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REGULATORY NEWS

CONTENTS

US Agencies Wrestle with GE Crops, While EU May Knock Out Clones

Phillip Jones

For the first time, a US regulatory agency proposes to limit the cultivation of genetically engineered (GE) corn. The Environmental Protection Agency's proposal concerns GE corn engineered to synthesize *Bacillus thuringiensis* (Bt) toxin to kill rootworm. EPA officials are not concerned that the GE corn poses a health threat; they want to preserve the efficacy of the insect-killing plants.

"This proposal responds to reports of widespread corn rootworm resistance to two Bt corn traits," the EPA stated in a *Federal Register* announcement. "EPA believes that the proposed enhancements would prolong the effectiveness of Bt PIPs [plant-incorporated protectants] for corn rootworm control significantly—which is important because of the long safety record of these PIPs. If used properly, PIPs greatly reduce the need for conventional pesticides and the risks they may present to human health and the environment."

The US Department of Agriculture reported that US farmers planted Bt toxin-producing GE corn on about 80% of cornfields. Widespread cultivation of the corn and repeated planting over consecutive years account for the selection of toxin-resistant rootworm populations. Researchers have found rootworms resistant to Bt toxin in Iowa, Nebraska, Illinois, and Minnesota. In particular, reports document corn rootworm resistance to the Bt toxins, Cry3Bb1 and modified Cry3A.

The EPA's proposal contains measures to delay the development of Bt toxin resistance in rootworms. For example, two measures are crop rotation and the growth of GE corn varieties that synthesize more than one type of Bt toxin. The EPA would apply both measures in "red zones," where corn rootworm infestations and the growth of Bt toxin-producing GE corn are common. The agency identified red zones in Iowa, Illinois, Nebraska, Indiana, Wisconsin, Minnesota, and South Dakota.

The EPA opened a 45-day comment period, which initially ended on March 16, but was extended for an additional 30 days. The agency is considering 87 comments submitted about the proposal.

GE Food Labels: USDA Enters the Melee

For years, state legislators have been drafting bills that would require labels on food products containing ingredients from GE crops. Yet a hodgepodge of state-based food label laws is impractical.

Congress has also struggled with GE food label laws that would fashion a uniform standard for all states. As an example, Senator Barbara Boxer (D-CA) introduced the Genetically Engineered Food Right-to-Know Act (S. 511) in February. The bill would amend the Federal

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ISB welcomes your comments and encourages article submissions. If you have a suitable article relevant to our coverage of agricultural and environmental applications of genetic engineering, please email it to the Editor for consideration.

Food, Drug, and Cosmetic Act (FD&C Act) to prohibit the sale of food that has been genetically engineered or that contains GE ingredients, unless that information is clearly disclosed to consumers. Both S. 511 and the counterpart House bill (H.R.913) reside in committees.

If the Genetically Engineered Food Right-to-Know Act became law, then the Food and Drug Administration would bear the responsibility of devising GE food labeling rules. Currently, the FDA refuses to require GE food labels. The agency takes the position that the FD&C Act does not create the authority to mandate labeling based on the method of food production if the agency considers the final food product to be safe. To determine if a food is safe for consumption, the FDA focuses on the characteristics of the food and its components, rather than the fact that a new method was used at some point to produce the food. In brief, the agency considers product, not process.

A news leak revealed that the USDA will issue a GE food label that does focus on process. During May, the Associated Press obtained a copy of an email sent by Agriculture Secretary Tom Vilsack to USDA employees in which he described a new certification scheme. The new label is offered through the agency's established Process Verified Program. For a fee, the USDA offers companies that supply agricultural products or services the chance to assure customers that the companies provide consistent quality products or services. If the agency approves a company's claim, then the company can market its products with a USDA process verified label. For the new GE food scheme, a label reads "Non-GMO/GE Process Verified."

In his email message, Vilsack explained why the USDA created the label. "Recently, a leading global company asked AMS [Agriculture Marketing Service] to help verify that the corn and soybeans it uses in its products are not genetically engineered so that the company could label the products as such," Vilsack said. "AMS worked with the company to develop testing and verification processes to verify the non-GE claim."

When the story broke, SunOpta contacted *The New York Times* and identified itself as the "leading global company." The Toronto-based business has most of its facilities in the United States, and specializes in sourcing, processing, and packaging natural and certified organic food products. The USDA process verified claim applies to corn and soy that SunOpta plans to process in its plant in Hope, Minnesota.

"The USDA came in and looked at our entire process from the beginning to the end, from how we work with farmers and growers to shipping and the quality analysis we do," SunOpta's Lisa Robinson told *The New York Times*. As a result, the USDA certifies that the "[p]roducts verified as Non-GMO are made from ingredients that were not produced using genetic engineering (GE) and meet SunOpta's standard of 99.1% Non-GMO/Non-GE minimum (or testing specification 0.9% GMO/GE Maximum)."

Vilsack said that "other companies are already lining up to take advantage of this service." It seems unlikely, however, that the USDA's new labeling scheme will satisfy advocates of mandatory GE food labeling. They claim that voluntary USDA labels will not educate consumers about the ingredients in their food. Instead, a voluntary system would create inconsistency in labeling and cause more confusion for consumers.

In the EU, Not Everybody Loves a Clone

Animal cloning enables breeders to improve the quality of their livestock. Desirable characteristics include the ability to thrive in a changing climate, resistance to disease,

a body type better suited to production (e.g., dairy cows with large, well-attached udders), and other qualities. For instance, a cattle rancher may want beef cattle with a high fertility rate to replace animals sent to slaughter. A breeder can clone cattle with high fertility rates to increase the number of breeding animals available to make food production livestock.

The possibility that food products from clones or their offspring may enter the marketplace has inflamed controversy. In 2008, the US Food and Drug Administration issued its "Final Risk Assessment, Management Plan and Industry Guidance on Animal Clones and their Progeny." The FDA decided that "meat and milk from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals." The agency noted that it had insufficient information to decide about the safety of food from clones of other animal species.

Questions about the appropriateness of any farm animal cloning remain unsettled in Europe. During 2007, the European Executive asked the European Group on Ethics for Science and New Technologies to provide an opinion about the ethics of cloning, an issue that arises from health complications associated with the cloning process. At the same time, the EU Commission asked the European Union's Food Safety Authority (EFSA) for a scientific opinion about whether it would be safe to eat meat and milk from cloned animals.

Both groups issued their opinions in 2008. The European Group on Ethics did not see convincing arguments to rationalize the production of food from clones and their offspring: "[C]onsidering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified." With regard to food safety, EFSA decided that "it is very unlikely that any difference exists in terms of food safety between food products from clones and their progeny compared with conventionally-bred animals." However, EFSA did voice concerns about negative effects on animal health and welfare.

According to the 1997 EU Novel Foods Regulation, food produced from non-traditional breeding techniques, such as cloning, must pass pre-market approval based on a scientific food safety assessment by EFSA before the food can be imported or sold in the EU. The regulation is silent about the offspring of clones. Attempts to add measures about food from clones and offspring of clones failed during 2008 and 2011. On December 18, 2013, the Commission announced a proposal to initiate a five year moratorium on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes. The moratorium reflected concerns about cloning-related animal welfare. The Commission also proposed a moratorium on the marketing of food from cloned animals in the EU. The proposals did not cover offspring from cloned animals or products derived from these offspring.

Citing animal welfare and ethical concerns, Members of the European Parliament (MEPs) recently drafted proposals that go beyond the Commission's; the proposals were adopted by members of the environment, public health, and food safety committee, and the agriculture and rural affairs committee. The MEPs extended the scope of the Commission's proposed moratorium to an absolute ban that would include all agricultural animal species. The ban would also cover all imported meat and milk products from the descendants of cloned animals, and included a demand to implement a system to guarantee the traceability of these products.

A vote on the proposals is scheduled for the September plenary session. If approved, the changes could be incorporated into legislation as early as next year.

Selected Sources

"Animal Cloning," *FAS/USEU* Website. (May 28, 2015). Available at: http://www.usda-eu.org.

Aubrey, Allison, "USDA To Certify Non-GMO Foods With New Label," *NPR* Website. (May 15, 2015). Available at: http://www.npr.org.

"Ban not Just Animal Cloning, but Cloned Food, Feed and Imports Too, Say MEPs," *European Parliament* Website (June 17, 2015). Available at: http://www.europarl.europa.eu.

Barbière, Cécile, "Parliament Demands Moratorium on Cloned Animal Products," *EurActiv Media Network* Website (June 19, 2015). Available at: http://www.euractiv.com.

Bunge, Jacob, "Limits Sought on GMO Corn as Pest Resistance Grows," *The Wall Street Journal* Website (March 5, 2015). Available at: http://www.wsj.com.

"EU Ethics Group Advises Against Cloning Animals for Food," *EurActiv Media Network* Website (January 18, 2008). Available at: http://www.euractiv.com.

Jalonick, Mary Clare, "USDA Develops New Government Label for GMO-free Products," *Washington Post* Website (May 14, 2015). Available at: http://www.washingtonpost.com.

McNally, Robert, "EPA Proposal to Improve Corn Rootworm Resistance Management," *Federal Register* 80: 4564-4565 (January 28, 2015).

"Proposed Framework to Prevent Corn Rootworm Resistance," *EPA* Website (January 28, 2015). Available at: http://www.epa.gov.

Strommay, Stephanie, "U.S. Approves SunOpta System for Detecting Genetically Modified Crops," *The New York Times* Website (May 15, 2015). Available at: http://www.nytimes.com.

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Sweetpotato Is a Naturally Transgenic Crop

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Background

The acquisition of new genes that confer a selective advantage is an important factor in genome evolution. Whereas it has long been recognized that exchange of genetic material between species is an important aspect of prokaryotic evolution, in recent years it has emerged that significant parts of eukaryotic genomes also originate from the exchange of genetic material among related or unrelated species. This phenomenon known as 'horizontal gene transfer' (HGT) is now considered to be a rare but significant source of molecular variability and a driver of evolution. A particular case of HGT was discovered more than three decades ago when the natural occurrence of a T-DNA transfer from *Agrobacterium rhizogenes* to a progenitor of the genus *Nicotiana* was reported. These T-DNA sequences are naturally present in several *Nicotiana* species, are transmitted to the progeny, and do not cause hairy root or tumor-like symptoms. A similar phenomenon has recently been reported in *Linaria vulgaris*. However, neither *Nicotiana* nor *Linaria* plants are eaten, and such findings have not been associated with crop domestication. The initial discovery was also made long before the commercialization of transgenic crops had become a controversial issue with the general public and so was largely ignored in the ensuing debate over potential safety issues associated with transgenic crop plants.

Discovery of T-DNAs in sweetpotato

In the course of a high throughput sequence analysis of *small interfering RNA* "siRNAs" of sweetpotato plants, siRNAs homologous to T-DNA-like sequences from *Agrobacterium spp.* were discovered in sweetpotato (*Ipomoea batatas* (L.) Lam., cultivar 'Huachano'). This prompted us to investigate the presence of T-DNAs in the genome of this landrace.

Through Genome Walking techniques, starting from the identified siRNA-sequences, two large T-DNA regions from *Agrobacterium* spp. were found inserted into the sweetpotato genome (**Fig. 1**). Sequence analysis revealed that the first region, *Ipomoea batatas* T-DNA1 (*Ib*T-DNA1), had at least 4 ORFs with significant homology to *Agrobacterium* tryptophan-2-monooxygenase (*iaaM*), indole-3-acetamide hydrolase (*iaaH*), C-protein (*C-prot*), and agrocinopine synthase (*Acs*; **Fig. 1B**), and a partial inverted repeat of *iaaM*.

The second region, *Ib*T-DNA2, contained at least 5 ORFs with significant homology to *ORF14*, *ORF17n*, *RolB/RolC*, *ORF13* and *ORF18/ORF17n* of *A. rhizogenes* (**Fig. 1A**). The flanking sequences (**Fig. 1A**) of *Ib*T-DNA1 showed significant homology (tblastx) to an exon of F-box protein encoding plant genes. This presumed sweetpotato genome sequence was a near perfect nucleotide match to several transcript sequences from the sweetpotato gene index (https://research.cip.cgiar.org/confluence/display/SPGI/Home; contig 02446) and a sweetpotato transcriptome shotgun library at NCBI (JP111314.1), which were predicted to encode F-box proteins (*e-value*= e-177).

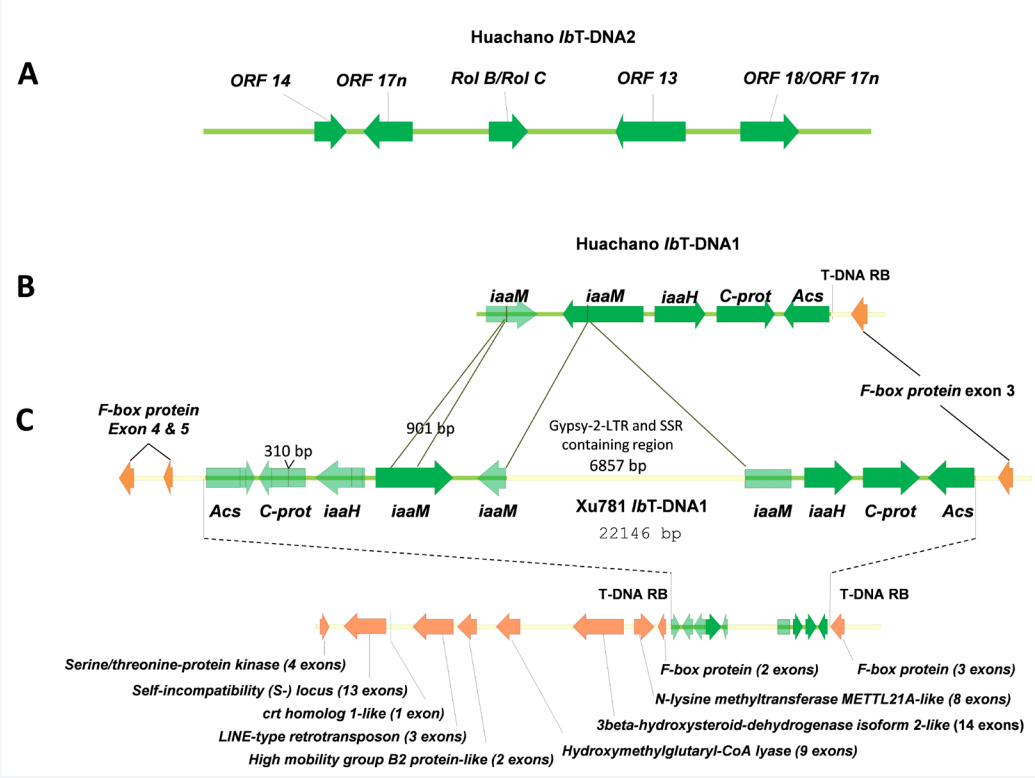

Figure 1. Organization of the T-DNAs in the genome of sweetpotato. The sequences in (A) and (B) were obtained by genome walking and the joining of partial sequences identified through small RNA sequencing and assembly, from 'Huachano'. (C) Genomic structure of region surrounding *Ib*T-DNA1 in cultivar 'Xu781'. This genomic region includes predicted plant genes shown in orange, and T-DNA encoded genes shown in green. A comparison between 'Huachano' and 'Xu781' *Ib*T-DNA1 shows varios insertions and deletions indicated by lines drawn between figures B and C. Transparent green colors indicate the reading frames are interrupted.

The T-DNA insertion into the sweetpotato F-Box gene was corroborated by sequence analysis of a Bacterial Artificial Chromosome (BAC) clone that was identified by screening a previously generated BAC library of sweetpotato cultivar 'Xu781' using primers specific to *iaaM* and *C-prot*. The BAC sequence (79,655 bp) revealed that the complete *Ib*T-DNA1 encompassed 21,564 bp, located between two T-DNA border-like sequences. It consisted of an inverted repeat of the *Acs* : *C-prot* : *iaaH* : *iaaM* gene cassette including a region, containing short sequence repeats and several segments with similarity to Gypsy 2 type LTR transposons, inserted in one of the *iaaM* repeats (**Fig. 1C**), and a deletion of 310bp in one of the *C-prot* repeats. *Ib*T-DNA1 was bordered by sequences corresponding to putative exons matching transcripts of predicted F-Box proteins, suggesting that it was inserted into an intron of this gene. The presence of additional predicted genes in the BAC region (**Fig. 1C**) suggests that *Ib*T-DNA1 is located in a transcriptionally active region of the chromosome, and this conjecture is supported by the near perfect homology to sequences available in published sweetpotato transcriptomes, except for the predicted LINE-type retrotransposon LIb DNA.

Southern blot analysis was performed to confirm the insertion of both T-DNAs into the sweetpotato genome (**Fig. 2**). An estimated 4 copies of each T-DNA appear to be present in the sweetpotato genome. Hybridization with a probe for *Ib*T-DNA1 (*C-prot* region) produced several bands that also appeared when hybridized to the probe corresponding to the flanking plant DNA, confirming their physical linkage. Additional bands found for the flanking DNA suggest that at least two additional copies, unlinked to *Ib*T-DNA1, are present in the genome and are likely the origin of the identified transcripts.

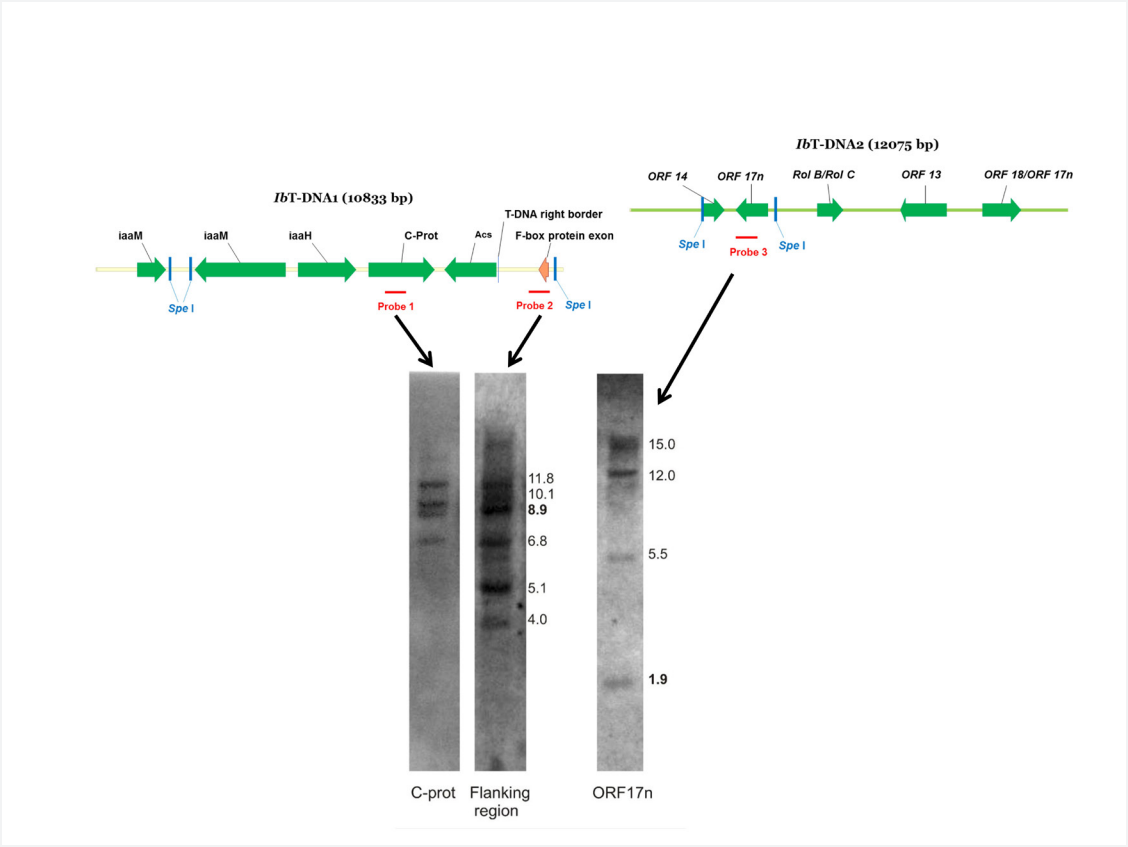

Figure 2 Southern blot analysis on *Spe*I digested DNA from cultivar 'Huachano' using probes corresponding to IbT-DNA1 and 2 encoding genes and flanking plant DNA as indicated above the blots.

At present it is unclear if the T-DNA copies observed on the Southern blots are allelic in origin or result from independent T-DNA insertions. Further analysis, including wild relatives of sweetpotato, will be instrumental in elucidating this.

Expression of the ORFs on the two T-DNAs was tested by qRT-PCR using 'Huachano'. This analysis revealed the presence of mRNAs of these genes in leaf, stem, root, shoot apex and storage root tissues.

In order to examine the presence of these T-DNA sequences in the cultivated sweetpotato gene pool, PCR-analyses were performed for each of the 4 ORFs of *Ib*T-DNA1 and the *rolB/rolC* and *ORF13* of *Ib*T-DNA2. A total of 291 genotypes, collected in South and Central America, Africa, Asia, and Oceania, and representing the global cultivated (hexaploid) sweetpotato gene-pool, were analyzed. In addition ten tetraploid and two diploid wild relatives were also included in this analysis. *Ib*T-DNA1 was present in all hexaploid sweetpotato samples but none of the wild relatives. In contrast, *Ib*T-DNA2 was present in 26 hexaploid and two of the wild genotypes among a total of 92 genotypes examined.

In *Nicotiana*-evolution, the *rol*-containing genotypes are rooting-prone, while the others are shoot-producing. Since *rolB/rolC* and *ORF13* from *Ib*T-DNA2 are absent from some sweetpotato genotypes, segregation of these genes and a possible phenotypic correlation with root parameters was examined, using primers for *RolB/RolC* and *ORF13*, in the progeny of a cross between the cultivars Beauregard (negative) and Tanzania (positive). Among the progeny of this cross, 76/80 were positive for *ORF13* suggesting that *Ib*T-DNA2 is present on 5 out of 6 homeologous sweetpotato chromosomes in cv. Tanzania. Thirteen of these 76 plants did not contain *rolB/rolC*, indicating the presence of a variant of *Ib*T-DNA2. Significant correlation was found between the presence of *rolB/rolC* and total root yield, in this segregating population. No segregation of *iaaM* from the *Ib*T-DNA1 fragment was observed in the PCR screening of this population.

Conclusions and Perspectives

Our data provide evidence of an ancient HGT between an *Agrobacterium* strain and an ancestor of the cultivated sweetpotato. *Ib*T-DNA1 was found in all tested hexaploid accessions from different regions of the world but in none of the closest wild relatives. The tested genotypes are from two different germplasm collections and laboratories, and were analyzed independently in two different labs, demonstrating that the presence of *Ib*T-DNA1 is a general feature of the domesticated sweetpotato and not the result of a laboratory accident. The presence of *Ib*T-DNA1 in all hexaploid genotypes examined, and the lack of segregation in the progeny of the analyzed cross, suggests that this cassette is fixed in the cultivated sweetpotato genome—in contrast to its close relatives. It is therefore conceivable that one or more of the transferred genes contributed to the expression of a trait that was subsequently selected for during domestication. The genes identified on the two T-DNAs indicate that the transforming *Agrobacterium* most likely was *A. rhizogenes* with *Ib*T-DNA1 corresponding to TR-DNA (typically contains the auxin biosynthesis genes iaaM & iaaH) and *Ib*T-DNA2 to TL-DNA (harbouring the rol genes). However, the gene order is different from that of any *A. rhizogenes* T-DNA known today. A blastN search for all genes on the T-DNA region resulted in a different top hit for every gene, with best matches to genes either from *Agrobacterium tumefaciens*, *A. vitis*, or *A. rhizogenes*. Phylogenetic analysis of several of the genes places the sweetpotato T-DNA genes in a separate clade as compared to their corresponding *Agrobacterium* genes sequenced to date. The fact that the gene organization and DNA sequences of the T-DNAs are related to, but considerably different from, the ORFs of known Ri and Ti-plasmids from well-characterized *Agrobacterium* strains highlights that the *Agrobacterium* strain which transferred its T-DNA into the sweetpotato genome is not one of the common laboratory strains and might even be evolutionarily extinct.

Although several transcriptomes of sweetpotato have been published, no reports were made of the presence of *Agrobacterium* related transcripts. We postulate that standard procedures in sequencing may result in the omission of T-DNA sequences in plant sequence reads, since bacterial sequences are typically filtered out as contamination. It was the discovery of siRNAs related to T-DNA genes that alerted us to the eukaryotic origin of these sequences.

This finding raises a number of interesting scientific questions and opportunities: What are the roles of the T-DNA encoded genes, if any, in sweetpotato physiology/phenotype. Auxins are involved in many plant processes, including root and shoot development. Could these genes confer traits that stimulate storage root formation or robust rooting of cuttings (sweetpotatoes are multiplied through planting stem cuttings)? Knock out experiments using gene-editing technology might be able to illuminate such questions. Alternatively, closely linked genes may be involved in domestication traits, or perhaps even the interruption of the F-box gene itself may have contributed. On the other hand, study of *Ib*T-DNAs in related *Ipomoea* provides an opportunity to better understand progenitors of cultivated sweetpotato and the fate of exogenous transgenes after HGT (speed of evolution, control of expression). In that respect it is unfortunate that none of the genomes from related *Ipomoea* sequenced to date contain either of the T-DNAs.

Several recent genome sequencing studies have indicated that cross-kingdom gene transfer between organisms is more widespread than initially believed. It is likely that more examples of HGT in eukaryotes and crop plants will be discovered. Our data demonstrate that T-DNA integration, and subsequent fixation, also occurred naturally during the evolution of sweetpotato, a food crop which has been eaten for millennia, evidently without any health concerns for the consumers. Consumers and anti-GMO organizations have generally equated transgenic technology with the perceived dangers of GMOs, as they consider it unnatural and thus dangerous by default. This report of a naturally transgenic crop, which has been transformed through the exact same mechanism as many of todays commercialized GMOs, and likely provided an important agricultural trait delivered by bacterial transgenes in the process, provides a powerful example to challenge such thinking. In the best case it will stimulate the public who have doubts about the inherent safety of GMOs and genetically engineered crops to reflect on their pre-conceived ideas and come to a more balanced opinion on the issue.

On the other hand these results will no doubt provide food for thought for regulators of GM crops. Noteworthy, one of the T-DNA insertions found in this study has interrupted an endogene, which is considered

an unacceptable feature for GM crops according to most current regulation. Likewise the presence of multiple copies, including apparent rearrangements, evident for the discovered sweetpotato T-DNAs, is an impediment for deregulation of GM crops in most cases. Furthermore, the current handling of GM dossiers may have to be modified in some countries. For example in the USA, while some GM crops developed by particle bombardment would not be regulated because a plant pest was not used to perform the engineering, plants that have been in contact with *Agrobacterium* to introduce the genes do need to be regulated. Obviously sweetpotato has been in contact with *Agrobacterium* during evolution, which was able to insert T-DNAs into its genome, and thus may challenge consistent application of such regulations.

Source:
Kyndt T, Quispe D, Zhai H, Jarret RL, Ghislain M, Q-C Liu, Gheysen G, Kreuze JF (2015) The genome of cultivated sweetpotato contains Agrobacterium T-DNAs with expressed genes: an example of a naturally transgenic food crop. *Proceedings of the National Academy of Sciences of the USA* 112, 18: 5844–5849, *doi: 10.1073/pnas.1419685112*

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Improving Transparency and Ensuring Continued Safety in Biotechnology

Posted by John P. Holdren, Howard Shelanski, Darci Vetter, Christy Goldfuss

July 02, 2015

Source: https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology, which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The Framework was updated in 1992. While the current regulatory system for biotechnology products effectively protects health and the environment, advances in science and technology since 1992 have been altering the product landscape. In addition, the complexity of the array of regulations and guidance documents developed by the three Federal agencies with jurisdiction over biotechnology products can make it difficult for the public to understand how the safety of biotechnology products is evaluated, and navigating the regulatory process for these products can be unduly challenging, especially for small companies.

These circumstances call for revisiting the Coordinated Framework once more. Accordingly, today the White House is issuing a memorandum directing the three Federal agencies that have oversight responsibilities for these products—the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Department of Agriculture (USDA)—to update the Coordinated Framework, develop a long-term strategy to ensure that the system is prepared for the future products of biotechnology, and commission an expert analysis of the future landscape of biotechnology products to support this effort.

Increasing transparency & predictability in biotechnology regulation

The goal of the effort is to ensure public confidence in the regulatory system and improve the transparency, predictability, coordination, and, ultimately, efficiency of the biotechnology regulatory system. Here is a bit more detail about the

effort's three components:

- **First, the Administration will update the Coordinated Framework, after public input, by clarifying the current roles and responsibilities of the EPA, USDA, and FDA in the regulatory process. This update will help clarify which biotechnology product areas are within the authority and responsibility of each agency and outline how the agencies work together to regulate products that may fall under the authorities of multiple agencies.**
- **Second, the Administration will develop a long-term strategy, after public input, to ensure that the Federal regulatory system is well-equipped to assess efficiently any risks associated with the future products of biotechnology. This will include performing periodic horizon-scanning of new biotech products, coordinating support for the science that informs regulatory activities, developing tools to assist small businesses as they navigate the regulatory system, and creating user-friendly digital tools for presenting the agencies' authorities, practices, and basis for decision-making.**
- **Third, the Administration will commission an outside, independent analysis of the future landscape of the products of biotechnology. The Administration has already asked the National Academies of Sciences, Engineering, and Medicine to conduct such an analysis.**

More details on the elements of each of these components can be found in the memo to agencies that was issued today.

We want to hear from you

The Administration recognizes the importance of public engagement throughout this process. As part of this process, the Administration will hold three public engagement sessions over the year in different regions of the country. The first listening session will occur in Washington, D.C. in fall 2015. In addition, the update to the Coordinated Framework will undergo public notice and comment before it is finalized. If you would like to be kept up to date on these activities, including details on the listening sessions, please sign up here: *https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology*

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