

## Transgenic animals



Consensus documents on the biology of animal species are available for Atlantic Salmon *Salmo salar* (2017) and mosquito *Aedes aegypti* (2018); mosquito *Anopheles gambiae* is under preparation.

## New breeding techniques

New Breeding Techniques (NBTs) is a broad term covering a range of techniques that are different from conventional breeding methods. Genome editing, one of them, is developing fast and receives increased attention.

Since 2013, both WPs have engaged in information-sharing regarding major developments related to NBTs, views on risk/safety assessment of NBT products and related regulatory issues.

### Key events:

- Workshop on Environmental Risk Assessment of Products derived from NPBTs (2014)
- Workshop on High-Throughput DNA Sequencing in the Safety Assessment of GE Plants (2016)
- Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation (2018)

More on OECD work on NBTs at:

[www.oecd.org/environment/genome-editing-agriculture/](http://www.oecd.org/environment/genome-editing-agriculture/)

## OECD PROGRAMMES ON RISK/SAFETY ASSESSMENT OF BIOTECHNOLOGY PRODUCTS

1. **The Working Party on the Harmonisation of Regulatory Oversight in Biotechnology** deals with the environmental safety of transgenic organisms (biosafety);
2. **The Working Party for the Safety of Novel Foods and Feeds** focuses on foods or feeds derived from transgenic organisms.

Purpose of the two programmes:

- i) to assist countries evaluating the potential risks of transgenic products (plants, animals, micro-organisms) and ensure high safety
- ii) to foster communication and mutual understanding of relevant regulations in countries
- iii) to facilitate harmonisation in risk/safety assessment of biotech products, reducing costs and potential for non-tariff barriers to trade

## Participants

- OECD member countries
- Non-member economies: Argentina, Brazil, P.R. China, Costa Rica, India, Kenya, Paraguay, Philippines, Russian Federation, Uruguay, South Africa, Viet Nam, others
- International Organisations: FAO, WHO, UNEP Convention on Biological Diversity, Codex Alimentarius, others
- Observers: Business at OECD (BIAC), African Biosafety Network of Expertise (AUDA NEPAD-ABNE), others

## OECD and Risk/Safety Assessment in Modern Biotechnology

### Food, Feed and Environmental Safety



The safety of products derived from modern biotechnology is a challenging issue as genetically-engineered crops are widely cultivated, and foods and feeds derived from them are marketed.

Modern biotechnology is applied to crop plants, animals and micro-organisms, aiming to develop varieties with new characteristics such as improved resistance, enhanced composition, adaptation to growing environment, processing aspects and other traits.

Modern biotechnology products are rigorously assessed by governments to ensure high safety standards for environment, human food and animal feed. Such assessments are essential for a healthy and sustainable agriculture, industry and trade.



All publications available on:  
[www.oecd.org/biotrack](http://www.oecd.org/biotrack)

## OECD “CONSENSUS DOCUMENTS”

The OECD Consensus Documents are useful to applicants for commercial uses of transgenic organisms, to national regulators and risk assessors, as well as the wider scientific community.

ORGANISMS	ENVIRONMENTAL SAFETY “Biology of...”	FOOD/FEED SAFETY “Composition of...”
<b>CROP PLANTS</b>		
Alfalfa	–	No.13 (2005)
Barley	–	No.12 (2004)
Cassava	No.57 (2014)	No.18 (2009)
Common Bean	No.59 (2015)	No.27 (2015)
Cotton	No.45 (2008)	No.11 (2009)
Cowpea	No.60 (2015)	No.30 (2018)
Grain Sorghum	No.62 (2016)	No.19 (2010)
Maize	No.27 (2003)	No.6 (2002) <i>under revis.</i>
Oilseed Rape <i>incl.</i> Canola	No.54 (2012)	No.24 (2011) - Canola
Peppers	No.36 (2006)	–
Potato	No.8 (1997)	No.33 (2020)
Pumpkins	No.53 (2012)	–
Rice	No.14 (1999) <i>under rev.</i>	No.28 (2016)
Safflower	No.68 (2020)	–
Soybean	No.15 (2000)	No.25 (2012)
Sugar Beet	No.18 (2001)	No.3 (2002)
Sugarcane	No.56 (2013)	No.23 (2011)
Sunflower	No.31 (2004)	No.16 (2007)
Sweet Potato	–	No.20 (2010)
Tomato	No.63 (2016)	No.17 (2008)
Wheat	No.9 (1999) <i>under rev.</i>	No.7 (2003)
<b>FRUITS</b>		
Apple	No. 66 (2019)	No.31 (2019)
Bananas	No.48 (2009)	–
Papaya	No.33 (2005)	No.21 (2010)
Stone Fruits	No.24 (2002)	–
<b>MUSHROOMS</b>		
Cultivated Mushroom	–	No.15 (2007)
Oyster Mushroom	No.34 (2005)	No.26 (2013)
<b>TREES</b>		
12 temperate climate species <i>incl.</i> White birch, Douglas-fir, Larches, Pines, Poplars, Spruces	Nos. 12, 13, 16, 21, 22, 28, 38, 40, 41, 43, 44, 49 (1999 to 2010)	n.a.
Eucalyptus	No.58 (2014)	

(February 2021)

## ABOUT THE OECD “CONSENSUS DOCUMENTS”

These practical tools compile science-based information relevant to risk/safety assessment of transgenic varieties intended for release in the environment. In addition, key composition elements (e.g. nutrients, toxicants) are used to compare novel foods/feeds with conventional ones. After consensus is reached among countries, the documents are published in two Series: Environmental safety, and Novel Food/Feed safety.

### Environmental safety



**Biology of plant species:** see table

**Traits:** Virus resistance; herbicide tolerance; insect pest control

**Microorganisms:** *Pseudomonas*; *Acidithiobacillus*; *Baculoviruses*; *Acinobacter*; Bacteria: taxonomy, detection methods, horizontal gene transfer, pathogenicity factors

**In progress:** Environmental Considerations for risk/safety assessment of plants; Biology of mosquito *Anopheles gambiae*, Micro-algae, updated Rice and Wheat biology, others

### Food and feed safety



**Composition of plant species:** see table

**Others:** Safety assessment of animal feedstuffs derived from transgenic plants

**In progress:** updated Maize composition, others

### Further reading:

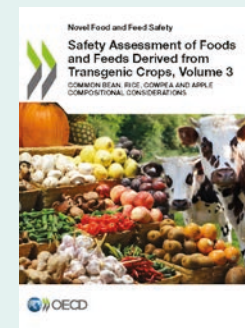
- Revised Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2020)
- Molecular Characterisation of Transgenic Plants
- Low Level Presence of Transgenic Plants in Seeds & Grains



### Compendium of Consensus Documents - Environmental Safety, Volumes 1 to 8

Volumes 1 to 8 compile the biology and other relevant consensus documents issued from 1996 to 2018.

Volume 9 will cover the 2019-2021 period (in preparation)



### Compendium of Consensus Documents - Novel Food and Feed Safety, Volumes 1 to 3

Volumes 1 to 3 contain the composition and other relevant consensus documents issued from 2002 to 2019.

Volume 4 will cover the 2020-2022 period (in preparation)

## PRODUCT DATABASE

The OECD BioTrack Product Database allows regulatory officials to easily share information on products from modern biotechnology. These products have been already approved, after risk/safety assessment, for commercial application (environmental release, food, feed or other use) in at least one country.

All consensus documents and the BioTrack Product Database are available, at no charge, at: [www.oecd.org/biotrack](http://www.oecd.org/biotrack)