



# Biosafety Data Requirements

Risk Assessment under GeneBEcons' regulatory options

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- My contribution does not represent an official opinion of the German Government
- I have no conflict of interest

# Risk Assessment: The Principle Logic

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## COMPARATIVE APPROACH

→ Compare the GMO and derived products to their non-GM counterparts – “as safe as”

Assessment of the identified differences regarding the:

### *Environmental impact*



### *Food/Feed safety*



### *Nutritional impact*



- **Intended effects**: those occurring because of the genetic modification
- **Unintended effects**: additional effects which were NOT the objective of the genetic modification

# Food/Feed Risk Assessment of of NGT plants under current GMO law

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## Molecular Characterisation

- Genetic modification
- Characteristics of the GM plant



## Food and Feed safety

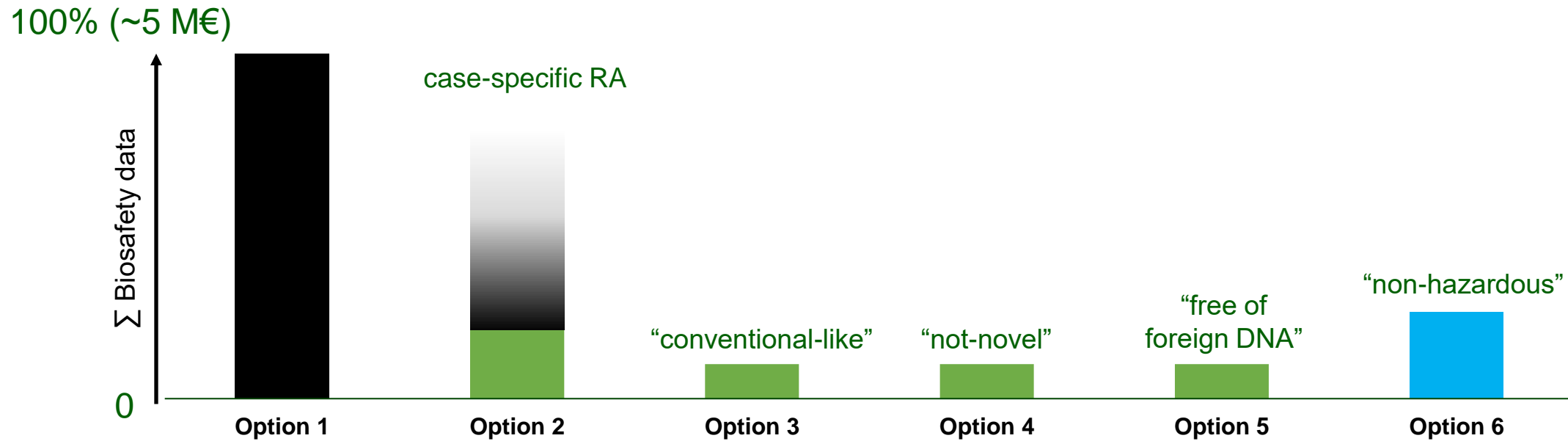
- Compositional and agronomic assessment
- Toxicological assessment
- Allergenicity assessment
- Nutritional assessment



# Leading questions to collect biosafety data

<b>Option 1</b> full data is required following the EFSA guidelines according to Directive 2001/18 EC and Regulation (EC) No 1829/2003	<b>Option 2</b> What data is required for an risk assessment of the concrete NGT plant in question?	<b>Option 3</b> Is NGT plant “conventional-like”? If not, is there a hypothesis of hazard?
<b>Option 4</b> Is there a novel trait introduced into the plant and if so, is it potentially hazardous?	<b>Option 5</b> Is NGT plant free of foreign DNA?	<b>Option 6</b> Is the NGT plant a low or high hazard?

# Biosafety data - minimum requirements

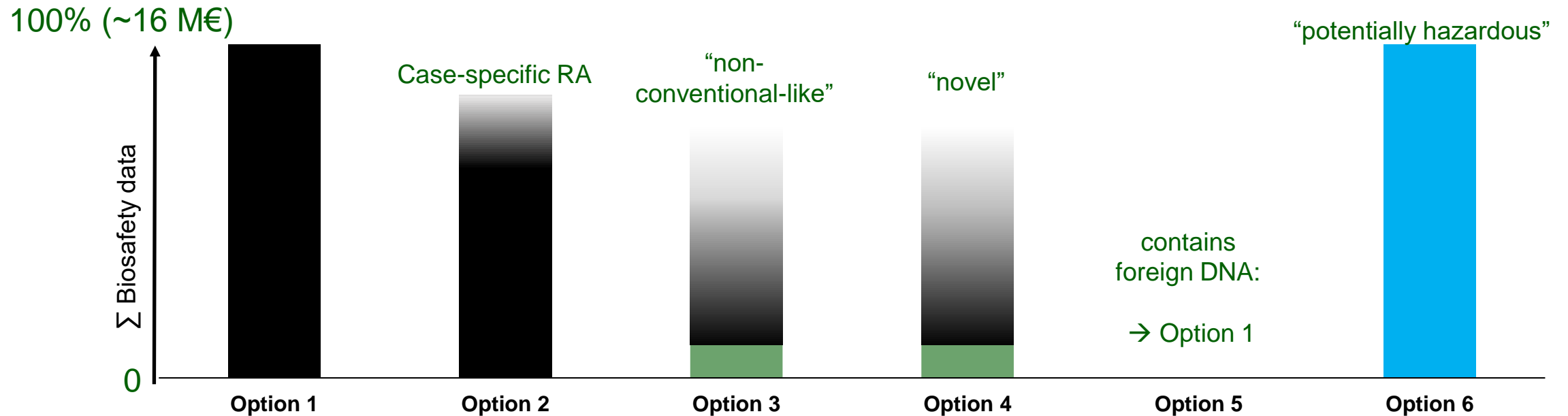


Scientific data for risk assessment (e.g. data from field trials; studies on toxicology; allergenicity and nutritional assessment)

Verification data to confirm the status of the NGT plant as requested by a Competent Authority

Verification data (registration) for hazard status provided by the applicant

# Biosafety data - maximum requirements



Scientific data for risk assessment (e.g. data from field trials; studies on toxicology; allergenicity and nutritional assessment)

Verification data to confirm the status of the NGT plant, as requested by a Competent Authority

Verification data for hazard status provided by the applicant

# Take Home Message

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**All** regulatory options of GeneBEcon require some level of biosafety data to ensure the NGT plant is **as safe as** comparable conventional plants



[www.genebecon.eu](http://www.genebecon.eu)



[@genebecon-eu-project](https://www.linkedin.com/company/genebecon-eu-project)



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