

**New genomic techniques (NGTs) – agriculture, food production and crucial regulatory issues**

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## Main Findings: Risks (1)

“Moreover, the GMO Panel was not mandated to provide a comprehensive literature review on the SDN-based technology and its unintended effects.”  
(EFSA, 2022f)

### **The EU Commission asked EFSA the ‘wrong’ questions:**

EFSA did not have a full mandate to assess all the relevant issues (intended and unintended effects).

### **The EU Commission drew the wrong conclusions from EFSA’s answers:**

The differences between conventional breeding and NGTs can be easily overlooked, but they can have serious consequences for health and the environment.

In fact, NGTs can cause extreme variants of biological characteristics as well as unintended genetic changes and effects which are unlikely to result from conventional breeding or natural processes.

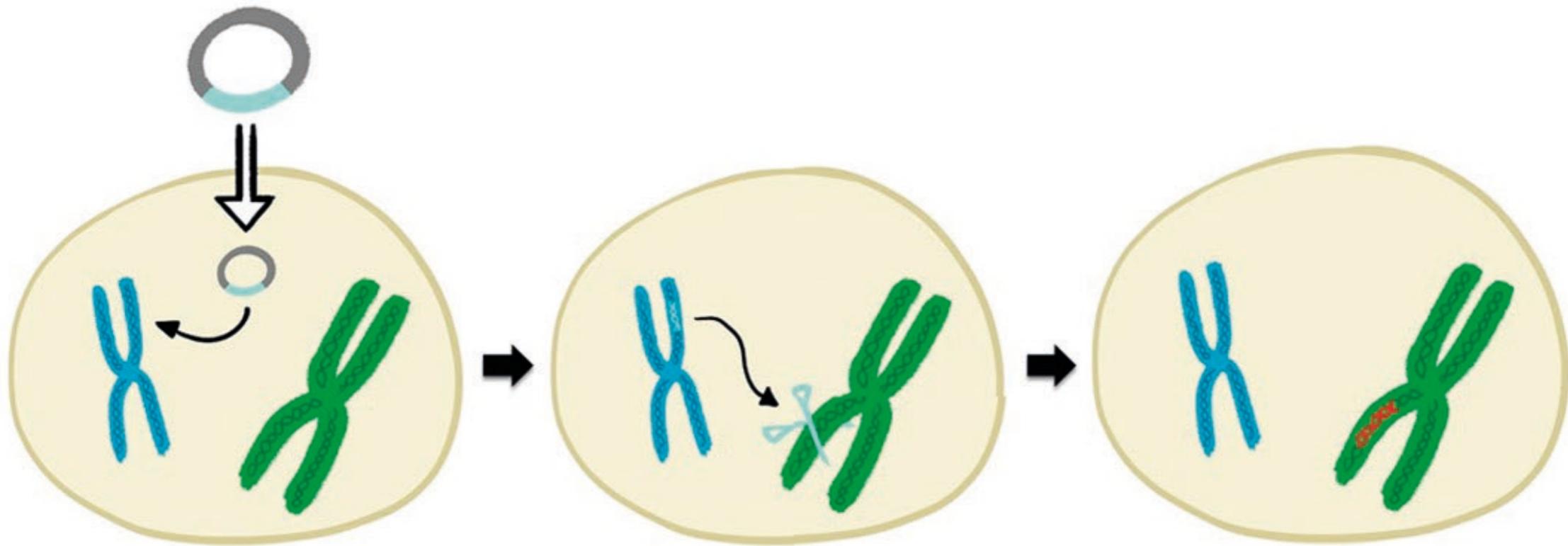


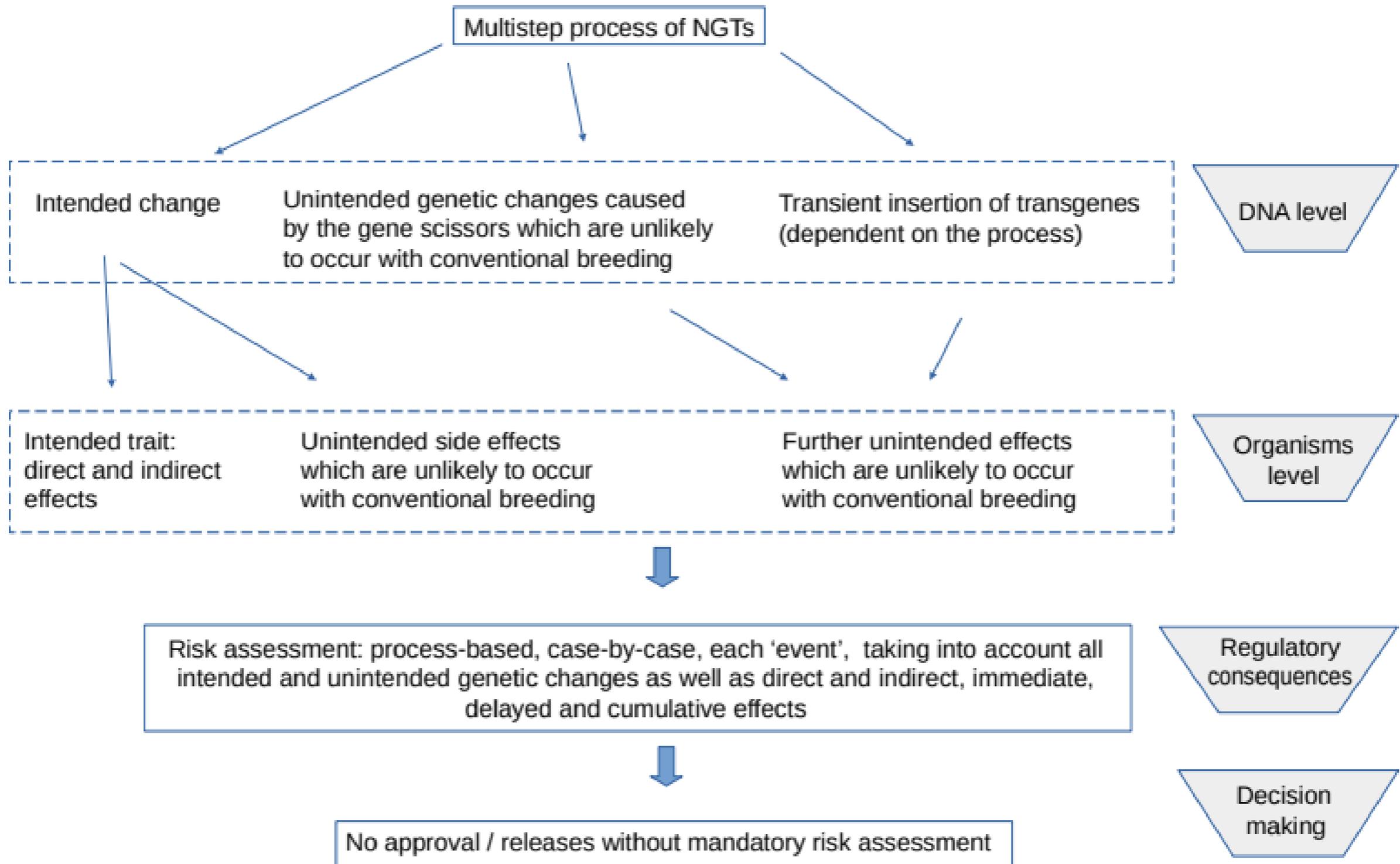
Figure 5: Applications of CRISPR/Cas, particularly in plants, are multistep processes, often including transgenesis (Old GE). First step: Non-targeted methods (such ‘gene guns’) are used to introduce the DNA for the nuclease into the cells. It is only in the second step that the nuclease acts in a targeted way.

# The risk of unintended genetic changes

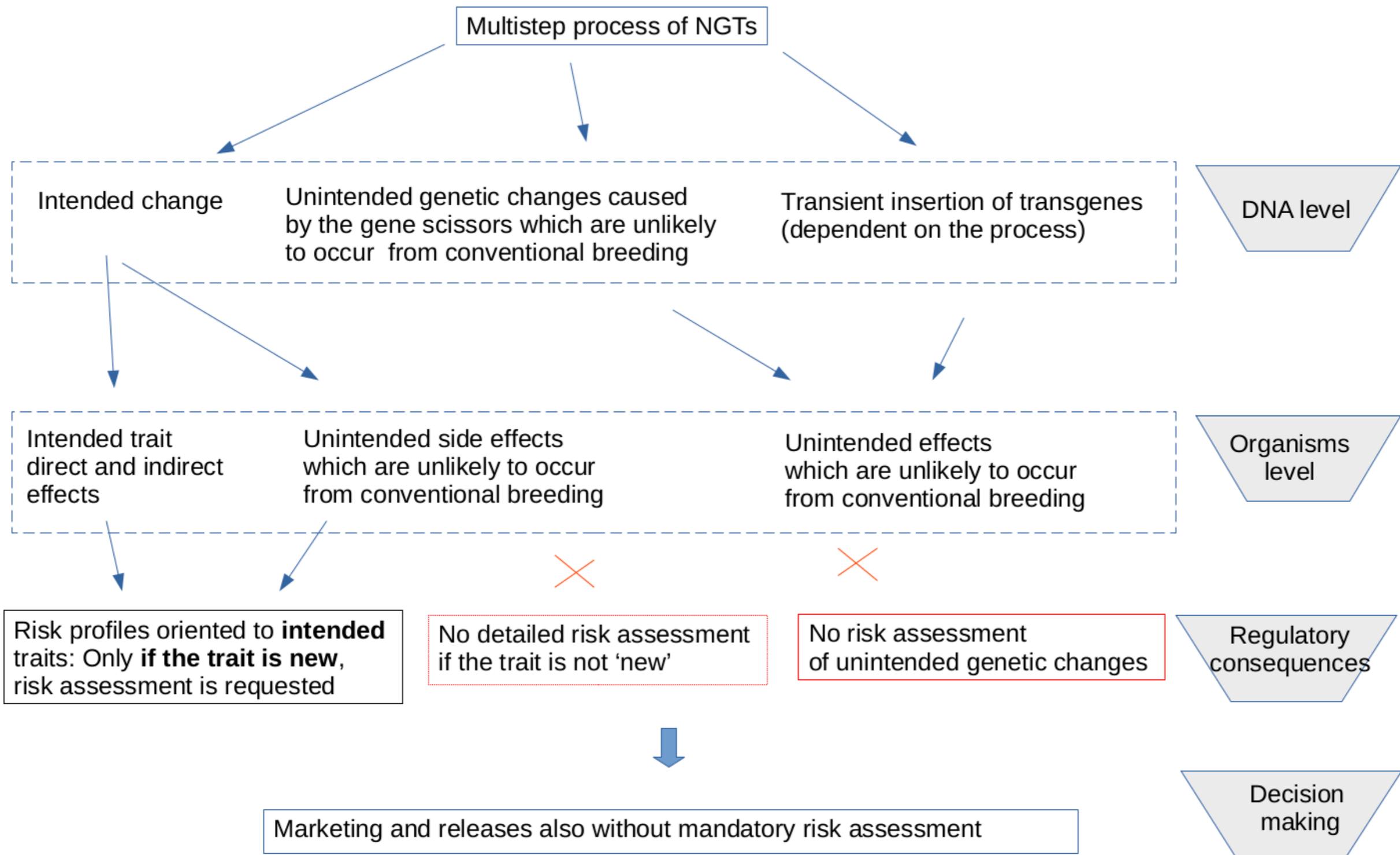


The cattle had been genetically engineered before 2016, but it was only in 2019 that scientists noticed that large parts of genetic material of the bacteria used in the process had also been introduced into the genome of the cattle. At that time, it was shown that the processes of genetic engineering had caused genes from bacteria to be not only unintentionally integrated into the genome of the cattle but passed on to the next generation.

If unintended genetic alterations remain undetected over longer periods of time, they may spread quickly and widely within larger populations. Therefore, as required in EU regulation, in each case, the intended and unintended changes have to be assessed thoroughly as well as its direct or indirect, immediate, delayed or cumulative effects on human health and the environment.



Current regulation of NGTs: Intended traits, unintended side effects and unintended genetic changes triggering the need for risk assessment.



**Scenario for a potential fragmentation of the EU GMO regulation for NGT plants derived from SDN (without the intended insertion of transgenes in the final organism) by introducing 'risk profiles' based on the intended traits.**

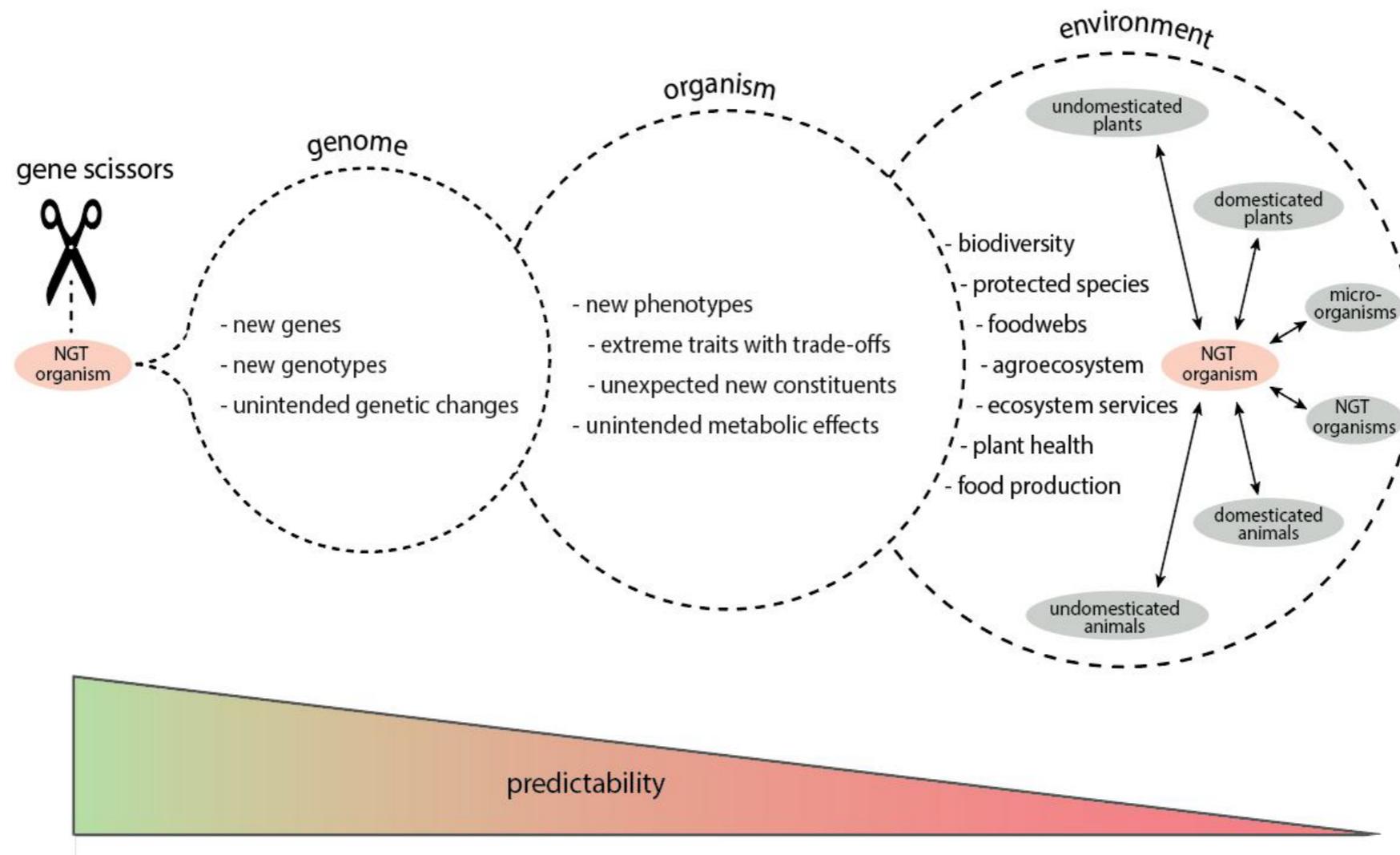
## **Main Findings: Risks (2)**

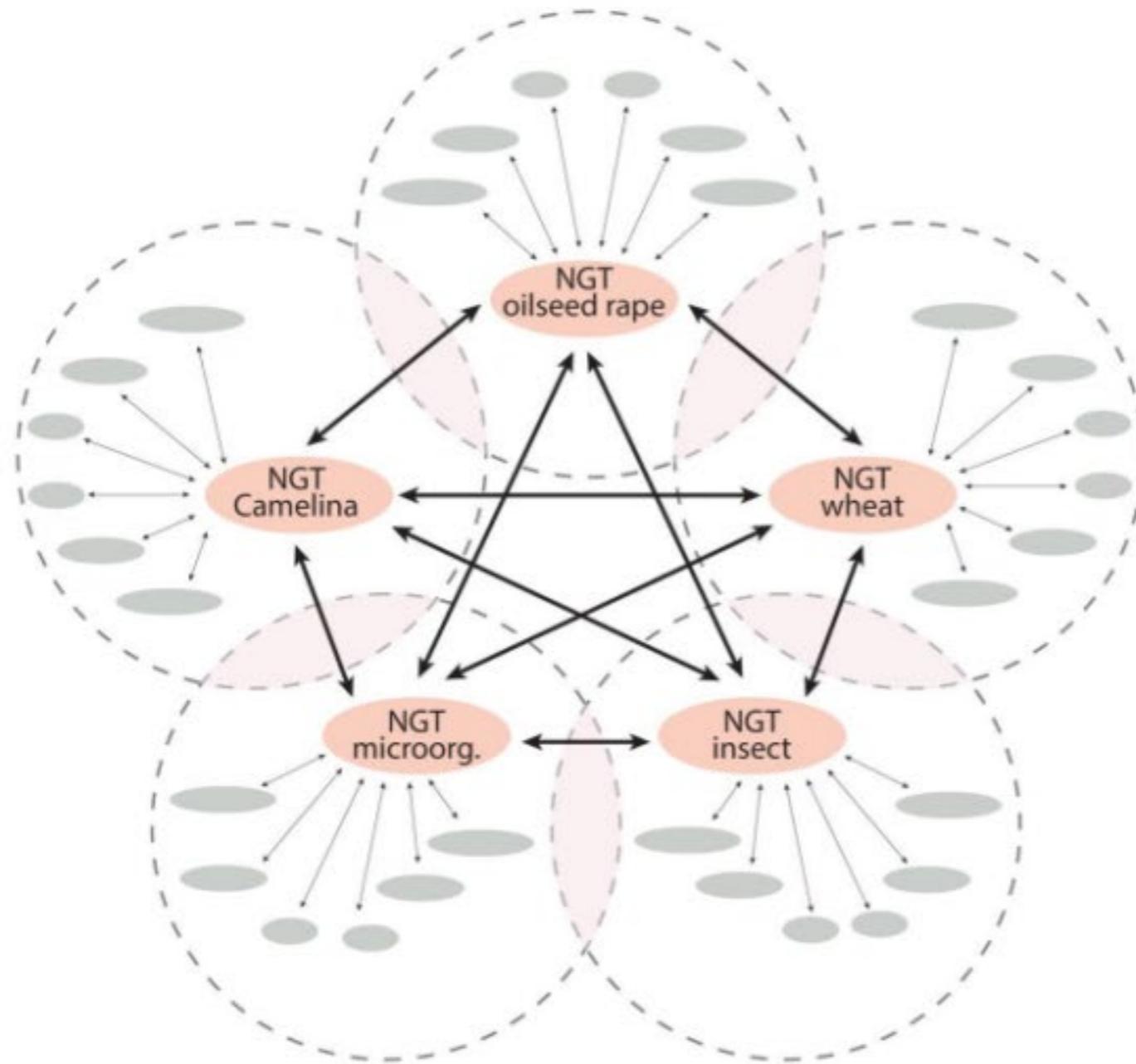
### **It is necessary to take cumulative effects into account:**

The wide range of species accessible to NGTs includes food plants and animal species as well as non-domesticated species, such as trees and other plants, insects, vertebrates and microorganisms.

Many of the species targeted by NGT-applications also have the potential to persist and spread over longer periods of time.

Risk assessment has to take into account cumulative effects if these organisms are released into a shared environment.





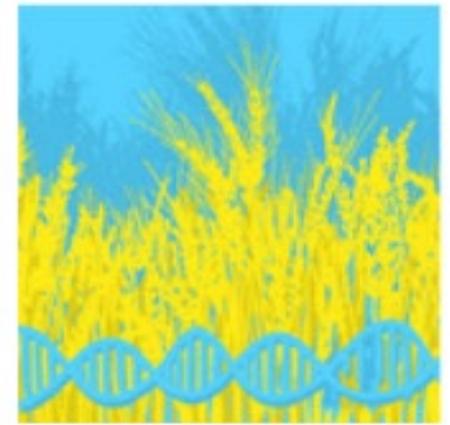
# **Main Findings: Socio-Economic Impact (1)**

**Technology assessment is needed to examine potential benefits:**

NGTs have a huge potential to alter the genome but this potential does not easily translate into real benefits.

Criteria are needed to distinguish empty promises from potential benefits.

## The example of wheat: extreme traits are impacting vigor



Traits such as reduction in gluten, acrylamide or resistance to fungal disease go along with trade offs which impact plant fitness.

Consequently, these plants may show unexpected reactions to environmental stress such as extreme climate conditions

Long time may be needed for further breeding to balance these effects.

It may be complicated to cross these traits with each other.

## **Main Findings: Socio-Economic Impact (2)**

### **It is necessary to take disruptive effects into account:**

If the EU regulations are weakened or fragmented, freedom of choice for consumers, future of organic agriculture and non-GE food production may be severely hampered or disabled.

Furthermore, patents on NGTs can also have negative effects on accessibility to biological material needed by conventional breeders.

Patent applied and granted in this field are targeting both: The technology and the gene variants of interest.

## Patent applications on the technology of NGTs comprising plants and seeds

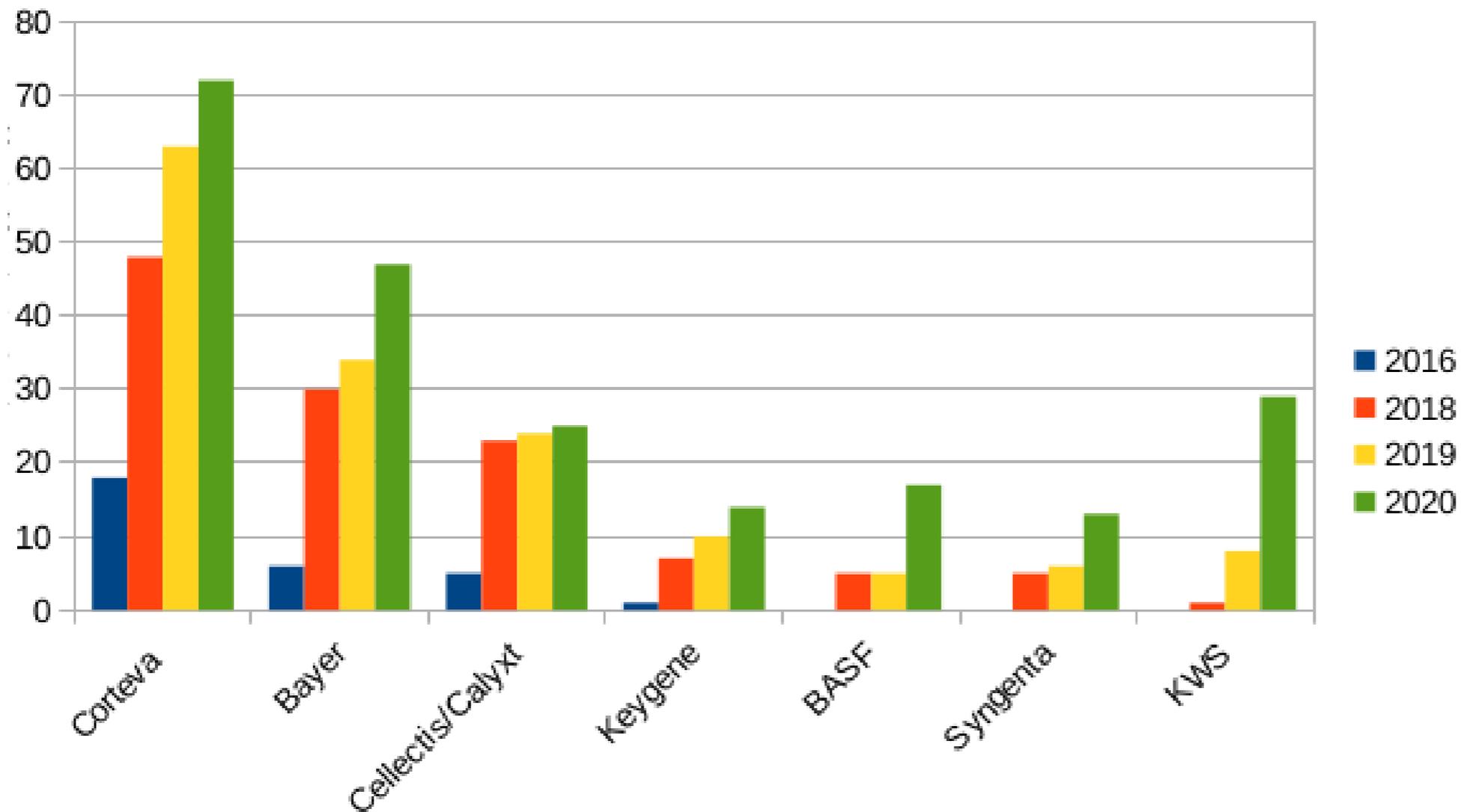


Figure 3: Number of international patent applications (WIPO /WO) on nucleases (CRISPR/Cas, TALENs, zinc finger or meganucleases) in the food plant sector up until the end of 2020<sup>12</sup> (number of patent applications accumulated<sup>13</sup>).

# Patent applications on biological resources

**Syngenta, WO2021154632 claims around 5.000 single nucleotide polymorphism (SNPs) detected in wild relatives of soybeans**

Table 1: SNP Positions within SEQ ID NO: 1 that are associated with increased resistance to ASR

Table 1 is organized as follows: (Position in Scaffold 22052, favorable allele, unfavorable allele)

(24,A,G)(2425,G,A)(3023,T,C)(3024,C,T)(3094,A,C)(3158,A,G)(3666,G,A)(4104,C,A)(4133,T,TTGCTGCTATAATCGATTAAGC)(4155,G,C)(4156,C,A)(4157,T,C)(4159,C,G)(4160,T,G)(4239,C,A)(4289,A,G)(4321,C,T)(4355,C,T)(4474,G,T)(4528,C,T)(4659,A,C)(4820,T,C)(4906,T,G)(5028,T,G)(5077,T,C)(5202,A,C)(5228,G,A)(5254,G,A)(5291,T,C)(5316,G,A)(5613,G,A)(5649,T,C)(5744,C,T)(5755,T,TGGGTCATGGC)(5758,GACAACA,G)(6029,A,C)(6133,C,T)(6183,T,A)(6210,A,ACT)(6599,T,C)(6695,G,A)(6931,T,TG)(6937,C,T)(7007,T,C)(7030,A,G)(7094,A,G)(7117,T,TA)(7322,T,C)(7467,A,G)(7530,G,C)(7558,G,A)(8071,A,G)(8367,A,G)(8524,T,C)(8691,T,G)(8729,A,C)(8877,G,A)(8913,G,T)(9001,A,ATG)(9005,A,G)(9007,G,A)(9008,G,C)(9010,A,T)(9199,T,A)(9311,C,T)(9447,T,C)(9568,A,G)(9595,T,C)(9648,T,A)(9871,A,AC)(9896,T,A)(9911,C,T)(10105,C,T)(10319,C,T)(10443,A,G)(10487,A,C)(10497,A,G)(10567,T,C)(10738,A,C)(10914,G,T)(10945,T,A)(11114,A,C)(11134,C,A)(11155,G,T)(11219,A,G)(11272,C,T)(11869,A,G)(11975,AT,A)(12370,C,T)(12403,C,T)(12474,C,T)(12567,G,C)(12734,G,A)(12997,C,A)(13052,A,G)(13071,G,A)(13101,C,T)(13103,A,G)(13174,C,A)(13210,C,G)(13257,C,G)(13430,A,G)(13474,T,C)(13589,G,C)(13823,A,C)(13943,TA,T)(14093,A,G)(14246,C,T)(14277,G,A)(14303,A,C)(14337,G,A)(14877,T,G)(14907,T,C)(14926,A,G)(15061,C,T)(15405,A,G)(15525,A,C)(15722,T,C)(15783,C,A)(15809,A,T)(15907,ATGCATAGT,A)(15991,G,A)(16377,A,T)(16418,A,G)(16437,A,G)(16590,G,A)(16695,T,C)(16725,A,C)(16729,A,T)(16951,C,T)(17006,T,C)(17302,G,A)(17588,G,A)(17679,G,A)(18002,A,G)(18620,G,T)(18631,A,G)(18673,C,T)(19024,G,T)(19060,G,A)(19260,G,A)(19349,G,A)(19535,C,A)(19559,T,C)(19693,T,C)(19773,A,C)(19830,A,G)(20155,A,G)(20235,T,G)(20382,C,T)(2046
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# Patent applications on biological resources

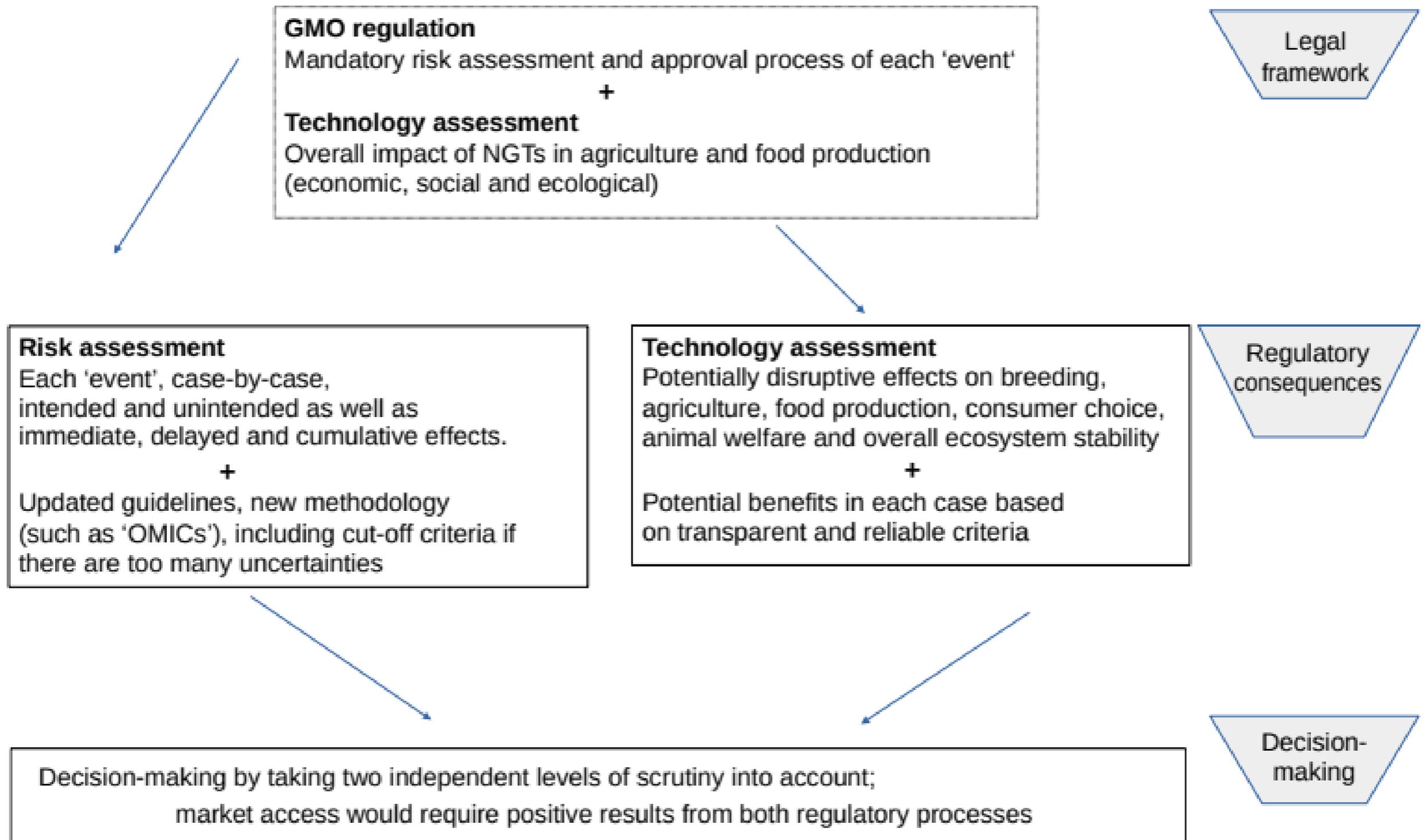
Syngenta, WO2021154632 claims  
around 5.000 single nucleotide  
polymorphism (SNPs) detected in  
wild relatives of soybeans

WO 2021/154632

PCT/US2021/014861

## THAT WHICH IS CLAIMED IS:

1. An elite *Glycine max* plant having in its genome a chromosomal interval chosen from SEQ ID NOs: 1, 2, 3 or a portion of any thereof, wherein said chromosomal interval confers increased Asian soy rust (ASR) resistance as compared to a control plant not comprising said chromosomal interval.
2. The plant of claim 1, wherein the chromosomal interval is chosen from SEQ ID NO: 1 or a portion thereof.
3. The plant of claim 1 or 2, wherein the chromosomal interval comprises a SNP marker associated with increased ASR resistance wherein said SNP marker corresponds with any one of the favorable SNP markers as listed in Tables 1-3.
4. The plant of claims 1-3, wherein the chromosomal interval is derived from *Glycine tomentella* chromosome 20.



Improving the EU GMO regulatory framework from the perspective of the precautionary principle by updating risk assessment standards and introducing a corresponding framework for a technology assessment