assessment of the genetically engineered potatoes on February 12, 2013. Simplot submitted additional information on September 30, 2013, August 25, 2014, and October 30, 2014. These communications informed FDA of the steps taken by Simplot to ensure that food and feed from F10, E12, J3, J55, G11, and H50 potatoes comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Simplot has conducted, it is our understanding that Simplot has concluded that food and feed derived from F10, E12, J3, J55, G11, and H50 potatoes are not materially different in composition, safety, and other relevant parameters from potato-derived food and feed currently on the market, and that genetically engineered F10, E12, J3, J55, G11, and H50 potatoes do not raise issues that would require premarket review or approval by FDA.

It is Simplot's responsibility to obtain all appropriate clearances, including those from the Environmental Protection Agency and the United States Department of Agriculture, before marketing food or feed derived from F10, E12, J3, J55, G11, and H50 potatoes.

Finally, as always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meet applicable legal requirements, including disclosure of any material differences in the food. It is our understanding that F10, E12, J3, J55, G11, and H50 potatoes may be used in various food applications. Depending on the particular food application, differences between the F10, E12, J3, J55, G11, and H50 potatoes and conventional potatoes may be considered material information requiring disclosure under Sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(n) and 343(a)(1)]. Companies marketing F10, E12, J3, J55, G11, and H50 potatoes or products containing F10, E12, J3, J55, G11, and H50 potatoes are advised to consult with CFSAN's Office of Nutrition, Labeling, and Dietary Supplements, Food Labeling and Standards Staff, to discuss any required or voluntary labeling including statements relating to attributes of these potatoes and their potential for reduced acrylamide levels or reduced black spots or any other type of claim.

Based on the information Simplot has presented to FDA, we have no further questions concerning food and feed derived from F10, E12, J3, J55, G11, and H50 potatoes at this time. However, as you are aware, it is Simplot's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of the text of this letter responding to BNF 000141, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000141, is available for public review and copying at http://www.fda.gov/bioconinventory.

Sincerely yours,

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

European Plant Science Organisation
www.epsoweb.org

Statement

Crop Genetic Improvement Technologies

Brussels, 26.2.2015

Crop genetic improvement technologies for a sustainable and productive agriculture addressing food and nutritional security, climate change and human health

EPSOs request to the European Commission

The European Plant Science Organisation welcomes the outcome of the majority opinion of the Member States expert working group (the "New Techniques Working Group") report (1) and asks the European Commission as a matter of urgency to provide a guideline document that follows these recommendations to provide legal certainty for science and industry concerning the application and exploration of New Plant Breeding Techniques (NPBTs).

Since an increasingly number of new breeding techniques will be developed, a more detailed and comprehensive discussion on a new approach for the regulation of new plants is required. This new approach might be based on the new characteristics of a product/trait and should take the following into account:

a. A clear and reliable definition, based on scientific evidence, of what constitutes a novel plant trait, and thus needs to be assessed by an appropriate body (legal certainty);

b. The need to avoid overregulation whereby an unwarranted number of processes and products will have to undergo expensive and lengthy authorization procedures (disadvantage for SMEs and scientists);

c. The need to uncouple the question of environmental risk and safety assessment from the question of labeling (consumer acceptance).

Contribution of the EU agriculture sector

The EU agriculture sector makes a vital contribution to building the Knowledge-Based Bio-Economy, to meeting the challenges of food security and safety, to mitigating the effects of climate change, to ensuring sustainable agriculture and to maintaining employment in Europe. The EU plant breeding sector is a strategic sector which has responded to several major global challenges over the past 100 years. It has contributed, and continues to contribute, to the creation of benefits for the EU economy and society as a whole: these positive effects can only be achieved if plant breeders can deploy all appropriate tools which include conventional breeding, genetic engineering, the New Plant Breeding Techniques and other emerging technologies. Additionally, the plant breeding sector should be supported by continuous funding opportunities for fundamental research as well as a clear, workable legislative framework.

Crop genetic improvement technologies are progressing rapidly

Crossing of superior plants followed by selection of improved progeny has, for a long time, been the basis for crop improvement. Such traditional breeding techniques have been complemented since the last century by chemical or radiation mutagenesis, translocation breeding and intergeneric crosses leading to a more sophisticated exploitation of natural genetic variation by plant breeders. The emergence of genetic engineering in the 1980s allowed the development of transgenic plants as an additional approach to complement plant

breeding techniques. These breeding techniques are complementary, not mutually exclusive and are essential tools to meet the challenges of agriculture. From the beginning, the potential risks of transgenic techniques were analysed and a complex GMO regulatory system was put in place. Since then, the development of breeding techniques has continued to progress rapidly resulting in even more sophisticated methods to create plants with new traits. Collectively, these techniques are summarized as New Plant Breeding Techniques (NPBTs). Among them, site directed nucleases (SDN) and other genome editing and modification techniques such as oligo-directed mutagenesis (ODM), allow the introduction of sequence-specific changes in the plant genome. Thus precision-based mutation approaches can now be used which, unlike chemical or radiation mutagenesis, do not create hundreds of additional mutations throughout a genome.

Current European legislation neither reflects the progress made in new crop genetic improvement approaches nor the positive economic, social or environmental impact of the resulting biological outcomes

The current EU GMO-legislative framework is focused on the technique used to produce a new plant, and not on the final trait/product. As some of the NPBTs require an intermediate transgenesis step, the plants obtained by these techniques may be considered as GMOs. This legislation is not reflecting the progress made in the development of new techniques. It also does not reflect the evidence accumulated by thousands of GMO biosafety studies clearly demonstrating that GM technology *per se* does not carry any greater risk of a negative impact on health and the environment than any other technology used in plant breeding**. Therefore, it would be more evidence- and science-based to evaluate the crop genetic improvement technologies including genetic engineering and the NPBTs and other future ones according to the potential impact of the resulting end product/trait rather than the technique used. (2)

The European Commission should create favourable regulatory conditions for the European plant breeding sector

The European Commission's delays in clarifying the legal status of the NPBTs weaken the competitiveness of the EU plant breeding sector. It is clear that for the plant breeding sector and the farming community at large, the status quo on this dossier is not an option and would have a significant negative impact on the current situation for EU farmers. EU farmers already suffer unfair competition from primary producers in other regions of the world regarding access to all appropriate tools including genetic engineering and NPBTs. It is important that the European Commission creates favourable regulatory conditions for the European plant breeding sector to maintain its position of worldwide leadership in the area of research and innovation.

The European plant science community calls upon policy makers to implement a science-based policy as a priority

The European plant science community is following the current debate on the legislative classification of NPBTs along the lines of European GMO legislation with great interest and concern. We are concerned that more and more processes and products will have to undergo expensive and lengthy authorization procedures, even in cases where no foreign DNA is contained in the resulting end product or where these products are completely indistinguishable from traditionally bred crops. We support the conclusions of the New Techniques Working Group (1) that the legal definition of a GMO does not apply to most of the NPBTs and that these techniques either fall under the exemptions already established by the legislation*** or should be exempted as they do not differ from plants obtained by traditional breeding. We support the requests of the Plant ETP (3) based on the reports of several scientific bodies that have assessed and evaluated NPBTs. The European plant science community calls upon policy makers to implement a science-based policy as a priority. For a new start in Europe, the plant science community encourages the new Commission President and his team of Commissioners and policy makers in the Member

States to work towards balanced support for all crop genetic improvement technologies that allow the plant science sector to address the Grand Challenges facing our planet.

** to avoid misinterpretation: this does not imply that conventional breeding should be restricted by similar regulations
*** techniques that are not considered to result in genetic modification (Annex I, Part B of Directive 2009/41/EC and Annex IA Part 2 of Directive 2001/18/EC) or yield organisms that are excluded from the Directive (Annex II Part A of Directive 2009/41/EC and Annex IB of Directive 2001/18/EC)

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Useful links

(1) New Techniques Working Group (2012) Final Report of the European Commission
(2) EASAC Report "Planting the Future"
(3) Plants for the Future ETP: Statement on New Breeding Technologies, September 2012
EPSO Working Group on Agricultural Technologies: www.epsoweb.org/agricultural-technologies-wogr
Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO statement on Crop Genetic Improvement Technologies, 26.2.2015
- EPSO statement on Plant Breeders' rights and patent rights, 26.2.2015
- EPSO statement on GMO cultivation – national opt-out, 26.2.2015

EPSO Science Based Policy, 1.9.2013
EPSO member institutes and universities: www.epsoweb.org/membership/members
EPSO representatives: www.epsoweb.org/membership/representatives

About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 220 leading research institutes and universities from 28 European countries, Australia, Japan and New Zealand. EPSO's mission is to improve the impact and visibility of plant science in Europe.
www.epsoweb.org

27 January 2015

Mr Vytenis Andriukaitis
Commissioner for Health & Food Safety
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels

Open letter to the Commission on new genetic engineering methods

Dear Commissioner Andriukaitis,

In the interest of protecting the environment and public health, genetically modified crops are subject to risk assessment, an authorisation process and labelling rules under EU law. All non-traditional breeding processes that change the structure of DNA using genetic engineering technologies or interfere with gene regulation fall within the scope of these GM regulations. Some are now calling on the European Commission to exempt new genetic engineering techniques from GM rules. The undersigned groups argue that such an exception could threaten the environment and our health, and would violate EU law.

Any attempt to engineer genomes by invasive methods can cause unexpected and unpredictable effects. For example, "cisgenesis" - a genetic engineering technique that uses genes from the same species - is still genetic engineering and is therefore subject to unexpected and unpredictable effects caused by the genetic engineering process itself, and not by the trait or sequence inserted. New techniques to genetically engineer plants and animals, such as so-called DNA scissors (nucleases) and interventions in gene regulation, raise additional concerns.

Most of these techniques are so new that there is not sufficient information to properly assess the risks. Some also allow more radical changes to plant genomes than genetic engineering methods currently used in commercialised products.

We call on the Commission to reject any attempt to exclude these new techniques from EU regulation.

EU laws on genetic engineering should continue to be based on the precautionary principle, transparency and traceability. These same principles must apply to all new genetic engineering techniques and applications.

In particular, we urge the Commission to ensure that:

- Organisms produced by these new techniques will be regulated as genetically modified organisms under existing EU regulations (Directive 2001/18). This means that they will require a full risk assessment before any approval or authorisation is given.

- Any food, feed and seeds as well as other breeding material produced using such new techniques will be labelled and fully traceable throughout the food and feed supply chain.

- Nothing in the TTIP and CETA negotiations will limit Europe's sovereignty and ability to regulate new genetic engineering methods and products as GMOs.

- Current GM health and environmental safety testing requirements are strengthened in light of the enhanced ability of these new techniques - individually or in combination - to alter the genetic code of plants, animals and other organisms.

We would be very happy to elaborate on our concerns in a face-to face meeting and await your response.

Yours sincerely,

Francesco Panella, President, Bee-life European Beekeeping Coordination
Nina Holland, Researcher, Corporate Europe Observatory
Dr. Ricarda Steinbrecher, Co-Director, Econexus, UK
Andrea Ferrante, Coordinating Committee, European Coordination Via Campesina
Mute Schimpf, Food Campaigner, Friends of the Earth Europe
Dr Helen Wallace, Director, GeneWatch, UK,
Saskia Richartz, Acting Director, Greenpeace European Unit
Christoph Then, Executive Director, Testbiotech, Germany

THIS WEEK

EDITORIALS

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APRON STRINGS Hundred-million-year-old insect mothered young **p.134**

All that glitters

A review of the United Kingdom's progress towards 'gold' open-access research is instructive — for funders, publishers and scientists both at home and abroad.

In 2012, the United Kingdom took a bold leap on open-access publishing, announcing that all research articles produced by its publicly funded scientists should be made free to read. A fine pledge, but three years on, it has experienced some practical difficulties. It is instructive to examine them.

To quote the mantra of Research Councils UK (RCUK), the umbrella body for the seven national funding agencies that is overseeing the publishing conversion: "open access is a journey, not an event." Continuing that metaphor, it seems that the United Kingdom has been sent out as an advance party on this journey. Its scientists and publishers are scouting through thickets of confusion on their way to bringing about 'gold' open access. This is the system in which a published article is immediately made freely available, with maximum opportunity to reuse it for applications such as text-mining and translation.

Many nations have not set open-access policies. Others, including the United States, are loitering with little intent, and mandating only delayed access to an author's version of a peer-reviewed manuscript — a 'green' form of open access that ultimately benefits science less (see *Nature* **494,** 401; 2013). RCUK favours a mixed model, but one that gradually migrates towards gold. A review of its progress, published in March, serves as a useful guide and should be examined by funders, publishers and institutions (see go.nature.com/tz2orl).

One problem is that it is hard to track progress, good or bad. RCUK and many British institutions cannot systematically count RCUK-funded papers, let alone those published as open access. As a result, RCUK, although strongly confident, cannot be entirely sure whether the £17-million (US$25-million) open-access fund it gave to universities in 2013–14 has produced the desired result of at least 45% of its funded papers being either green or gold open access.

This underlines the need for researchers to use the ORCID system, a single digital identifier for individuals that links their published papers and grant applications. Use of FundRef, a service from non-profit publisher alliance CrossRef for reporting funding sources, is also essential.

Open-access licences are another major source of confusion. The London-based biomedical charity the Wellcome Trust, which has long mandated gold open access and provides the funds to cover it, reported last month that it now sees 87% compliance with its policy — but that only 66% of papers are accompanied by a liberal publishing licence that allows extensive reuse of text. Licence information, it says, is often ambiguous or contradictory, and records for open-access payments can be lost between authors and publishers.

RCUK says that the licence problem is compounded by researchers not understanding which licence they need to use to comply with the open-access policy, and by publishers offering a range of 'open' licences. (Since January, all 18 open-access journals owned by Nature Publishing Group have switched to using the fully liberal CC-BY 4.0 licence as a default, and to charging a flat fee.)

And then there are costs. All experiments should be encouraged in the evolving gold open-access market, but academics should know that fees for papers published in fully open-access journals are lower than those of 'hybrid' subscription journals that allow an open-access option. The Wellcome Trust says that the average fee levied by hybrid journals is 64% higher than that charged by fully open-access titles. British funders are now pondering steering the market by dissuading researchers from publishing in hybrid journals, as other countries have done.

"Britain looks increasingly isolated in its gold-leaning stance."

The RCUK review did not have the remit to question whether RCUK should continue to hand out money for gold open-access publishing. But with a new UK government in the offing and the country looking increasingly isolated in its gold-leaning stance, there must be a concern that the agency might end up scrapping its gold preference. Last year, four influential UK university-funding bodies announced a green open-access policy that will further steer academics towards delayed public archiving of manuscripts.

In conclusion: the road to gold open access will be bumpy and hard to navigate. But what is encouraging is that these issues are being aired, with publishers, funders and researchers talking to each other about the costs and challenges. The take-home message from the RCUK review is the need to keep discussing difficulties publicly — for only then can other nations learn from the United Kingdom's experience. ■

Seeds of change

The European Union faces a fresh battle over next-generation plant-breeding techniques.

The US plant-breeding company Cibus is proudly rolling out its first crop created with an innovative precision gene-editing technology: herbicide-tolerant oilseed rape.

The crop will be planted in the United States this spring and the firm already has authorization to cultivate it in Canada. The technology switches just a few nucleotides in a plant's DNA; the company's webpage points out that because it works without integrating foreign genetic material, the resulting plants cannot be stigmatized as transgenic. They will, it optimistically declares, "be globally acceptable".

Cibus, based in San Diego, California, hopes that plants imbued in this way with traits that improve their robustness or nutritional value will also find favour in the European Union (EU), where many countries vehemently oppose genetically modified (GM) crops created by transfer of specific foreign genes.

That hope has logic on its side, and it is not misplaced. In February, authorities in GM-hostile Germany told Cibus that they would not consider products created by gene editing as GM, but as products of conventional plant breeding. However, with new battle lines already being drawn, broader approval and acceptance are unlikely to be so simple.

The first battle for GM crops in Europe is currently drawing to an unsatisfactory close. EU legislation from 2001 dictates that the European Food Safety Authority (EFSA) must carry out a scientific risk assessment of any GM strain submitted for authorization. Member states must then vote on whether to pass it, obliging all of them to permit the crop's cultivation if it is approved.

But these votes have almost never yielded the required majority for or against any strain given the EFSA green light. And the European Commission has never dared to exercise its right to enforce a positive decision in cases of impasse. Instead, it has proposed new rules, which came into force last week, allowing EU member states to opt out of a requirement to allow cultivation on non-scientific grounds.

Although it is smart politics, the rule will not be enough to break through the authorization impasse, because all nations must still vote, and a qualified majority must be reached. So, in the next few weeks, the commission will propose further legislation that is likely to allow member states to opt out of the authorization process too. This could finally get the system going again, and give GM-friendly countries such as Spain a wider range of GM crops to choose from.

Meanwhile, science has moved on. Plants without foreign genes can now be created with a variety of methods and technologies that precisely tweak or change the regulation of a native gene. Such plants should reassure anti-GM lobbies that criticize the moral right of scientists to 'play God', and the alleged instability of foreign genes. But environmental groups such as Greenpeace seem far from convinced. In January, several groups wrote an open letter to the commission insisting that new methods that change DNA structure or interfere with gene regulation in any way should also be subject to the EU's tight GM regulations. They argue that the precautionary principle should continue to apply — and that because of the enhanced abilities of the technologies, the safety bar should in fact be raised.

The commission is again playing for time. In 2007, it appointed an expert panel to advise it on the ever-expanding plant-breeding toolbox. The panel's report was submitted in 2012 but never published. The commission now says that it has set in motion a "thorough legal analysis" of the definition of 'GM organisms' in its own legislation, and of the criteria for excluding certain technologies. The conclusions of the analysis, it warns, "cannot be anticipated".

"The European Commission is again playing for time."

Most plant scientists consider the new tools to be helpful extensions to normal plant-breeding practice. In many cases, they say, the plant products are indistinguishable from the original plants and are intrinsically even safer than GM plants. Two years ago, the European Academies Science Advisory Council, an umbrella group for national academies in Europe, argued that the time had come for regulators to abandon their fixation on plant technologies and instead carry out risk assessments on the individual plant products. In February, the European Plant Science Organisation, an independent body representing more than 220 research institutes and universities from 28 European countries, as well as Australia, Japan and New Zealand, reiterated the message.

Late last month, the Leopoldina, Germany's national academy of sciences, published a similar position paper in the hope of influencing its government, as the country deliberates anew the legal environment of its GM regulations. Both Germany and the commission are watching and waiting. In their letter to Cibus, the German authorities noted that their statement of readiness to consider products of gene editing as non-GM would be invalidated if the European Commission were finally to decide otherwise.

As Europe's first battle on GM staggers to an uneasy truce, a second — and perhaps more important one — is approaching. ■

Lunar affairs

A study in Nature *adds a dramatic twist to the backstory of a neighbour we thought we knew.*

In the stories of many human cultures, the Solar System is something of a family affair. The Norse people and the Incas of South America believed that the Sun and the Moon were brother and sister. A Native American myth has them as husband and wife (although the husband wants to eat his children, the stars). The Moon as a mother is a common theme.

Now scientists have suggested a rival celestial tale with a twist that is more common to terrestrial television dramas: the sudden appearance of a long-lost sibling. The early Earth had a near-identical geological twin, they say. The two young planets, of course, had a falling out and the twin vanished. But before it did so, it saddled Earth with an orbiting Moon-child.

The the origin of the Moon is a classic story that has been told many times. The latest version — written in a research paper on page 212 — still has some plot holes. But it is a cracking tale.

The time: some 4.5 billion years ago, in the earliest days of the Solar System. The place: hostile. A long time ago, if you like, in a galaxy not very far away. Thousands of adolescent protoplanets whizz around the Sun, bashing into each other, some breaking into smaller pieces and forming others as they soak up the freed materials. One of these protoplanets, lying not too far from the Sun and not too close, is what we now call Earth.

Enter, stage left, protoplanet Theia. Smaller than proto-Earth, it was raised in a similar neighbourhood. A chance meeting set the two on a collision course. The meeting is violent, and — here it helps if you imagine the most gravelly cinematic voice-over you can manage — life for both will never be the same again.

Theia becomes a giant cloud of dust infused with bits spewed from the injured proto-Earth, which quickly comes together to form the Moon. Earth gains a dependant.

The script might sound familiar; the plot more of a remake than of anything original. But here is the difference. Previously, many planetary scientists considered that it was too much of a stretch to say that young Theia and Earth were so closely related. It is much more plausible, given the chaos of the time, to present Theia as a random stranger. But that creates a continuity error: the mineral composition of rocks retrieved from the Moon is eerily similar to those of Earth.

Either Theia and Earth are related, or our best models of how the Moon formed are wrong. But if they are related, then why is it that the other bodies in the Solar System that we have studied seem to be so different from each other? What are the chances, given the number of objects out there at the time, that proto-Earth would be hit by a near clone?

The latest study runs computer simulations of those early days, to investigate the possible backstories of the major characters, including how and where they formed and their probable orbits. (A note to film directors: this bit is probably best presented as a montage.) The number crunching offers a realistic script: there is a one-in-five chance that proto-Earth and Theia could have formed at about the same distance from the Sun, so from the same stuff, and then run into each other to make the Moon. True, it is not a cut-and-dried ending that ties up all the loose ends before the credits roll. But all the best stories leave room for a sequel. ■

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