Proporcionalidad y eficiencia en la evaluación de riesgo de las plantas obtenidas mediante mutagénesis dirigida y cisgénesis

Josep M. Casacuberta, CRAG

Jornada sobre la iniciativa regulatoria para plantas obtenidas mediante mutagénesis dirigida y cisgénesis. MAPA. 29 Junio 2022

Mejora genética de plantas

- 10,000 años	Domesticación	Agricultura
1859	Darwin: teoria evolución	1. Introducción variabilitat genética 2. Selección
1865	Mendel: leyes de la herencia	
1950	Watson y Crick: estructura DNA	Introducción dirigida de caracteres
	Mutagénesis	Variabilidad inducida
1960-1970	Mejora técnicas cultivo “in vitro”	
1983	Transferencia génica en plantas	Introducción directa de genes
2007-2016	SDNs, CRIPR-Cas9	Edición genética

Mejora genética de plantas

Especies silvestres

Especies cultivadas

Especies mejoradas

- 10,000 años	Domesticación		Agricultura
1859	Darwin: teoria evolución		1. Introducción variabilitat genética 2. Selección
1865	Mendel: leyes de la herencia		
1950	Watson y Crick: estructura DNA		Introducción dirigida de caracteres
	Mutagénesis		Variabilidad inducida
1960-1970	Mejora técnicas cultivo "in vitro"		

Regulación específica

1983	**Transferencia génica en plantas**	**Plantas transgénicas**	**Introducción directa de genes**
2007-2016	**SDNs, CRIPR-Cas9**	**Plantas editadas**	**Edición genética**

I

(Actos cuya publicación es una condición para su aplicabilidad)

DIRECTIVA 2001/18/CE DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 12 de marzo de 2001

sobre la liberación intencional en el medio ambiente de organismos modificados genéticamente y por la que se deroga la Directiva 90/220/CEE del Consejo

Artículo 2

Definiciones

A efectos de la presente Directiva se entenderá por:

1) «organismo», toda entidad biológica capaz de reproducirse o de transferir material genético;

2) «organismo modificado genéticamente (OMG)», el organismo, con excepción de los seres humanos, cuyo material genético haya sido modificado de una manera que no se produce naturalmente en el apareamiento ni en la recombinación natural;

Según esta definición:

a) se produce una modificación genética siempre que se utilicen, al menos, las técnicas que se enumeran en la parte 1 del Anexo I A;

b) se considera que las técnicas enumeradas en la parte 2 del Anexo I A no dan lugar a una modificación genética;

Marco legal aplicable a los OMGs

Legislación en la UE: - Basada en el proceso (técnica empleada)

- Caso por caso (tiene en cuenta el producto)

(US), Canada…: - Basada en el producto

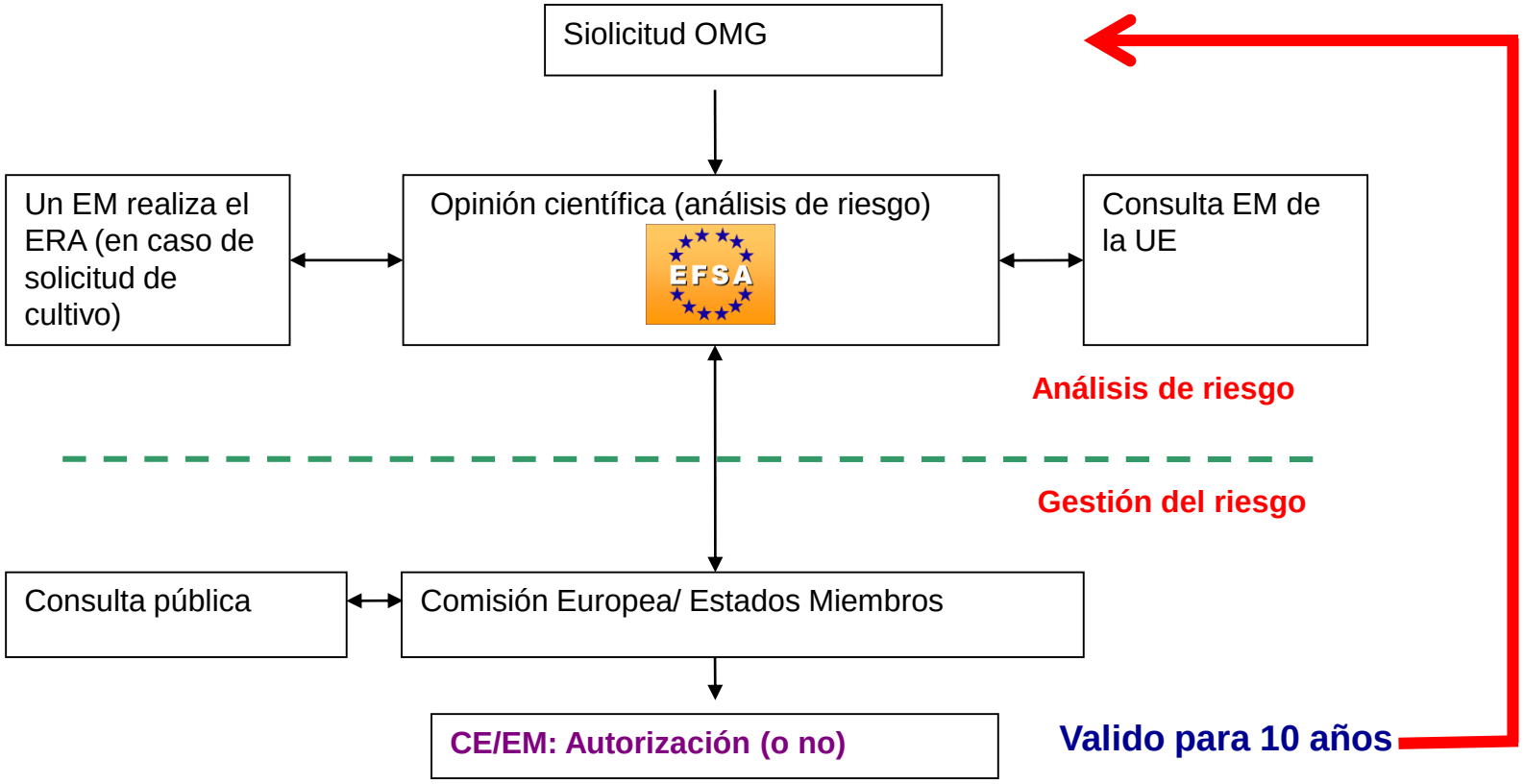
Marco legal para comercialización de OMGs en la UE

- La base del marco legal es un análisis de riesgo obligatorio

- Análisis de riesgo responsabilidad de EFSA, una entidad independiente de asesoría científica

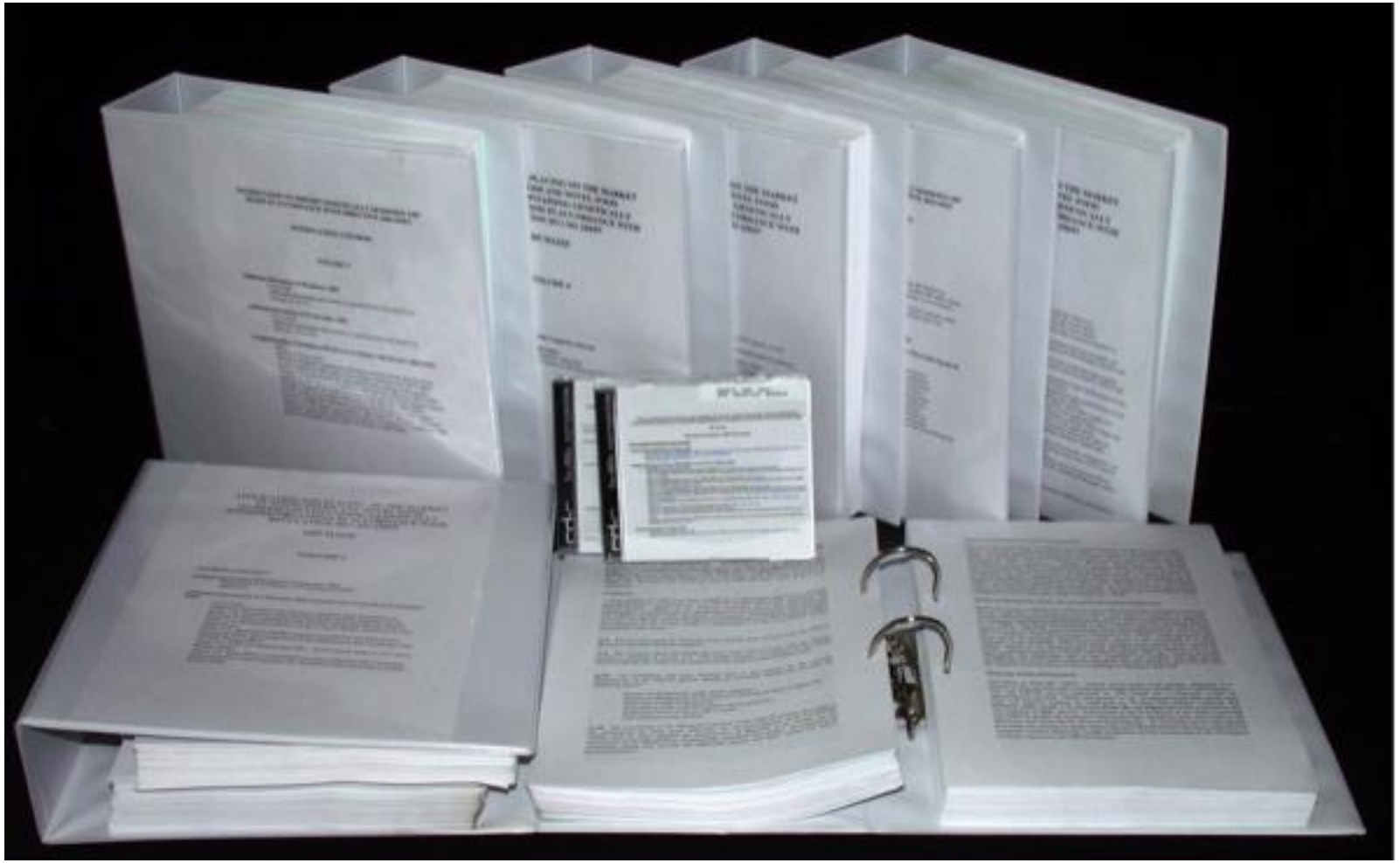
- Análisis caso por caso

Regulación (EC) 1829/2003 - GM food & feed
(Commission implementing regulation (EU) 503/2013)



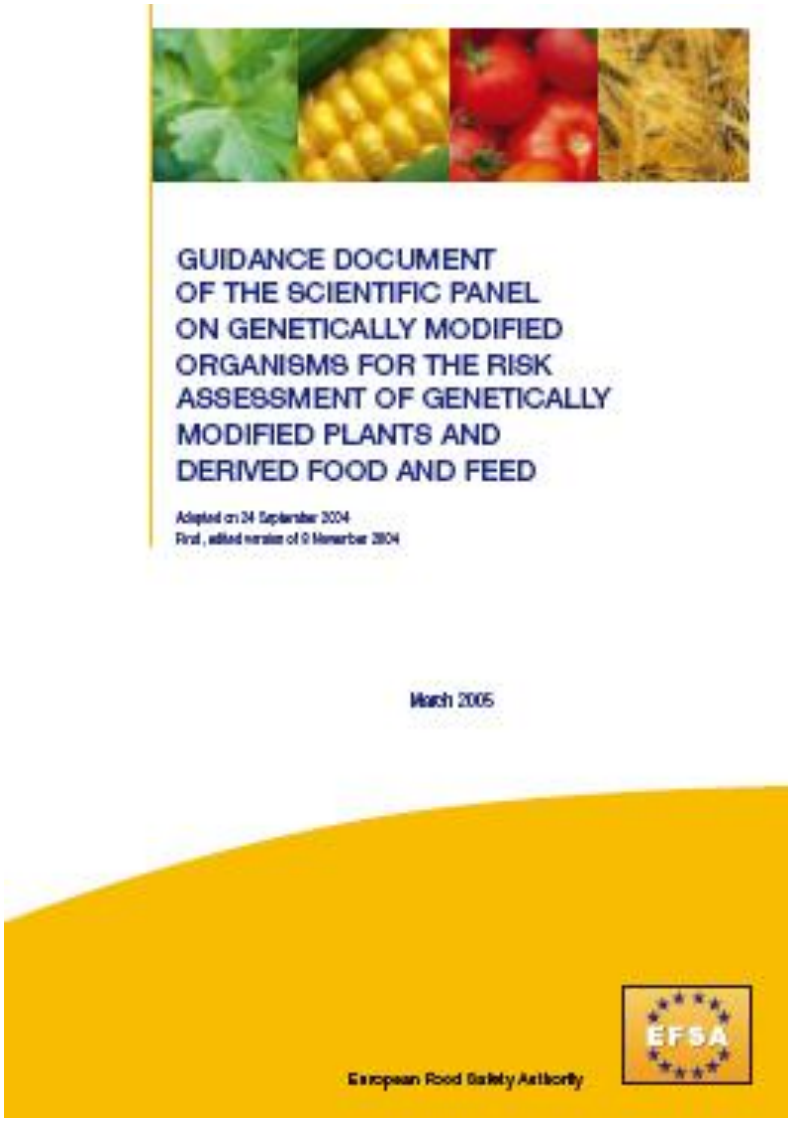
Método de detección para identificar y cuantificar el OMG

El dosier… un ejemplo



Coste aprobación: 5-10 años; € 10 Milllones

Guia de EFSA para el análisis de OGMs



- Adoptado en 2004
- Completado en 2005 (PMEM); 2006 (renovación), 2007 (eventos apilados); 2011…

Documento científico; guía, que se adapta caso por caso; flexible

- 2013 (Commision IR503/2013)

Texto legal (político); requisitos obligados; rígido

Comercialización de OGMs y productos derivados

- Consumo masivo desde hace casi 25 años

- No ha habido problemas relevantes para la salud humana o animal

- Las técnicas de obtención y análisis de OGMs han evolucionado y se han vuelto más precisas (secuencia)

- Y sin embargo la legislación es cada vez más prescriptiva y rígida

Es proporcional al riesgo real? Está adaptada a su propósito?

Edición génica (SDNs)

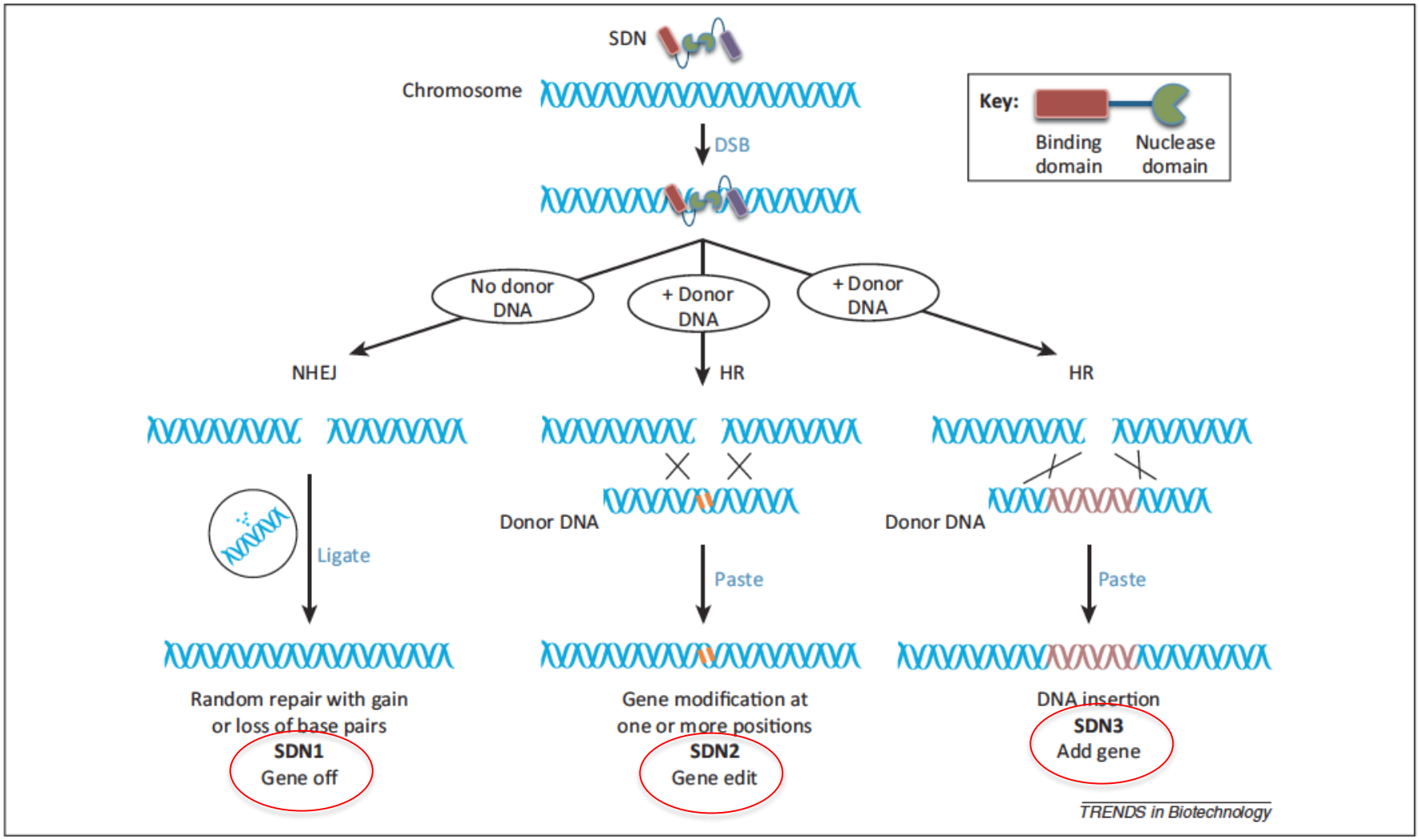


Figure 1. Different site-directed nuclease (SDN) techniques (SDN-1, 2, and 3). An SDN complex is shown at the top in association with the target sequence. The repair can take place via nonhomologous end-joining (NHEJ) or homologous recombination (HR) using the donor DNA. SDN-1 can result in site-specific random mutations by NHEJ. In SDN-2, a homologous donor DNA is used to induce specific nucleotide sequence changes by HR. In SDN-3 DNA is integrated in the plant genome via HR.

Regulación de plantas obtenidas por edición génica

- USA, Argentina, China, Japón, … han decidido desregular SDN1,(2)

- UE

    - Consenso científico en que SDN1/2 no deberían ser consideradas OMG.

    - Discusiones entre los EM de la UE desde 2008. Sin consenso.

    - Preguntas del Conseil d'État Francés al TJUE en 2017.

    - Decisión del TJUE en 2018. Las plantas editadas son OMGs

Published online: September 5, 2018

Opinion

EMBO reports

Proportionate and scientifically sound risk assessment of gene-edited plants

Josep M. Casacuberta & Pere Puigdomènech

An International Jour

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GM CROPS & FOOD
Biotechnology in agriculture and the food chain

Legal limbo

Europe is dragging its feet on gene-editing rules and scientists should push the issue.

Germany is having trouble deciding whether plants that are gene-edited should be regulated as if they were genetically modified (GM). Confused? You're not alone: the issue has split the German government and has left scientists across Europe in limbo.

Plant scientists say that new editing tools, including CRISPR–Cas9, involve no more than making tiny, precisely targeted changes to a gene that are indistinguishable from natural mutations. But opponents say that any form of meddling with genes is potentially perilous.

Germans attach great value to public dialogue. So on 14 February, the Leopoldina, Germany's national science academy, hosted a debate on the issue. Officials from the federal environment ministry and its office for nature protection spoke passionately in favour of ever-

environments. Others will determine whether the gene-edited plants have new traits that make them better crops. European scientists are competing with countries such as the United States, where gene-edited products are not considered equivalent to GM products, at least for now. And earlier this month the European Ombudsman stated that the legal limbo does not mean that gene editing should be put on freeze.

Some EU member states are forging their own way through the muddle. In 2015, Sweden decided that the technical and legal issues in favour of non-regulation were crystal clear and told its plant scientists that they could go ahead. It has promised to reverse its position should the EU decide on regulation.

"CRISPR techno already many g edited that ar for out trials."

Sabres

ANNUAL REVIEWS

Annual Review of Plant Biology

Risk Assessment and Regulation of Plants Modified by Modern Biotechniques: Current Status and Future Challenges

achim Schiemann,[1] Antje Dietz-Pfeilstetter,[1] rank Hartung,[1] Christian Kohl,[1] Jörg Romeis,[2] nd Thorben Sprink[1]

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New GMO regulations future for EU crop biot

John Davison & Klaus Ammann

To cite this article: John Davison & Klaus
Determining a new future for EU crop biote
10.1080/21645698.2017.1289305

EU politicians must trust plant science

The latest ruling by the European Court of Justice requires that crops created using gene-editing techniques such as CRISPR must go through the same lengthy approval process as conventional genetically modified (GM) plants (see *Nature* **560**, 16; 2018). This has surprised many scientists, who are concerned that it will complicate promising

acknowledging that approval of genome-edited plants calls for much less data than classic GM organisms, and by commanding greater respect for the work of scientific panels. This would promote scientifically sound risk analysis while complying with existing directives.

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Posibles salidas

- Reintroducir flexibilidad en el sistema

  . Reducir la información requerida caso por caso

  . Sin método de detección

- Cambiar en la legislación de OMGs

  . Tratar la edición génica aparte

Council of the European Union

Brussels, 24 October 2019
(OR. en)

12781/19

AGRI 479
AGRILEG 167
ENV 825

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	COUNCIL DECISION requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study

(4) The ruling brought legal clarity as to the status of new mutagenesis techniques, but also raised practical questions which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research and beyond. Those questions concern, *inter alia*, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the Union.

(5) The Council considers that a study is necessary to clarify the situation, in accordance with the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1], and in particular paragraph 10 thereof on the application of Article 225 and 241 of the Treaty on the Functioning of the European Union,

Article 1

The Council requests the Commission to submit, by 30 April 2021, a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law.

Article 2

1. The Council requests the Commission to submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study.

2. In accordance with usual practice, the Council requests the Commission to ensure that the proposal is accompanied by an impact assessment.

Opiniones de EFSA sobre la edición génica

- SDN-3. EFSA, 2012, 2020.

Uso de SDN-3 para transgenia minimiza los riesgos asociados a la inserción

- SDN1,2. EFSA, 2020

No hay riesgos asociados a la inserción

No se identifican riesgos adicionales al comparar con las técnicas de mejora clásica

EXECUTIVE SUMMARY

COMMISSION STAFF WORKING DOCUMENT

Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16

SWD(2021) 92

-Las NGTs tienen el potencial de contribuir a la resiliencia y sostenibilidad del sector agrícola

- EFSA no ha identificado nuevos riesgos asociados a estas técnicas

- Los expertos a nivel Europeo y Nacional reclaman más flexibilidad y proporcionalidad en el análisis de riesgo, aunque no todos los actores están de acuerdo en esto

https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_exec-sum_en.pdf

Legislation for plants produced by certain new genomic techniques

In preparation

Roadmap

Feedback period

24 September 2021 - 22 October 2021

FEEDBACK: CLOSED

UPCOMING

Public consultation

Planned for

Second quarter 2022

FEEDBACK: UPCOMING

Commission adoption

Planned for

Second quarter 2023

FEEDBACK: UPCOMING

About this initiative

Summary This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. It is based on the findings of a Commission st on new genomic techniques.

The aim is to maintain a high level of protection for human and animal health and the environr enable innovation in the agri-food system and contribute to the goals of the European Green D and the 'Farm to Fork' strategy.

Topic Food safety

Type of act Proposal for a regulation

Roadmap

FEEDBACK: CLOSED

Feedback period

24 September 2021 - 22 October 2021 (midnight Brussels time)

View feedback received >

Inception impact assessment - Ares(2021)5835503
English (265 KB - PDF - 5 pages)

Download

La nueva legislación tendría que :

- Asegurar un alto nivel de seguridad
- Ser científicamente sólida
- Ser proporcional al riesgo real
- Permitir obtener los beneficios que la ciencia y la técnica prometen
- Flexible para adaptarse a los cambios técnicos y al avance científico