NGTs and agriculture:

Sustainable?

Between high flying expectations and complex risks:

Why technology assessment is needed

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1. What is technology assessment (TA)?

2. Transgenic plants: Why TA would have been needed

3. NGTs: The crucial role of TA

4. Conclusions and solutions

Two pillars of EU GMO regulation and the premises of the precautionary principle

Risk assessment (EFSA): specific ‘events’ and their intended and unintended genetic changes, direct and indirect effects, immediate, delayed and long-term accumulative.

Risk management (political decision making): Authorisation and monitoring, criteria on sustainability, ethics and socio-economics, technology assessment.

Risk assessment and risk management both have to follow the **precautionary prinicple**. They are supposed to act as a ‘radar’ on ‘things that can go wrong’.

TA covers a wide range of issues

"New technologies can have a range of effects, potentially both positive and disruptive, that TAs can explore. GAO has broadly defined TA as the thorough and balanced analysis of significant primary, secondary, indirect, and delayed interactions of a technological innovation with society, the environment, and the economy and the present and foreseen consequences and effects of those interactions."

(US Accountability Office, GAO, 2021)

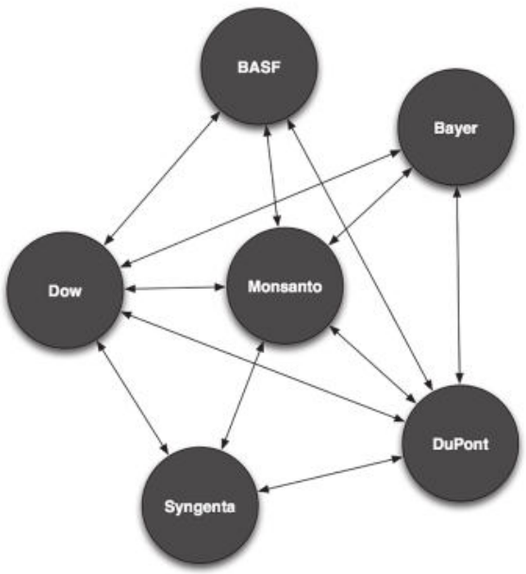
Different levels of TA

Prospective TA:
The overall impact of a technology before it enters the market.

TA of specific applications:
Checking the potentials and disadvantages in regard to intended purposes (like sustainability).

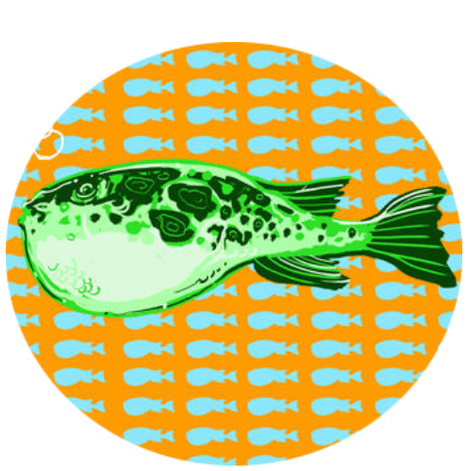
What experience do we have from transgenic plants?

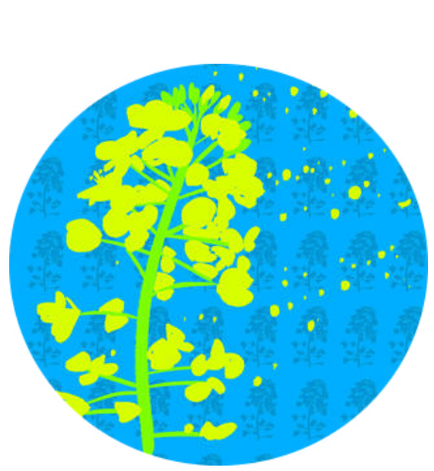
The introduction of transgenic plants into agriculture around 30 years ago was accompanied by many promises of benefits and high expectations, most of which have either not or only partially been realised. At the same time, there have been hardly any systematic or independent studies to objectively assess the actual impact of the transgenic plants on agriculture.

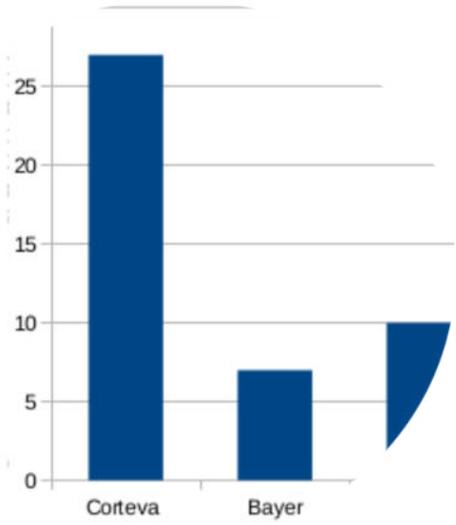


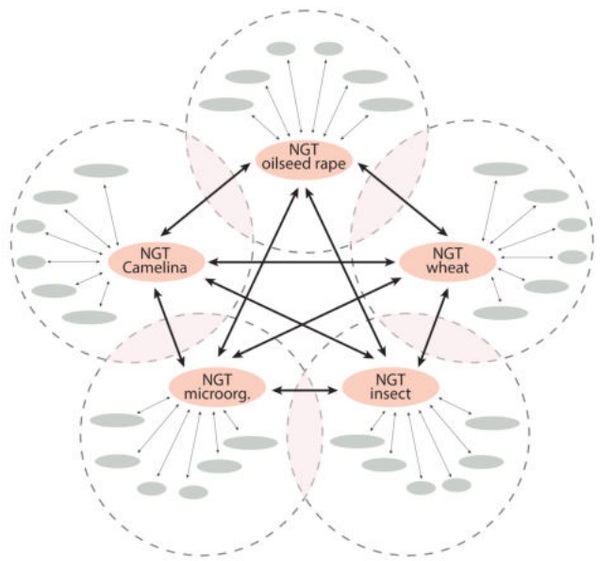
What reasoned concerns and expectations do we have on sustainability of NGTs?

While NGTs have a great potential for genetic changes, it is not easy to translate this potential into actual benefits.









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Claimed benefits of transgenic plants

OPEN ACCESS Freely available online

PLOS | ONE

A Meta-Analysis of the Impacts of Genetically Modified Crops

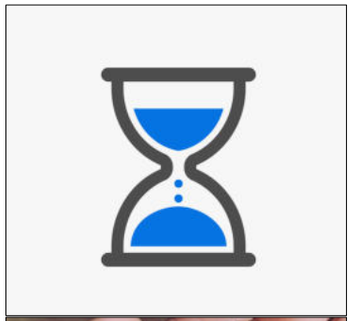
Wilhelm Klümper, Matin Qaim*

November 2014 | Volume 9 | Issue 11 | e111629

The study is purportedly showing, that cultivation of genetically engineered (GE) crops has:

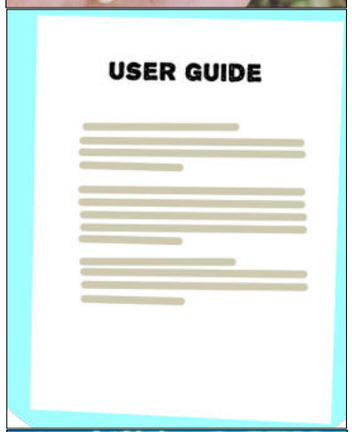
- reduced the use of pesticides worldwide by 37 %
- increased crop yields by 22 %
- increased farmers' profits by 68 %
- effects can be observed in all countries growing transgenic plants

What are the criteria?



How long have the plants already been cultivated?

Which seeds were used?



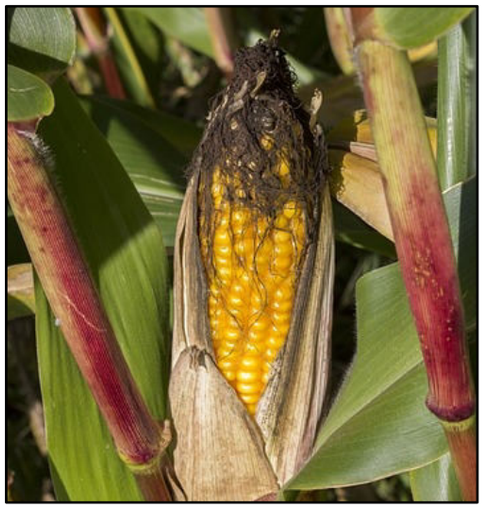
What management systems were available?

In which markets higher sales revenues were achieved?

⇛ **Criteria and methods for assessing the systemic impact of transgenic plants are largely lacking.**

How to compare contradicting findings?

The spread of glyphosate-resistant weeds in the US has increased costs for maize and soybean cultivation by 50-100 %. (Benbrook, 2012)

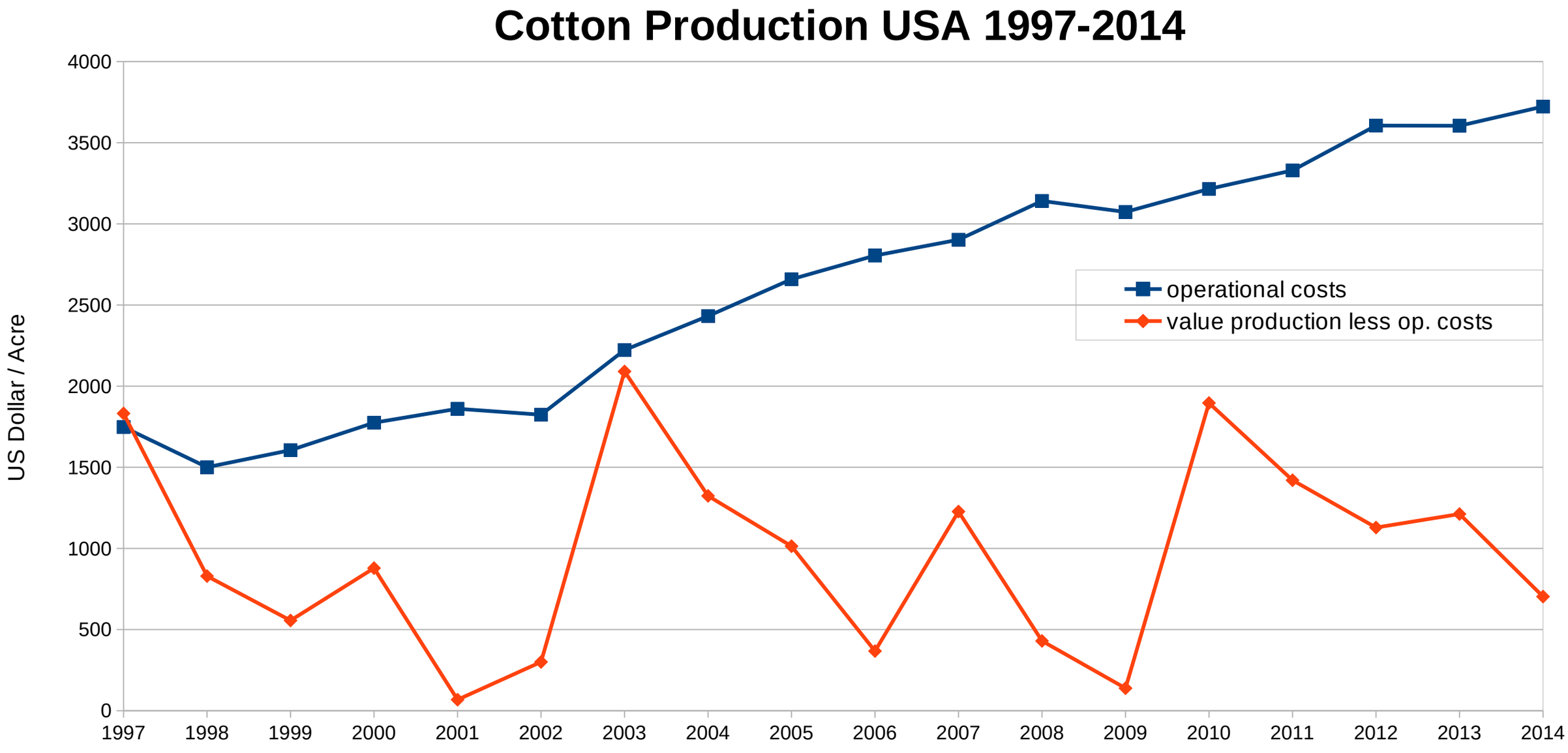


As a result of dramatically rising costs, cotton production in several US states declined by 60-70 %. (Service, 2013)

Similarly differentiated reports on lower yields, rising costs and lower returns are also available for Bt-cotton in China, India and South Africa, as well as for other transgenic crops at the global level.

Which data are relevant and reliable?

“The study reveals robust evidence of GE crop benefits for farmers in developed and developing countries.”(Klümper & Qaim, 2014)



www.ers.usda.gov

Development of herbicide-resistant weeds

"Although it cannot be stated that evolution of resistance to glyphosate will not occur, the ***development of weed resistance to glyphosate is expected to be a very rare event.****"*

(application for glyphosate-resistant Maize NK603 from 2000)

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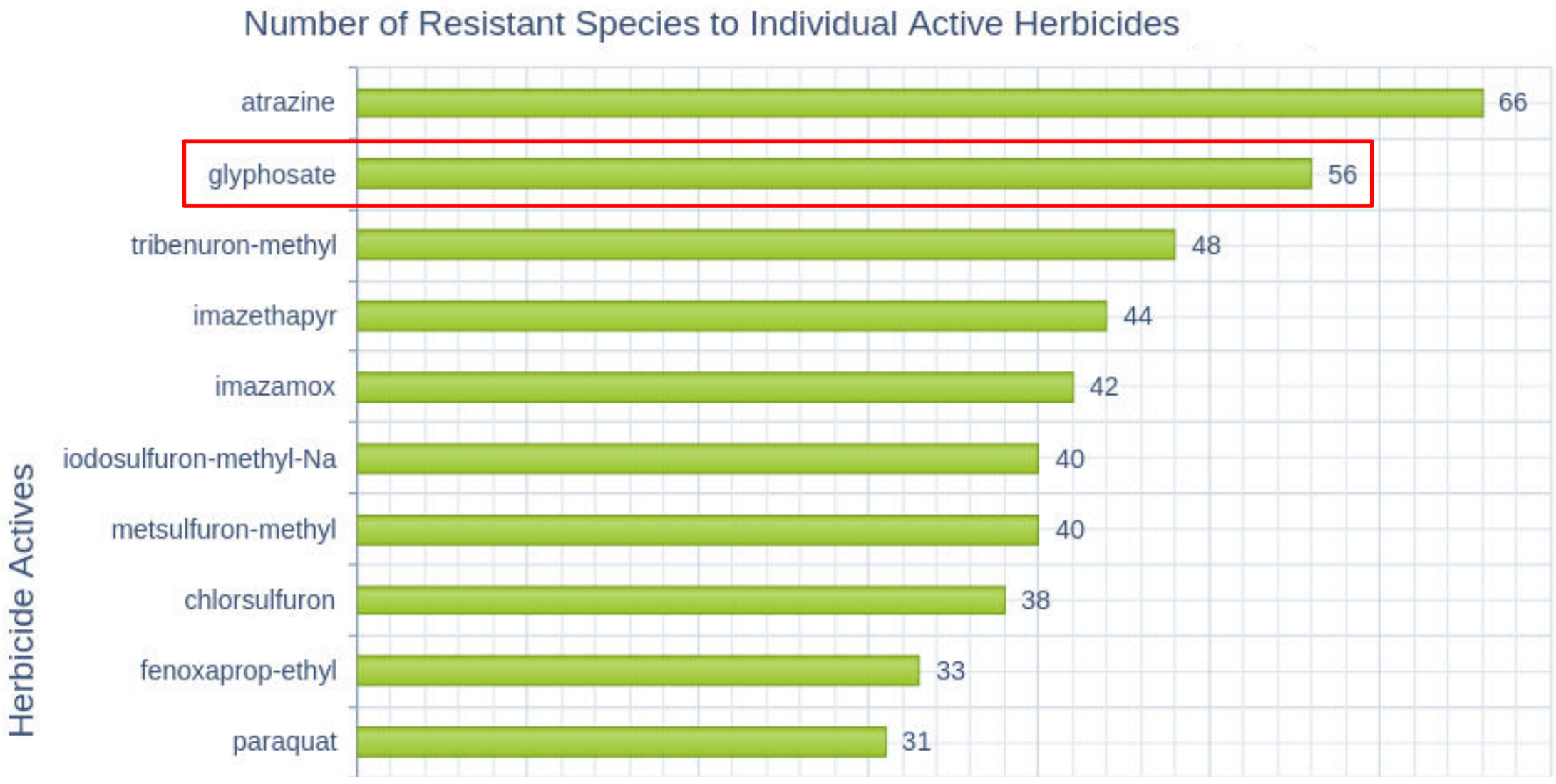
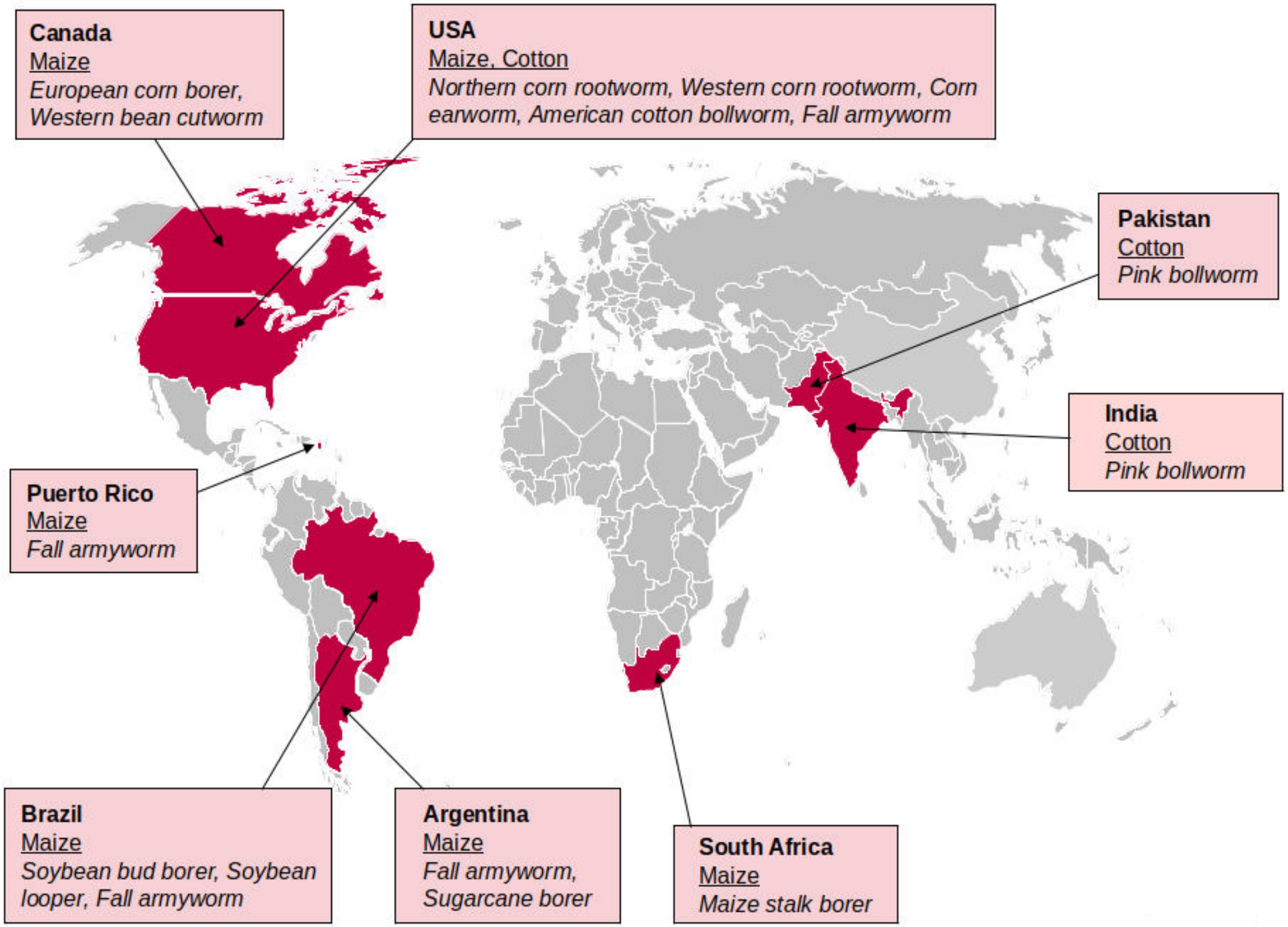
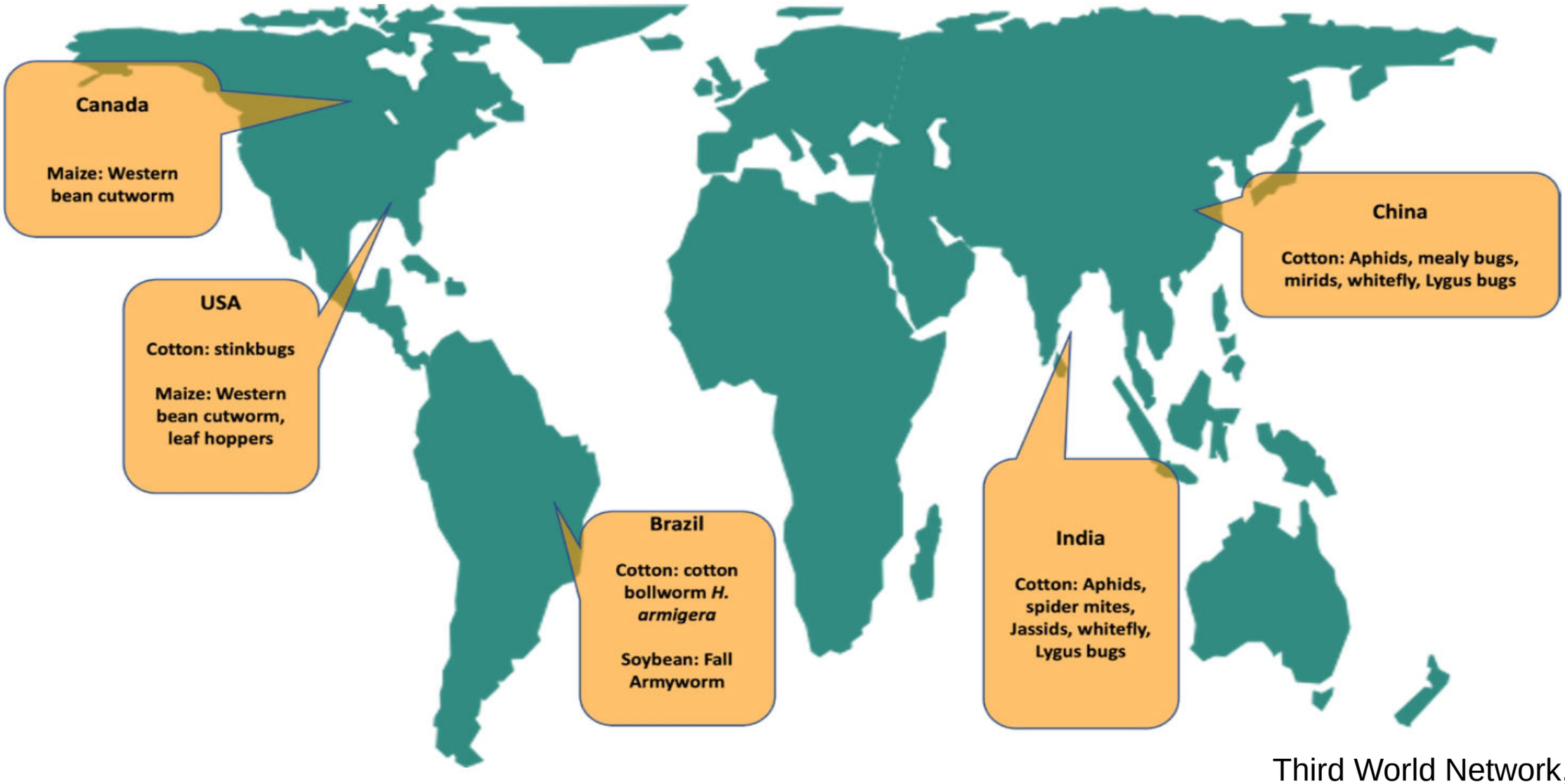


Increasing number of Bt-toxin resistant pest insects



according to Tabashnik et al., 2023

Increasing number of secondary pest infestations

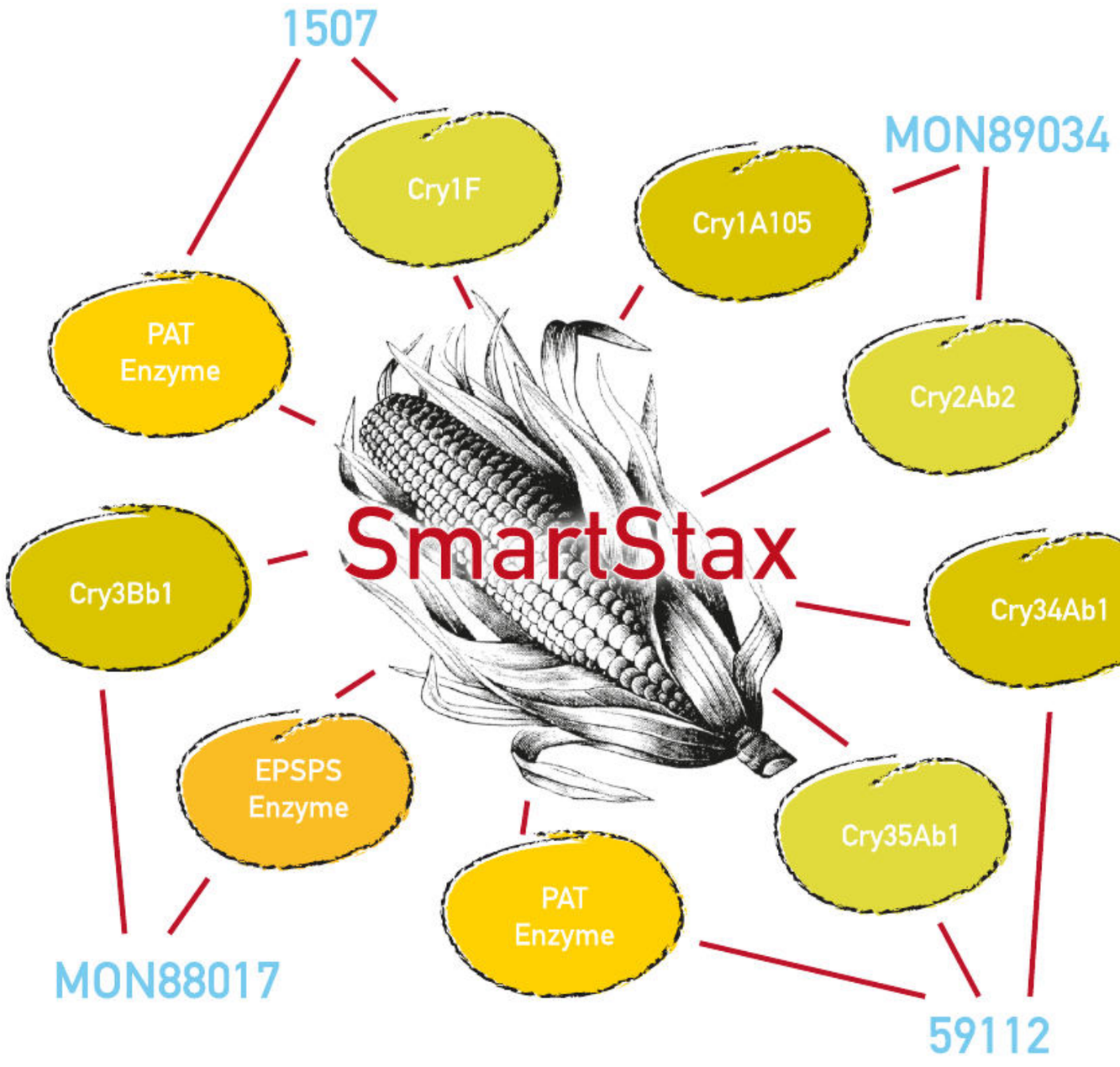


Third World Network, 2022

Transgenic plants are still susceptible to non-target pest insects

⇨ increased use of synthetic pesticides/costs for farmers

‘Arms race’ in the field

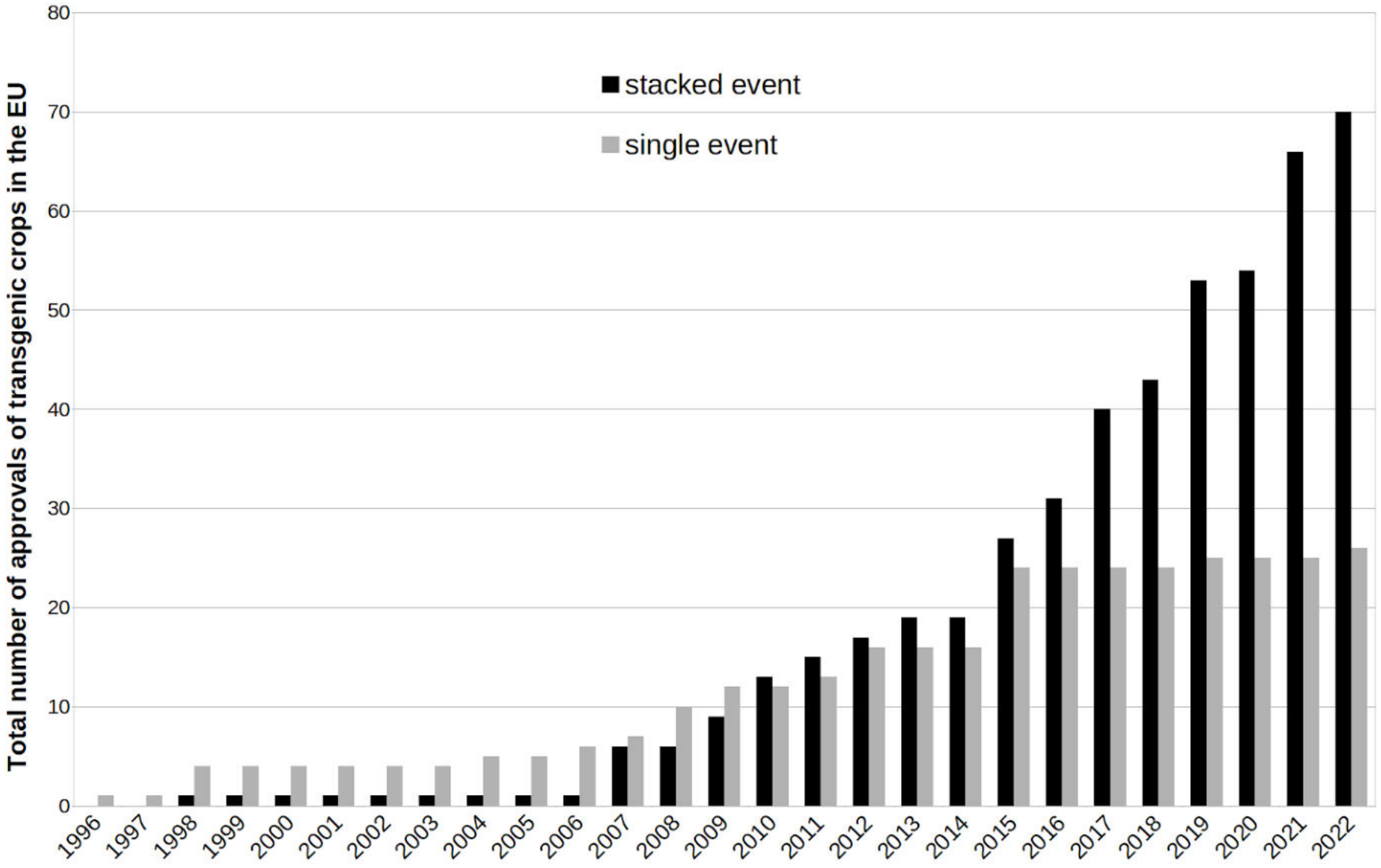


<u>SmartStax maize (Monsanto/Dow)</u>

- combination of four GE-events
- six different Bt-toxins
- resistant against two herbicides

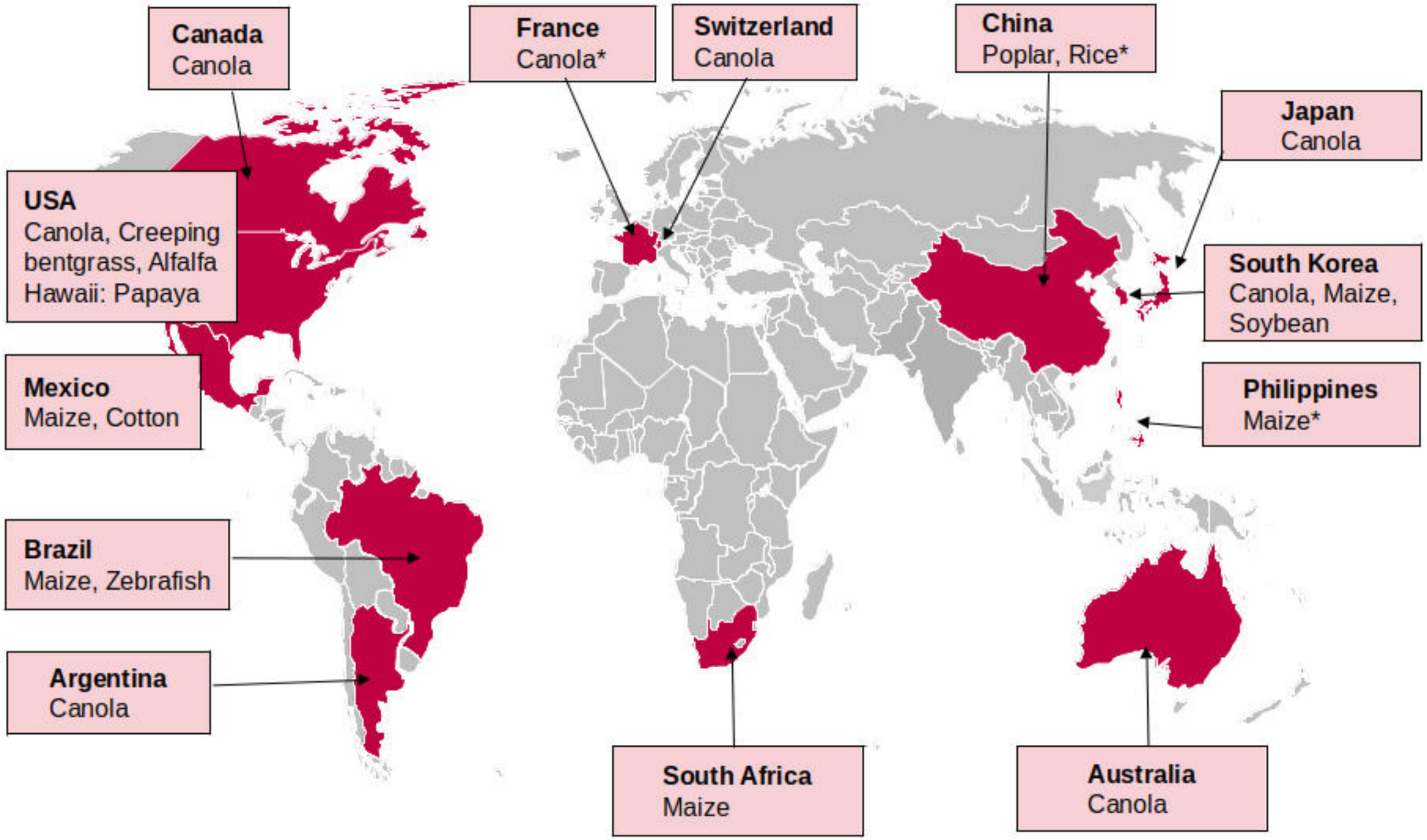
⇨ By stacking the intended traits, the risks and uncertainties of the parental plants are also combined.

Uncertainties regarding safety of imported crops



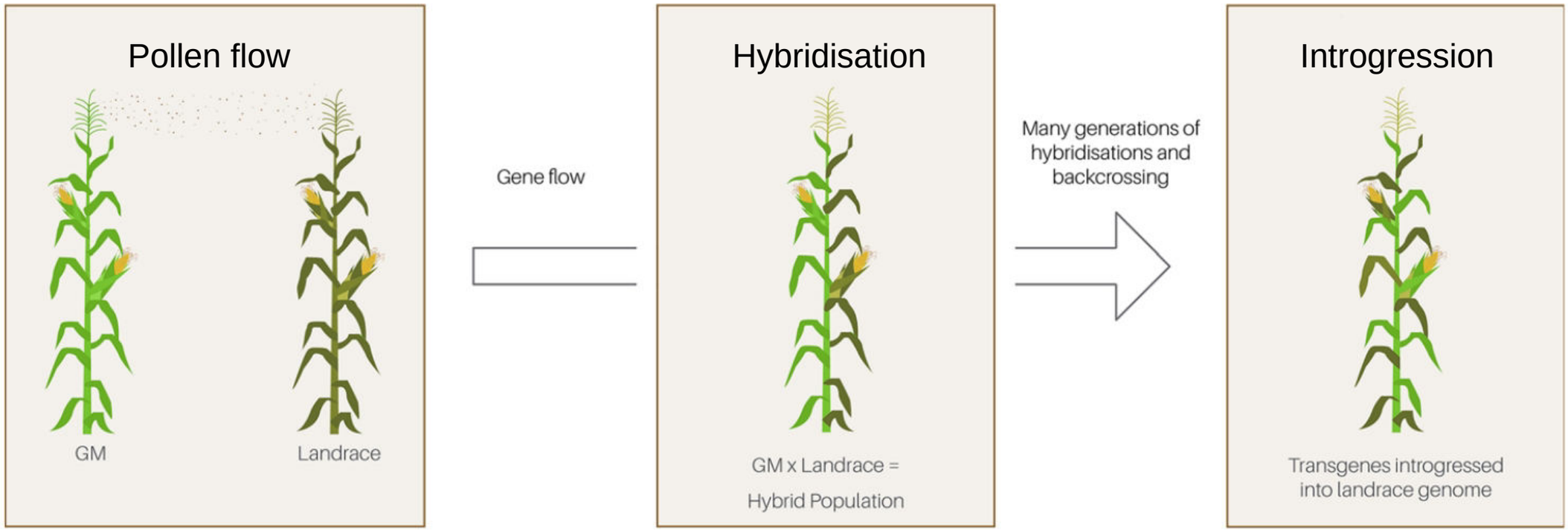
- Contamination with a cocktail of insecticides and herbicides
- Possible health effects can exceed the sum of the individual substances
- Consumption can change the composition of the microbiome (Glyphosate)
- Cocktail-effects have hardly been taken into account in risk assessment

Uncontrolled spread of approved transgenic organisms



January 2023
* not yet scientifically investigated

Contamination as an economic factor



Agapito-Tenfen & Wickson, 2018

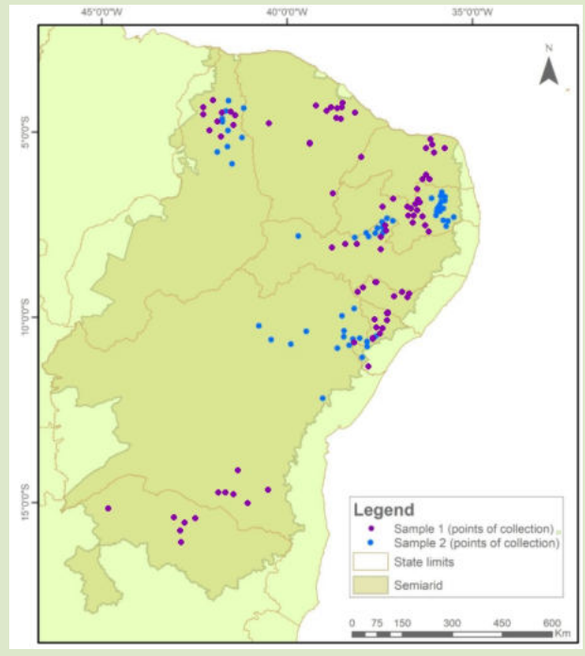
Canada:

„Since its introduction into the environment of Western Canada, GM canola has widely proliferated and has been found growing an land on which it was never intended to be grown.“

Hoffman/Beaudoin vs. Monsanto/Aventis CropScience, 2002

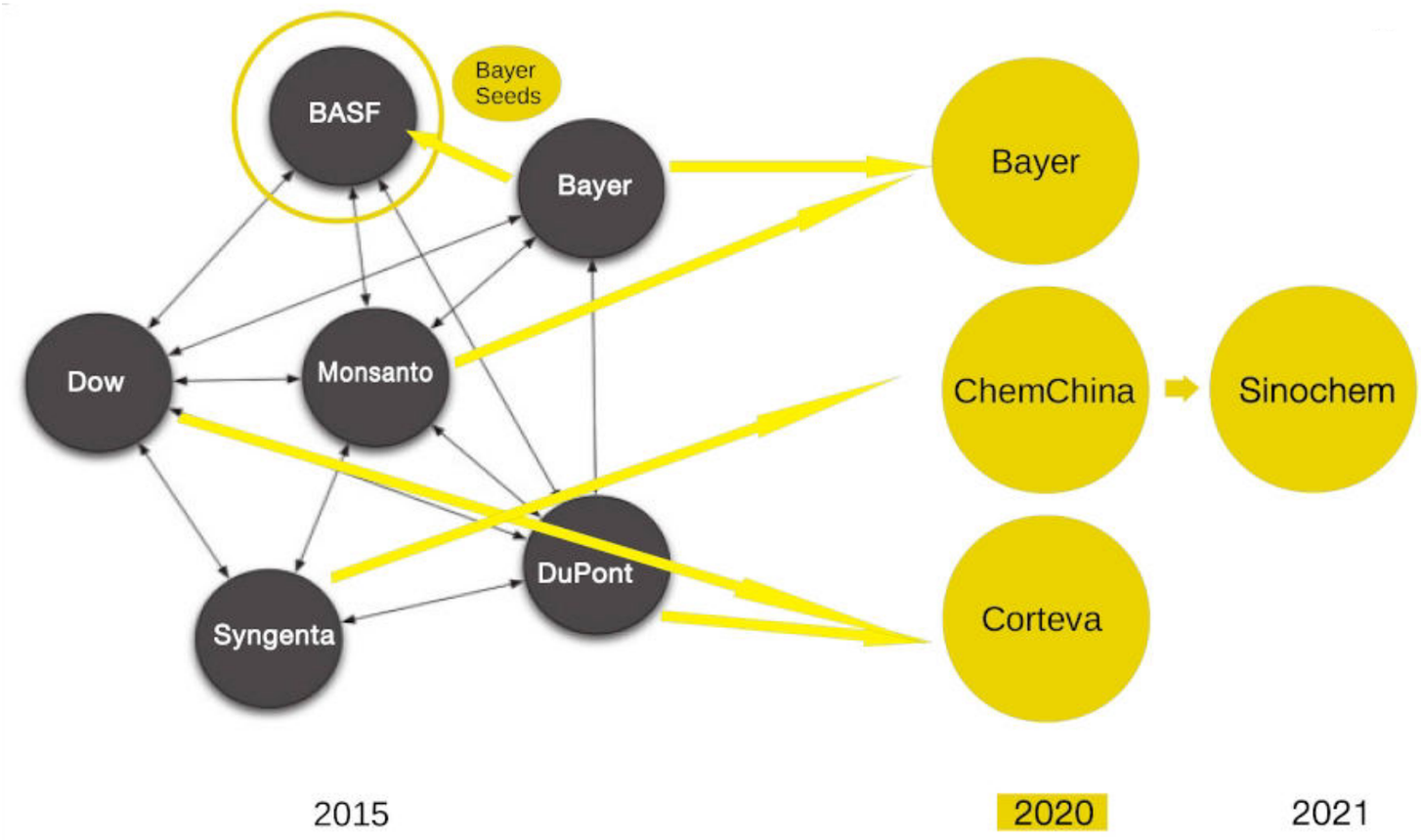
Brazil:

large-scale transgenic contamination (~1/3) of traditional maize varieties

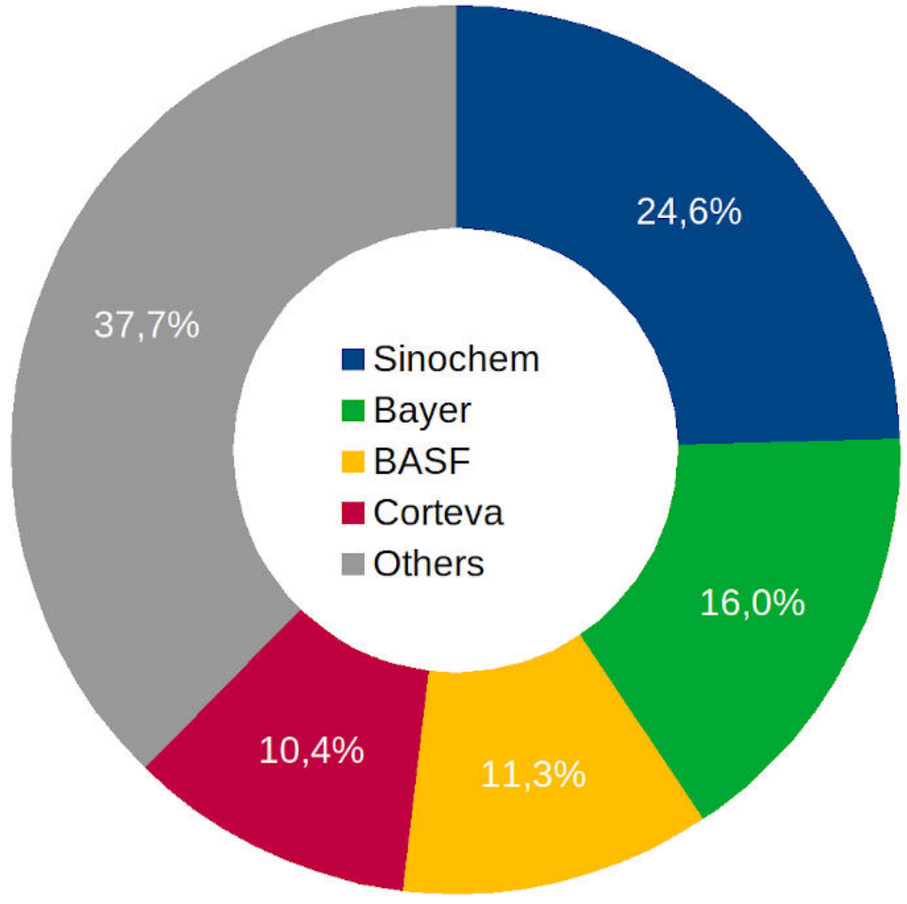


Fernandes et al., 2022

Seed market concentration



corporate concentration in the seed market



share of the world's top-4 agrochemical companies in global agrochemical sales in 2020

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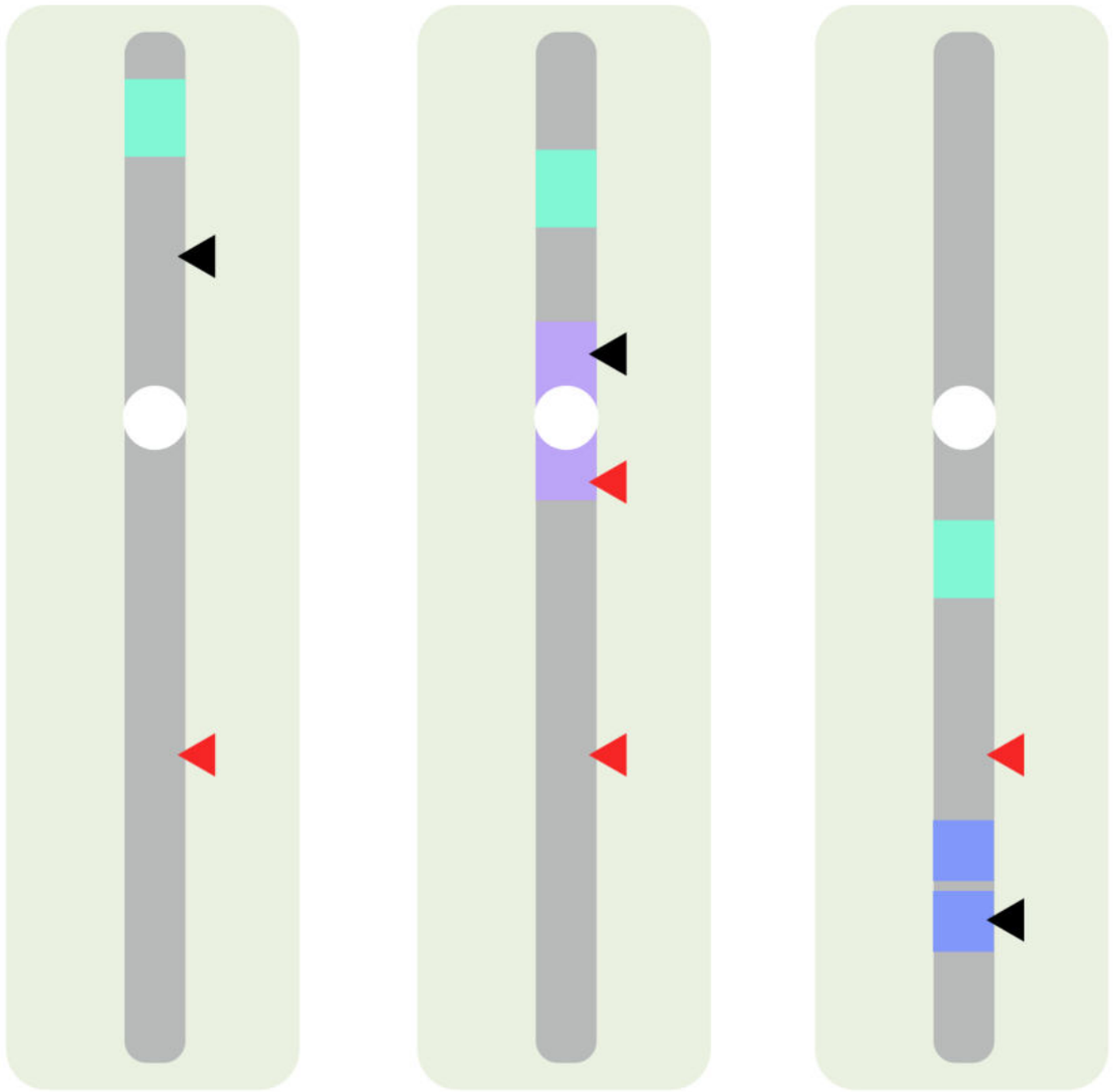
What is new about NGTs?

NGTs go along with a high technical potential to achieve genetic changes that can not be expected from conventional breeding (random mutagenesis). The differences between NGTs and conventional breeding are crucial for RA and TA.

NGT processes go along with specific risks that can not be denied. Therefore, we have to avoid misleading assumptions such as: “*After all, potential risks can only emanate from the modified traits of the organism as a product of the breeding process, and not from the process itself.*” (Leopoldina 2019)

The differences between conventional breeding and new genomic techniques (NGTs) can be easily overlooked, but may have severe consequences.



— examples of NGT applications in plants —

The applications of NGTs go along with intended and unintended genetic changes that are unlikely to occur from conventional breeding. The site of the genetic alteration, the resulting gene combination (genotype) and the biological characteristics of the organisms can be highly specific for NGTs, do not have a history of safe use and need to undergo risk assessment.

DNA of gene scissor is randomly integrated

mechanisms of cells to maintain and restore gene function can be overcome (e.g. protected DNA areas)

coupled genes can be divided

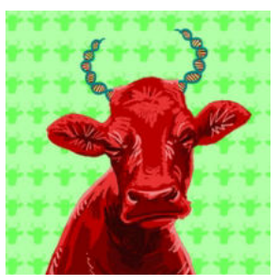
wanted mutation

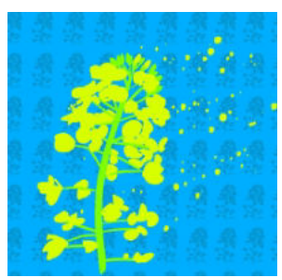
unwanted off-target mutation

Unintended effects if overlooked may become a major problem for future breeding

The example of **hornless cattle:** Only after some years scientists found **DNA of genetically engineered bacteria** had been introduced into the genome of the cattle unintentionally and inherited by its progeny. They identified DNA-sequences that are able to confer **resistance to antibiotics**. (Norris et al., 2020)

Without adequate risk assessment, the unintended genetic changes may remain undetected in the genome, and thus **spread and accumulate rapidly and widely into populations**.





https://www.testbiotech.org/en/limits-to-biotech

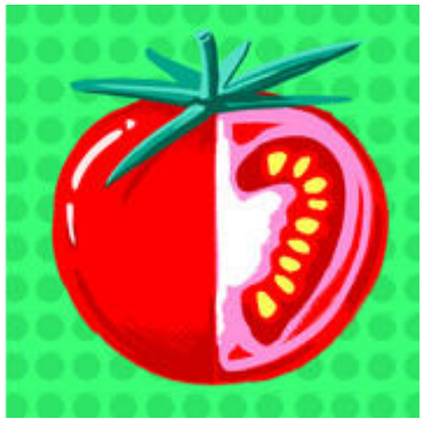
How promising are extreme traits?

NGTs, e.g. CRISPR/Cas, have a huge potential to alter the genome but this potential does not easily translate into real benefits.

The ‘depth of intervention’, in many cases, leads to ‘trade-off’ reactions (metabolic side effects). Such unintended effects can still emerge even in cases where the genetic intervention is targeted and precise.

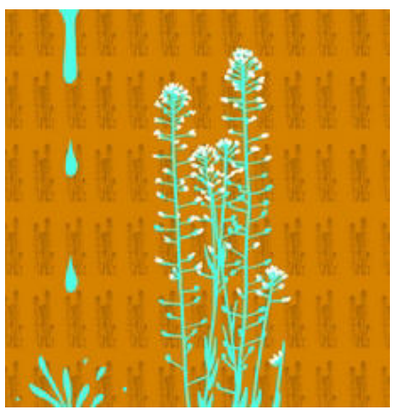
Traits & ‚trade-offs‘

GABA tomato: changed reactions to environmental stress are likely



Sea bream: vertebrate disorder

Acrylamid wheat: reduced germination and growth



Agrofuel camelina: changed reaction to plant pathogens are likely

www.testbiotech.org/en/limits-to-biotech

The scale of releases

Similarly to environmental pollution with plastics and chemicals, it is not always an individual NGT organism which may create the real problems, but rather the sum of diverse effects on the environment.

The concepts of nature conservation and environmental protection are largely based on the principle of avoiding interventions. These principles must also be applied in the field of genetic engineering.

Wide range of species, various traits, fast pace

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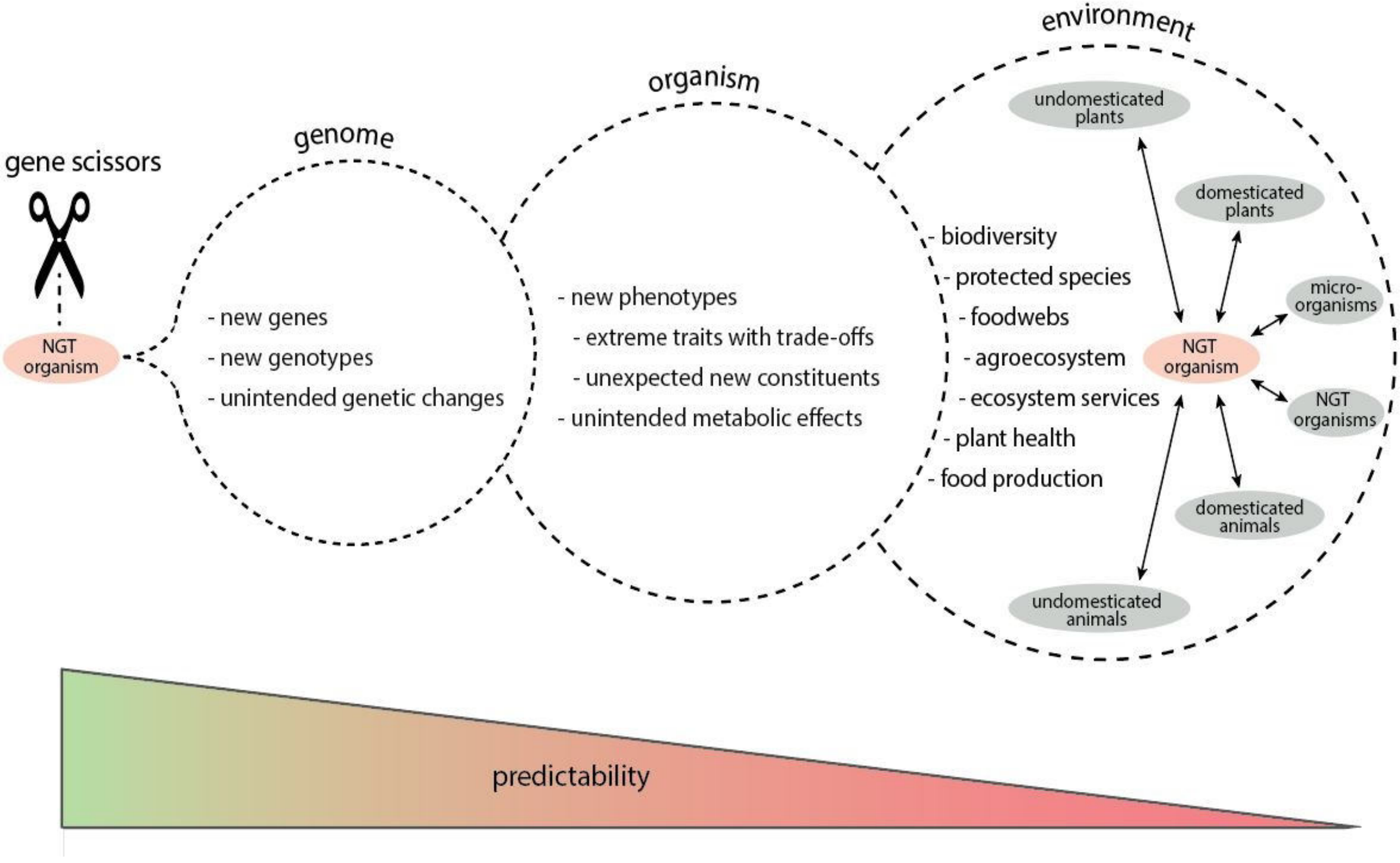
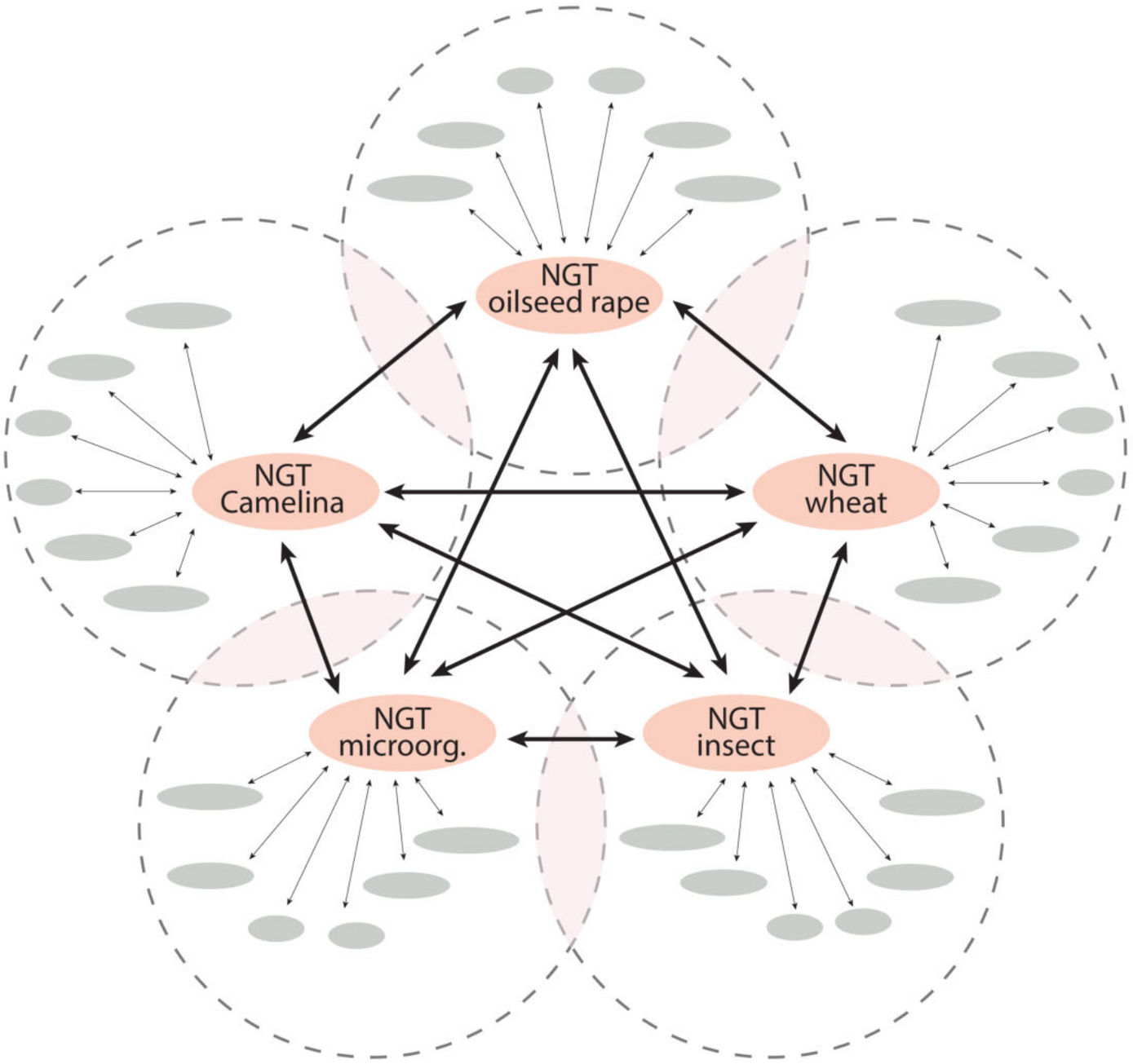


https://fachstelle-gentechnik-umwelt.de/en/home/

How to assess potential tipping points?

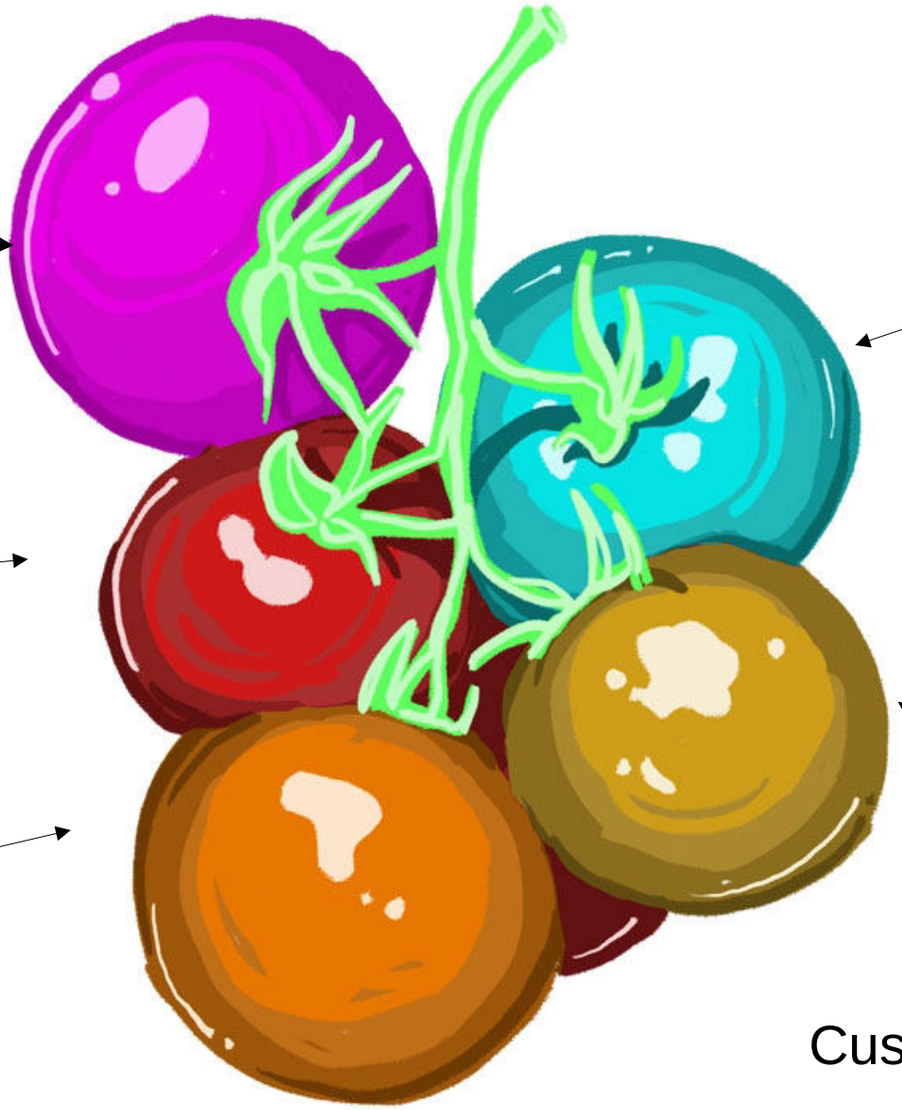


https://fachstelle-gentechnik-umwelt.de/en/home/

How to assess safety of mixed diets?

high concentration of GABA

high concentration of vitamin D



de novo
domesticated

easy to pick

Customized for urban gardening

https://www.testbiotech.org/en/node/3040

Disruptive effects on food and seed production

Take it onto the radar: If there is a large-scale introduction of NGTs into agriculture, this will not only affect the characteristics of distinct crops and livestock, but will also have extensive impacts on food production systems as a whole.

Disruptive negative effects on food production

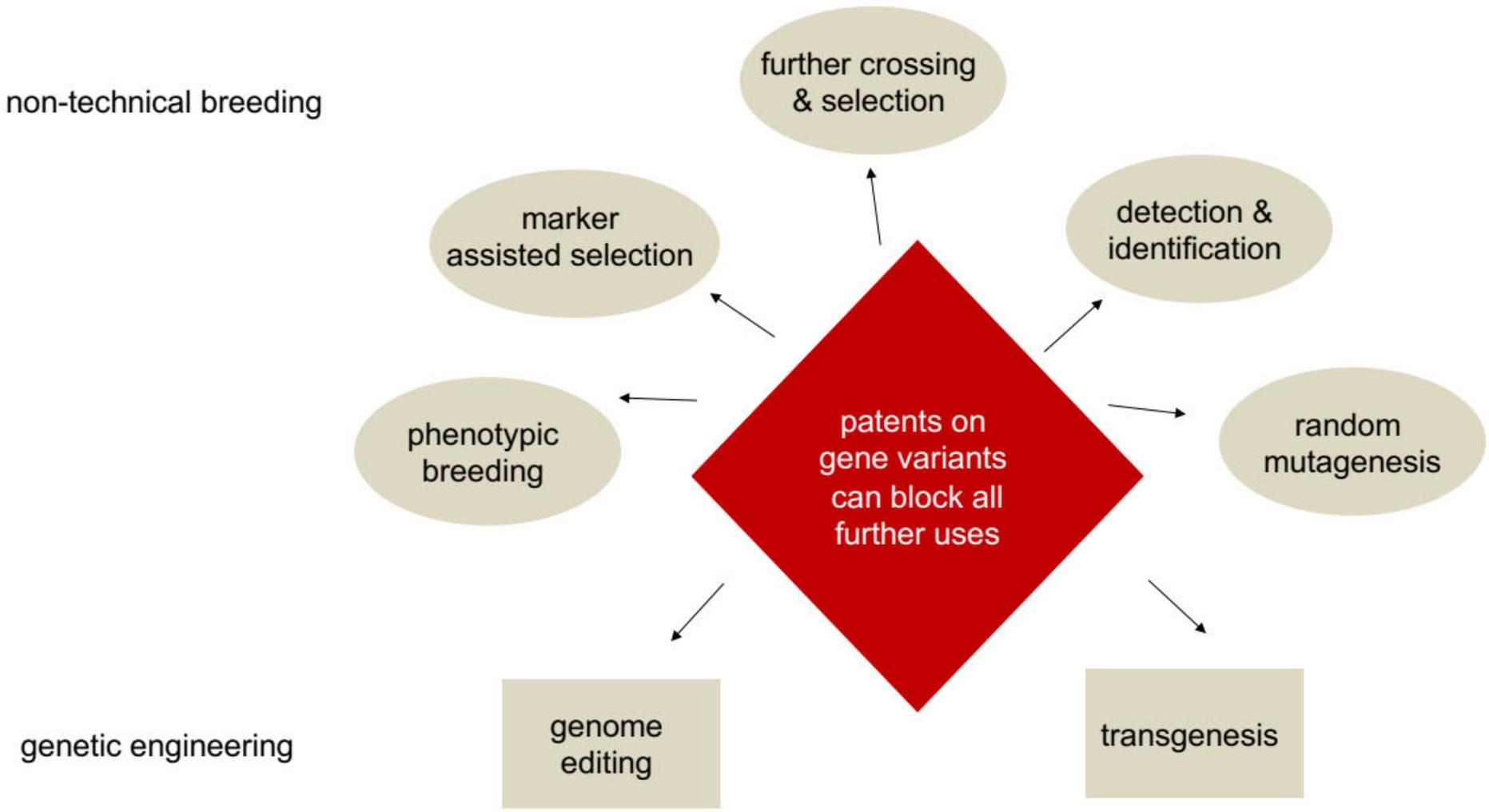
Disruptive negative effects of NGTs may occur on several levels.

For example, disruptive effects may impact the use of pesticides and fertilizers, which may not be reduced but (at least in some cases) significantly increased.

NGTs may also become disruptive in another sense if coexistence, labeling and traceability are weakened or fragmented.

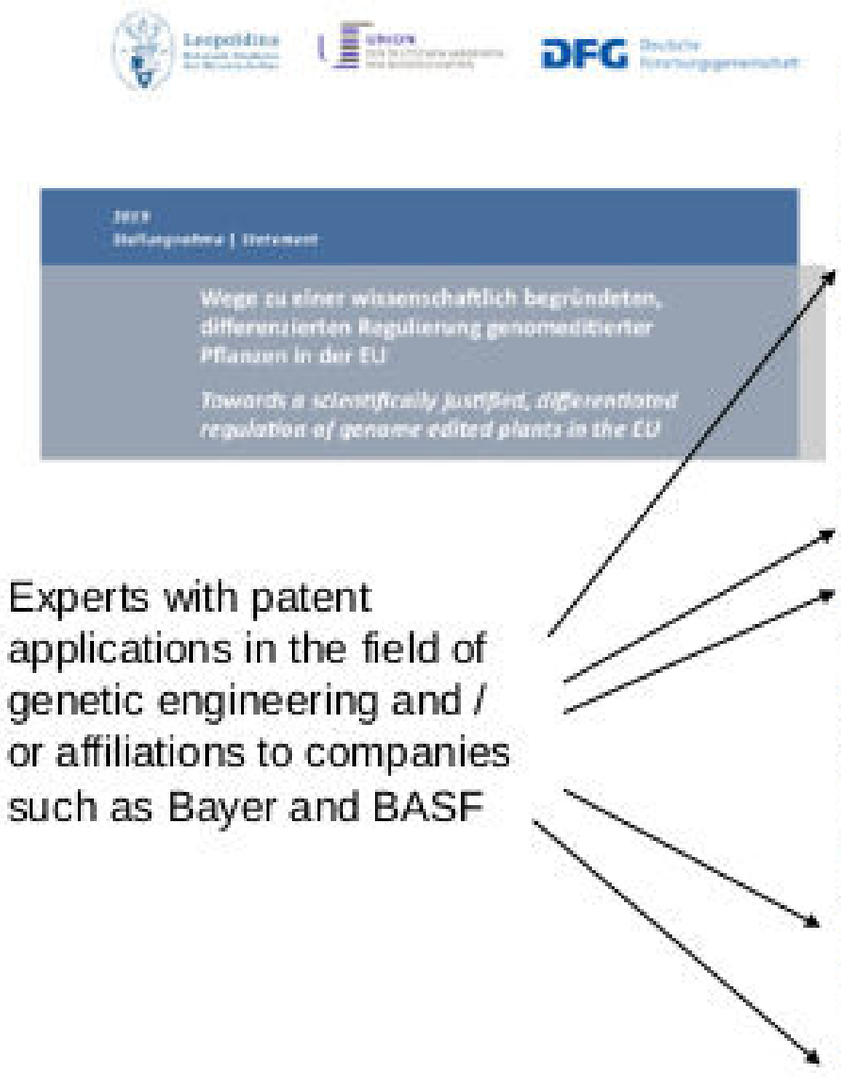
Disruptive effects on seed production

Patents on plant genes can block all further uses of plants and genes



https://www.no-patents-on-seeds.org/en/report2022

Disruptive effects: Patents and science



Members of the working group

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Dr. Ralf Wilhelm	Institute for Biosafety in Plant Biotechnology, Julius Kühn Institut, Quedlinburg
Prof. Dr. Ernst-Ludwig Winnacker	Gene Center of the LMU Munich

Figure 6: The list of experts named in the Leopoldina (2019) report, highlighting those who are involved in filing patent applications on GE plants.

https://www.testbiotech.org/node/2771

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The urgent need for technology assessment

The introduction of NGTs can not be regarded as sustainable if it may cause

- ecosystems to collapse
- health risks to accumulate in food without notice
- breeding being disrupted by patents
- companies do not have to provide detection methods
- disabling organic or non-GE agriculture
- the end of freedom of choice for consumers

The urgent need for technology assessment

TA requires appropriate criteria to make fact-based decisions about the sustainability and potential benefits of NGTs in agriculture.

This would make it possible to identify negative effects on breeding, agriculture and food production at an early stage and to avoid, that solutions through NGTs are becoming new problems for the environment, ecosystems and future generations.

For this, we need transparent, reliable and practicable criteria to distinguish traits with ‘real benefits’ from those which are simply ‘empty promises’.

Improve EU GMO regulation to strengthen the precautionary principle: Update risk assessment standards + introduce technology assessment

GMO regulation
Mandatory risk assessment and approval process of each 'event'
+
Technology assessment
Overall impact of NGTs in agriculture and food production (economic, social and ecological)

Legal framework

Risk assessment
Each 'event', case-by-case,
intended and unintended as well as immediate delayed and accumulated effects
+
Updated guidelines, new methodology (such as 'OMICs'), including cut-off criteria if there are too many uncertainties

Technology assessment
potentially disruptive effects on breeding, agriculture, food production, consumer choice, animal welfare and overall ecosystem stability
+
Potential benefits in each case based on transparent and reliable criteria

Regulatory consequences

Decision-making should imply two independent levels of scrutiny; market access would require positive results from both regulatory processes

Decision making

https://www.vzbv.de/sites/default/files/2022-11/vzbv-report_final_final.pdf

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further reading

English: https://www.testbiotech.org/node/3044

German: https://www.testbiotech.org/node/3042