Plant Breeding Innovation – between cumbersome biotech regulations and ambitious policy goals for sustainable agriculture

DanSeed 2021 Symposium

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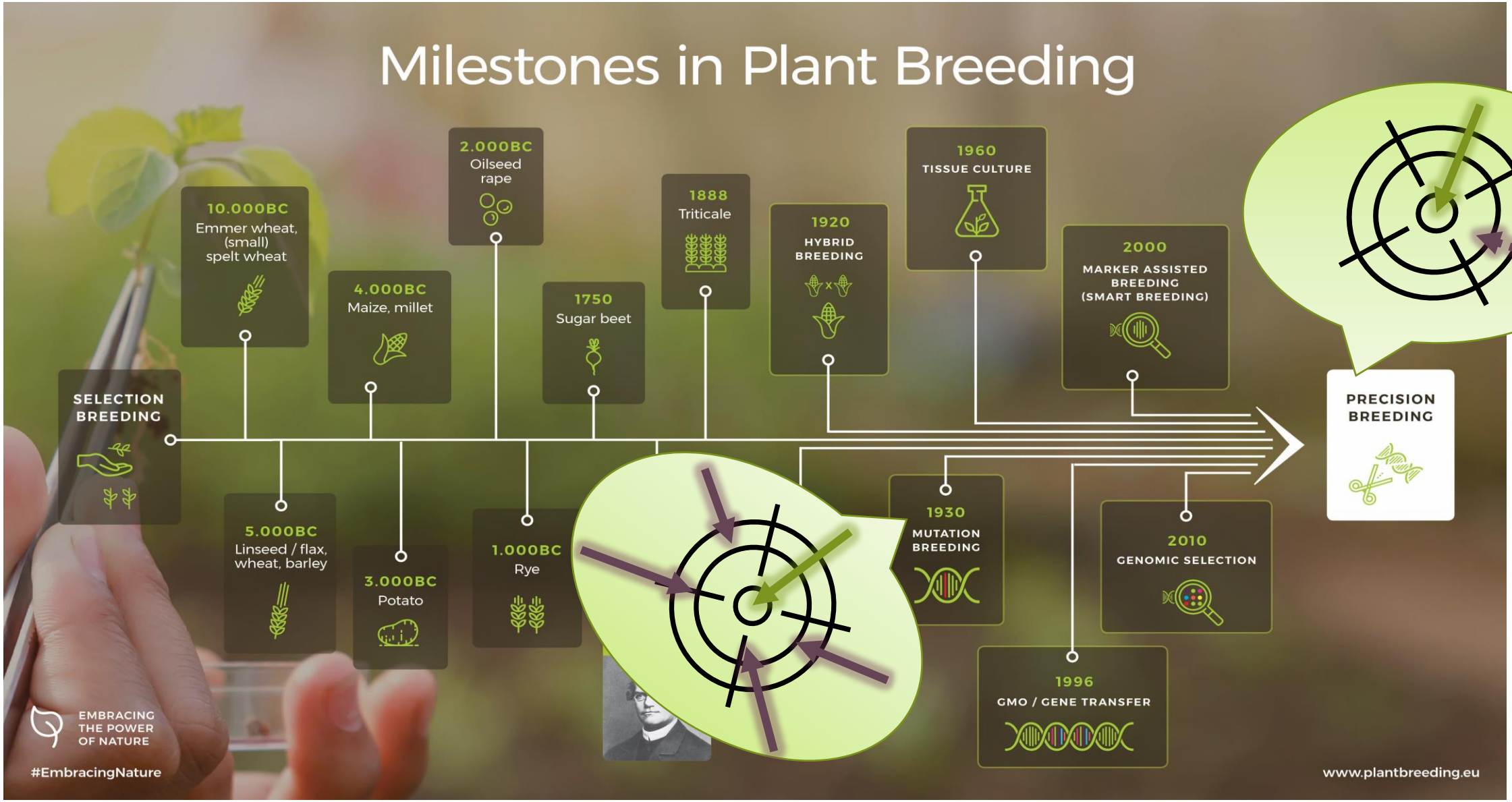
PLANT BREEDING INNOVATION: A HISTORY OF PROGRESS



The ECJ Court Case C-528/16 in a nutshell

1) Do organisms obtained by mutagenesis (old and new) constitute GMO's?

- **all plants obtained by any form of mutagenesis breeding are GMOs** as defined by Article 2(2) of Directive 2001/18

2) Are all organisms obtained through mutagenesis exempted from regulatory obligations according to Annex IB of Directive 2001/18?

- the mutagenesis exemption only applies to organisms obtained by methods of mutagenesis which **have conventionally been used in a number of applications and have a long safety record**

3) What room for Member States to legislate on exempted mutagenesis products?

- even for those plants to which the mutagenesis exemption of Annex IB applies, **Member States may still lay down national rules** subjecting these plants to similar obligations as the GMO Directive (compliance with EU law esp. with the rules on the free movement of goods)

Euroseeds' principle position for the Regulation of NBT Plants

Plant varieties developed through the latest breeding methods should **not be subject to different or additional regulations** if they **could also have been produced through earlier breeding methods** or by **natural processes** without human intervention.

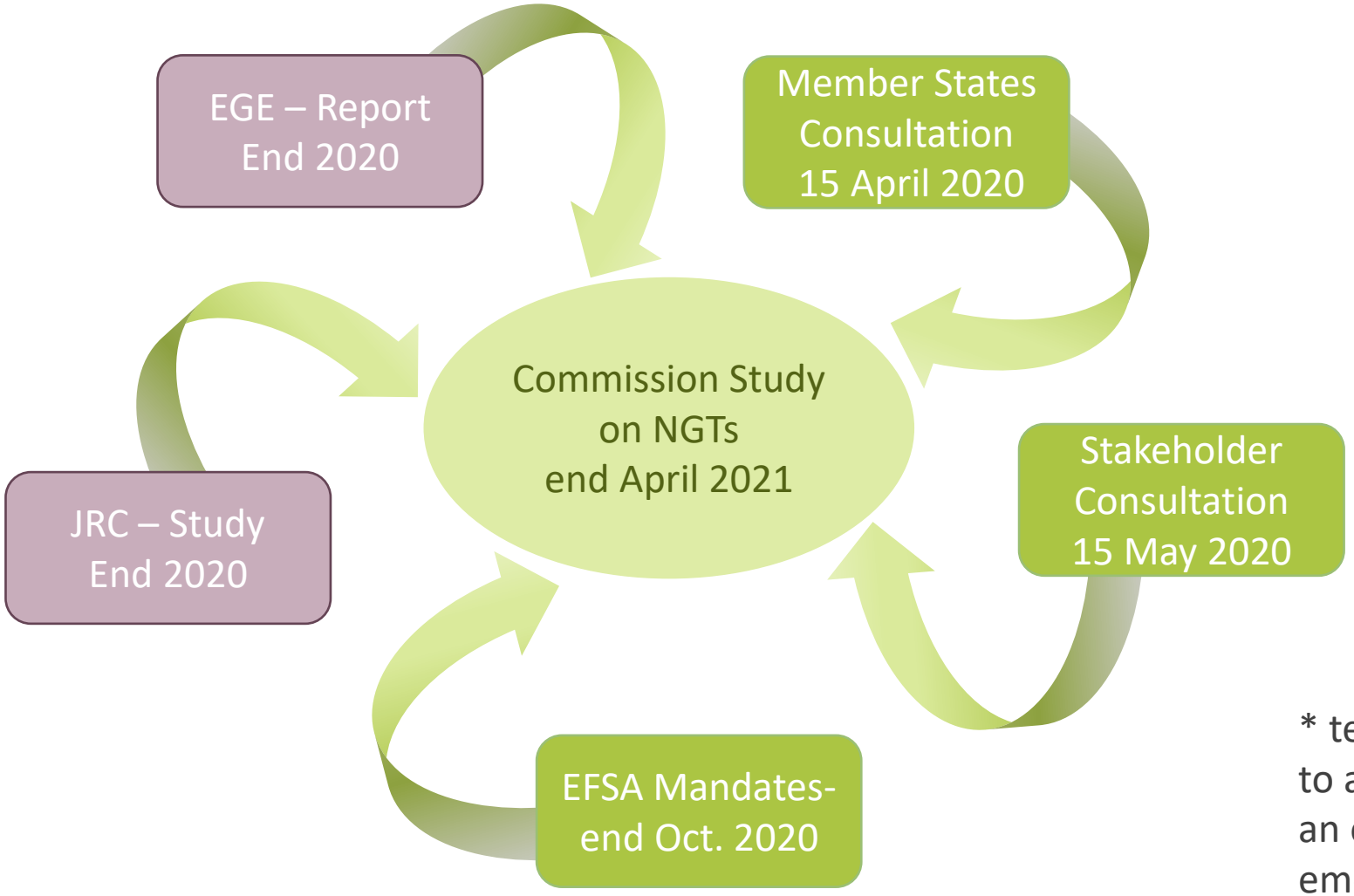
The genetic variation in the final plant product should **NOT be covered by the scope of the existing EU legislation for GMOs** if

- there is **no novel combination of genetic material** (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or
- the final plant product solely contains the stable insertion of inherited **genetic material from sexually compatible plant species**, or
- the genetic variation is the **result of spontaneous or induced mutagenesis**.

Our Goal

- The 2018 ECJ ruling on mutagenesis breeding puts all innovative breeding methods under the cumbersome GMO regulation
- The ruling of the ECJ of July is not in line with intention of the legislators that wanted to set specific rules for classical GMOs (transgenes) but NOT for mutagenesis derived plants
- We need a targeted amendment of the GMO-Directive 2001/18 that **excludes products of old and new mutagenesis breeding from its definition;**
- This would create
  - alignment of the EU's policy and rules with those established and being developed in the rest of the world;
  - legal certainty for EU operators by avoiding that Member States adopt individual national rules for products resulting from conventional, random mutagenesis.

Commission Study on NGTs* - Elements



* techniques, which are capable to alter the genetic material of an organism, and which have emerged or have been developed since 2001

The EU Policy Framework: Plant Breeding Innovation & The EU Farm to Fork & Biodiversity Strategy

- **50%** Pesticide use
- **20%** Fertilizer use
- **10%** productive farmland
- **> 25%** under organic production

https://ec.europa.eu/food/farm2fork_en

F2F and seed: THE THEORY

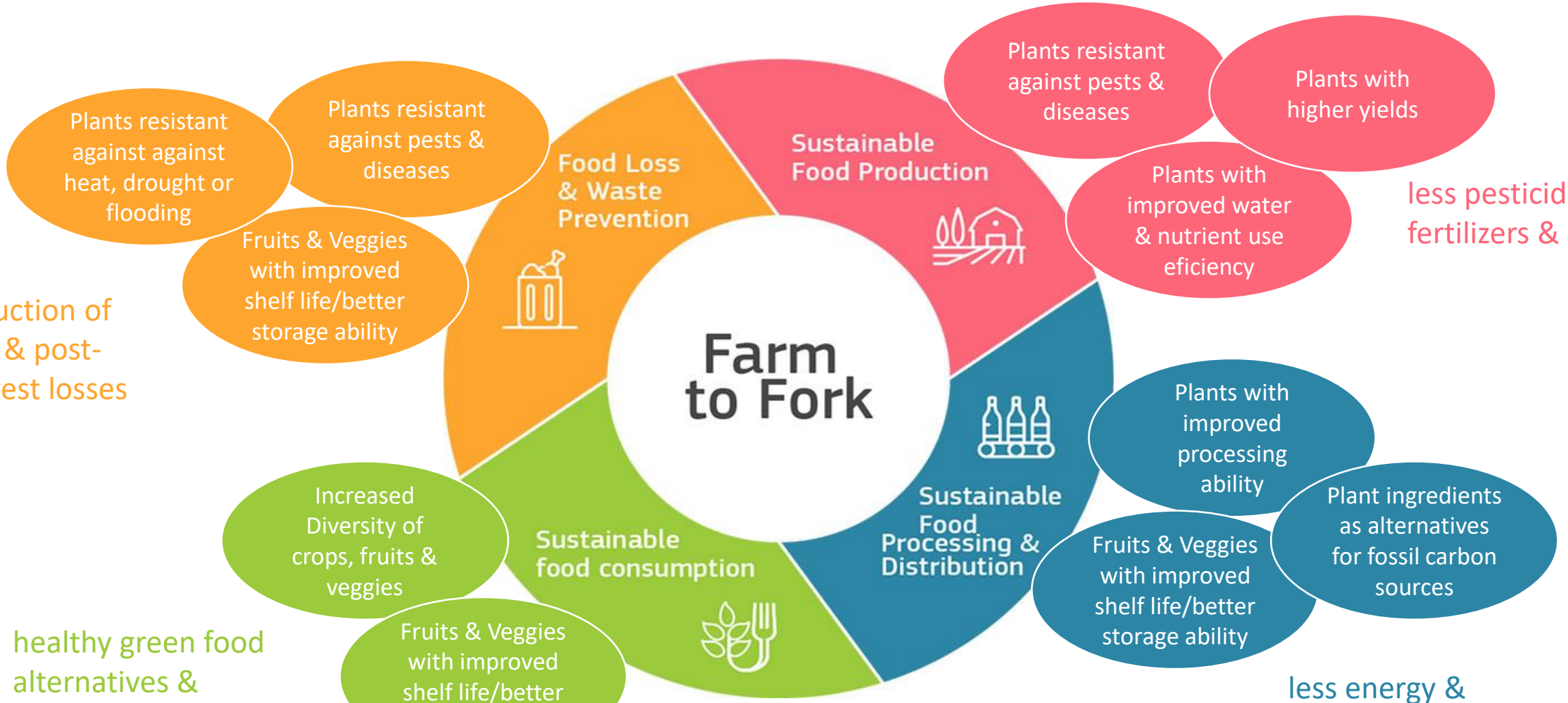
Role of Plant Breeding Innovation (PBI) and Quality Seed:

New innovative techniques, including biotechnology…, **may play a role** in increasing sustainability, provided they are safe for consumers & the environment while bringing benefits for society as a whole. They can also accelerate the process of reducing dependency on pesticides.

Sustainable food systems also **rely on seed security and diversity**.

Farmers need to have access to a range of **quality seeds** for plant varieties adapted to the pressures of climate change.

How can Breeding & improved Seeds contribute?



Reduction of pre- & post-harvest losses

less pesticides, fertilizers & land

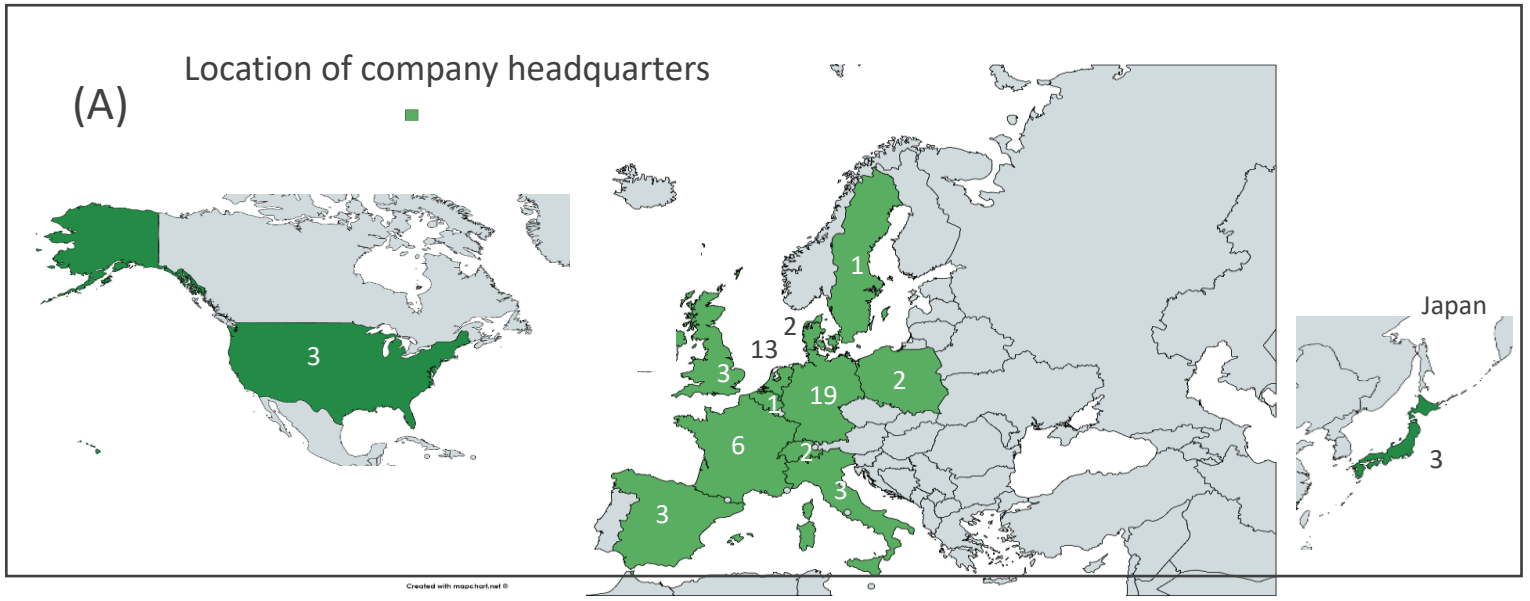
healthy green food alternatives & less food waste

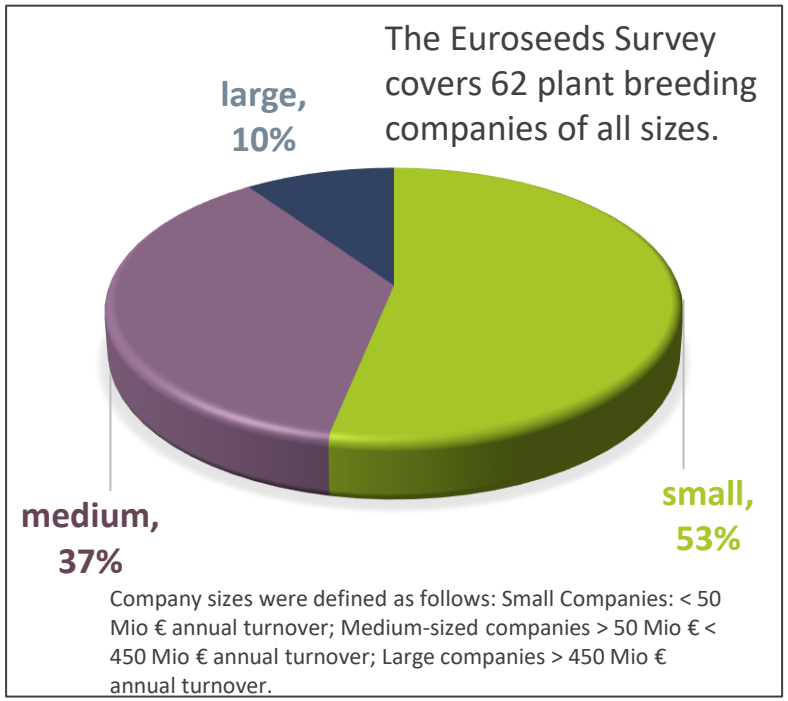
less energy & processing chemicals

https://ec.europa.eu/food/farm2fork_en

Euroseeds Survey on PBI R&D Activities

Euroseeds
Embracing Nature





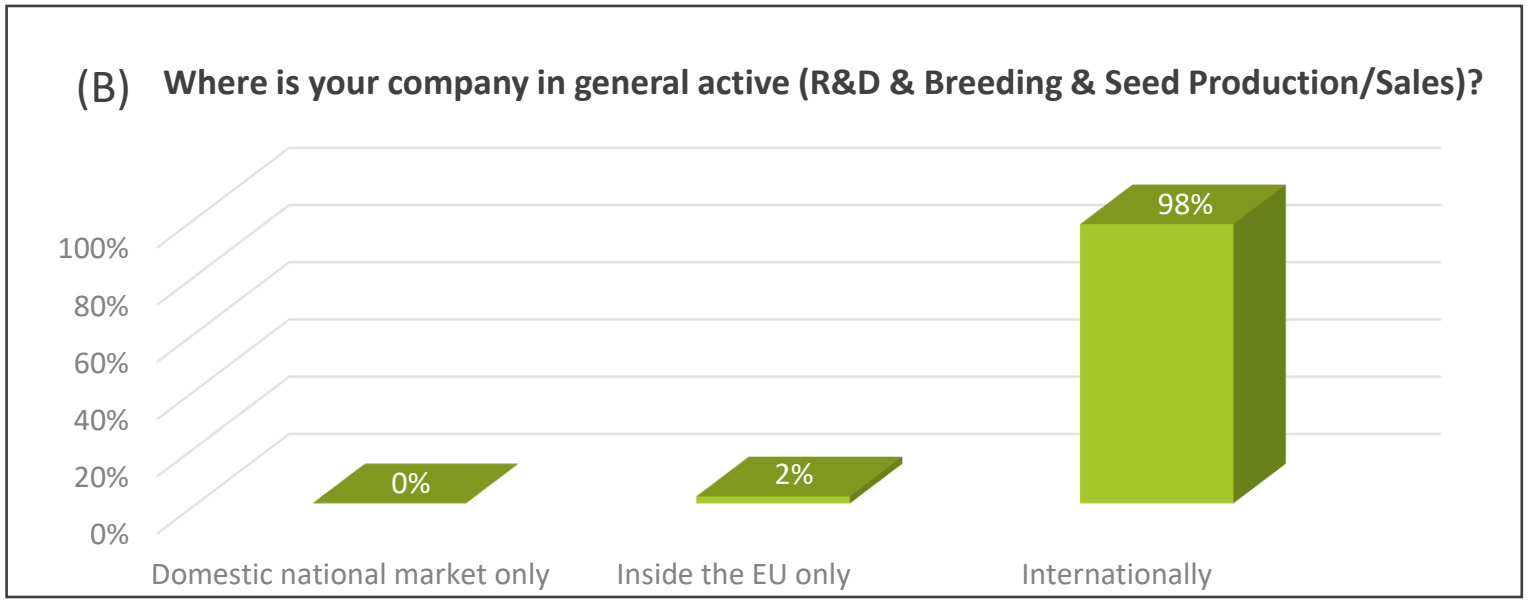


FIGURE 2 |
(A) Location of the headquarter of companies participating in the Euroseeds Survey. The figures indicate the number of company headquarters in a specific country.
(B) Geographies in which companies active in NBT-related R&D are generally conducting their R&D, breeding or seed production/sales activities.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Does your company currently have research and development (R&D) activities for NBTs?

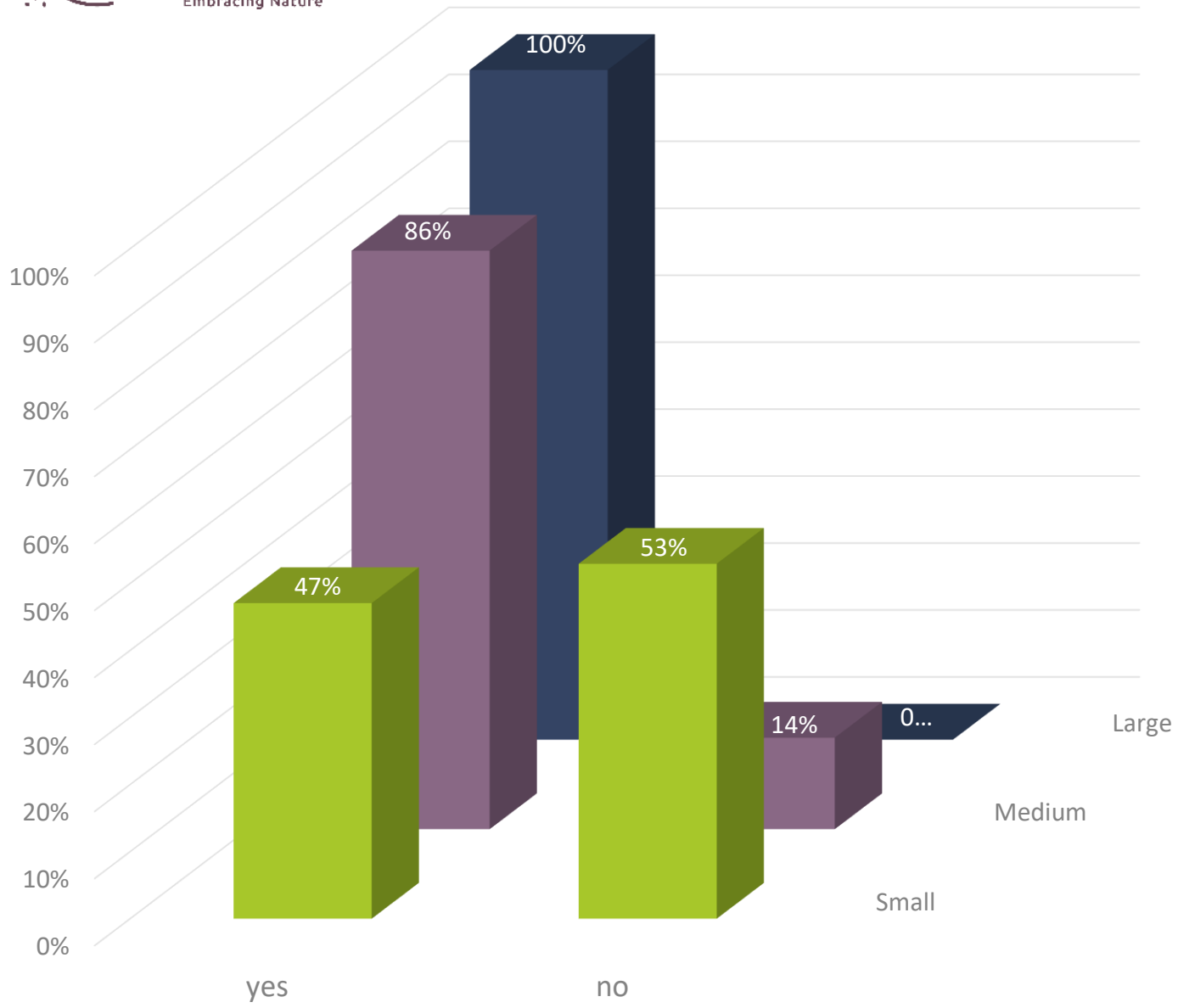


FIGURE 3 | Percentage of companies according to company size currently active in NBT-related R&D.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

In which form do your R&D activities for NBTs take place?

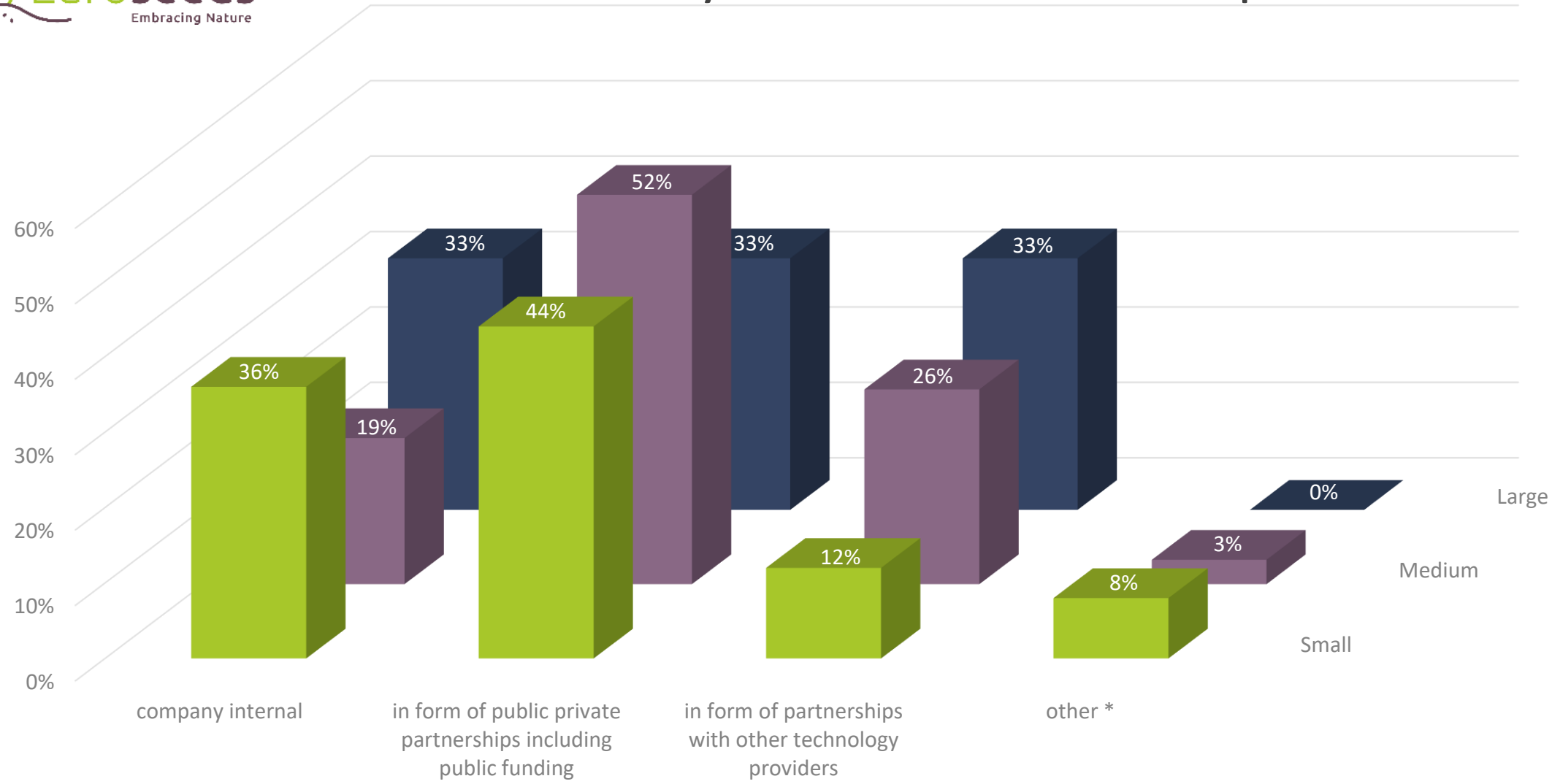


FIGURE 4 | Kind of NBT-related R&D activities relate to the total number of replies of companies grouped according to company size (multiple answers possible). Total numbers of replies were: small companies, 25; medium-sized companies, 31; large companies, 18. Additional aspects mentioned by companies under “other” activities were: commissioned company-funded work at public/independent research organizations authorized for GM work, engagement through charitable funding or funding of PhD projects.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Euroseeds
Embracing Nature

Where do your company's R&D activities for NBTs take place?

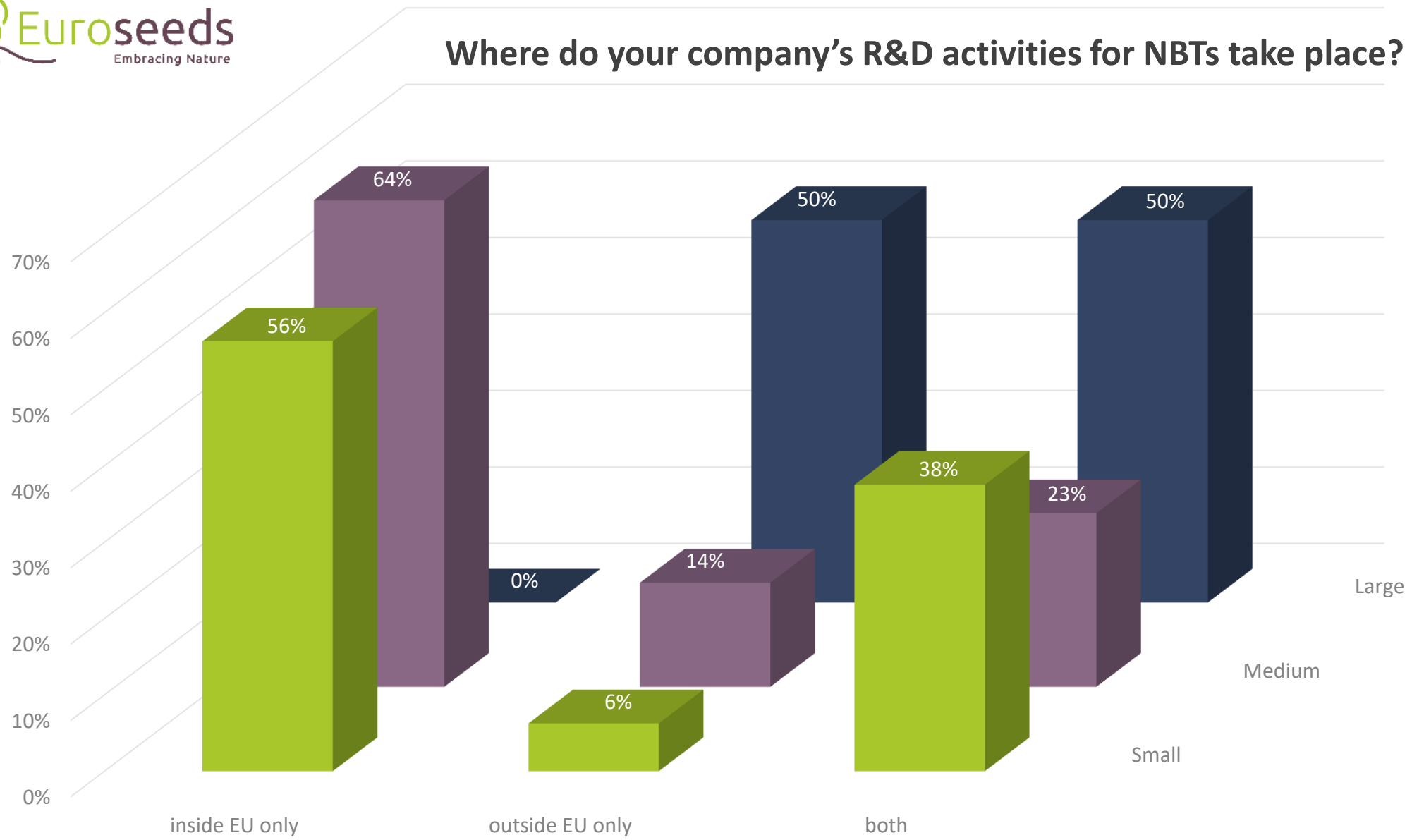


FIGURE 5 | Geographies in which the company's NBT-related R&D activities take place as to percentage of number of companies according to company size.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

In what kind of activities with NBTs is your company generally involved?

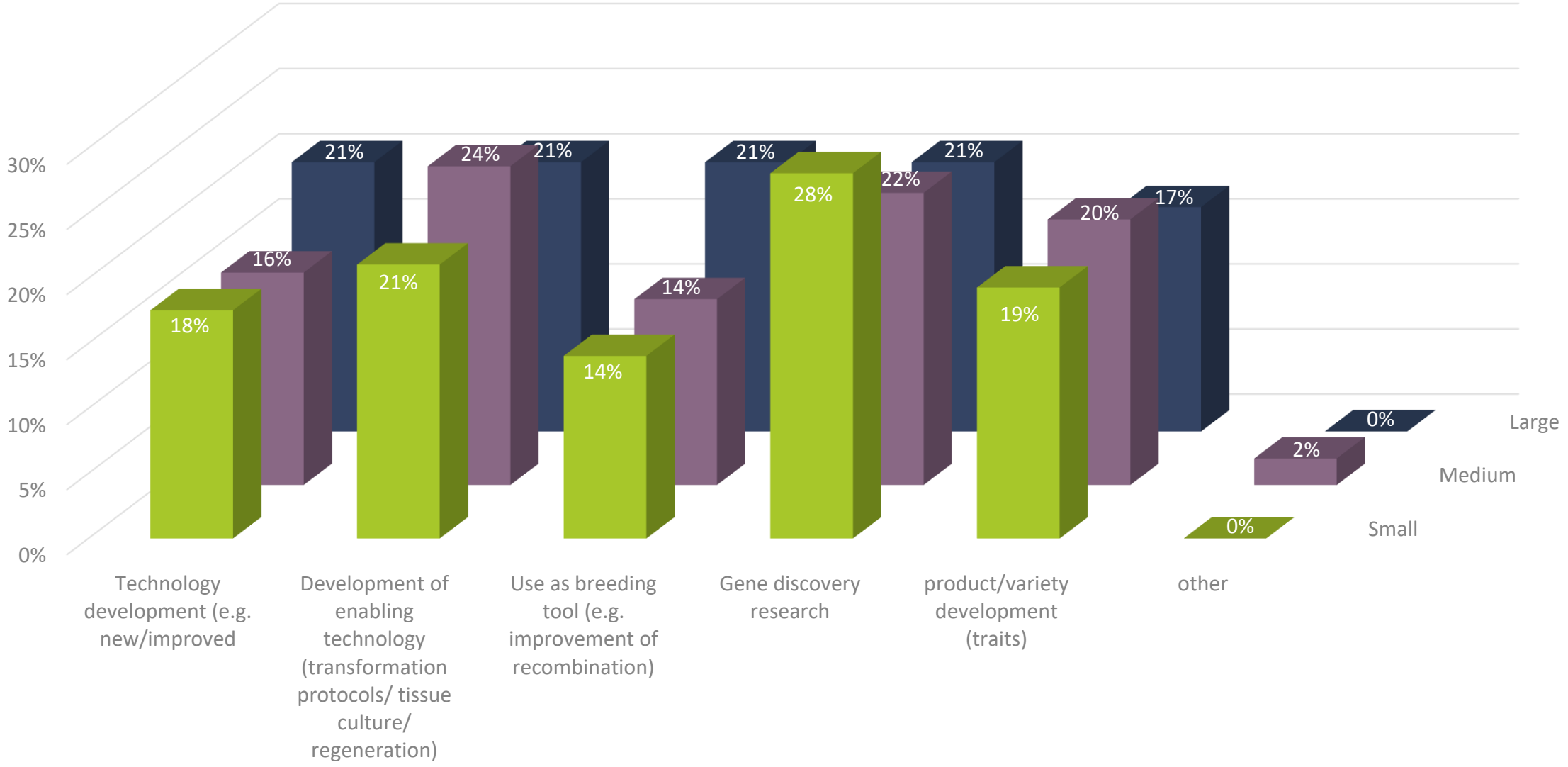


FIGURE 6 | Kind of activities with NBTs in which companies are generally involved as to percentages of total replies of companies grouped according to company size (multiple answers possible). Total number of replies: small companies, 57; medium-sized companies, 49; large companies, 29. In addition, companies mentioned under “other”: Contribution to science and academic advance.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

In which crops/crop groups is your company currently active in R&D with NBTs?

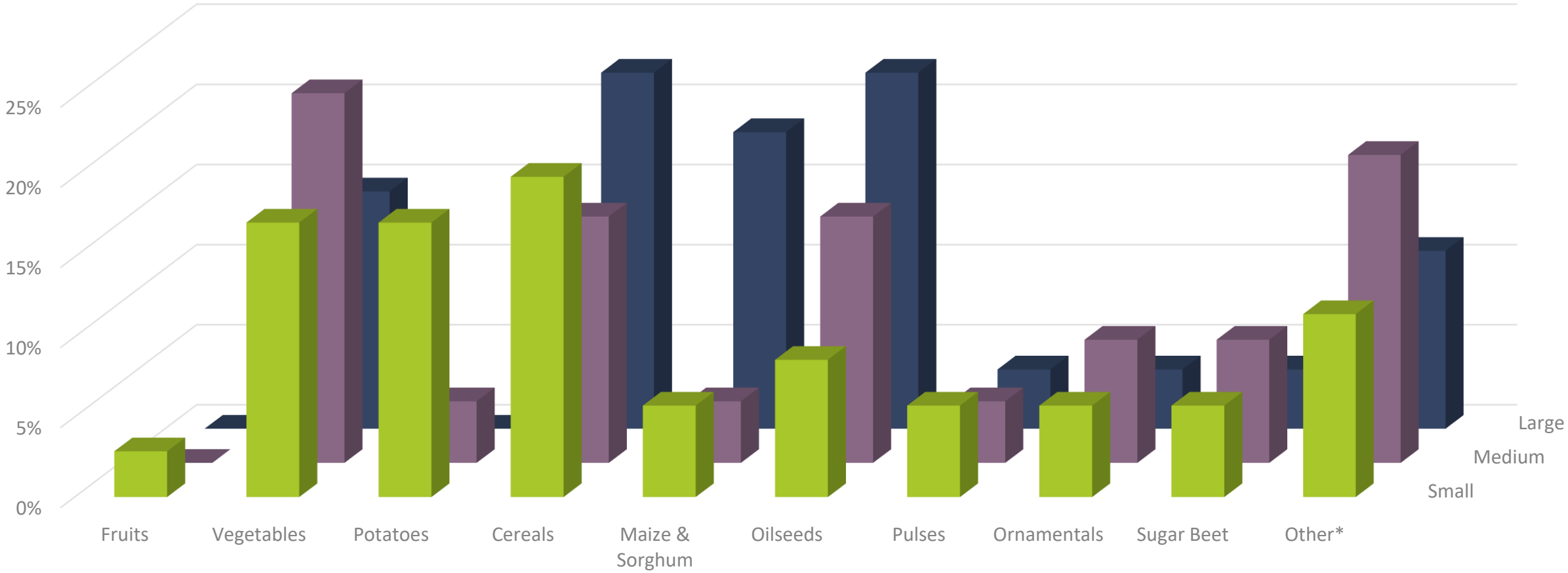


FIGURE 8 | Crops/crop groups for which companies apply NBTs. Percentages relate to the total number of replies of companies grouped according to company size (multiple answers possible). Total number of replies: small companies, 35; medium-sized companies, 26; large companies, 27. In addition, companies mentioned the following crops under "other*": soybean, cotton, rice, forage crops (grasses, legumes), chicory, model plants for gene discovery research, poppy for pharmaceutical industry, peanut, ornamentals as food and medical plants, hemp, dandelion, legumes, and stevia.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Which kind of goal/trait does your company address in R&D with NBTs?

Comparison of the Euroseeds data with the data from Modrzejewski et al. (2019)

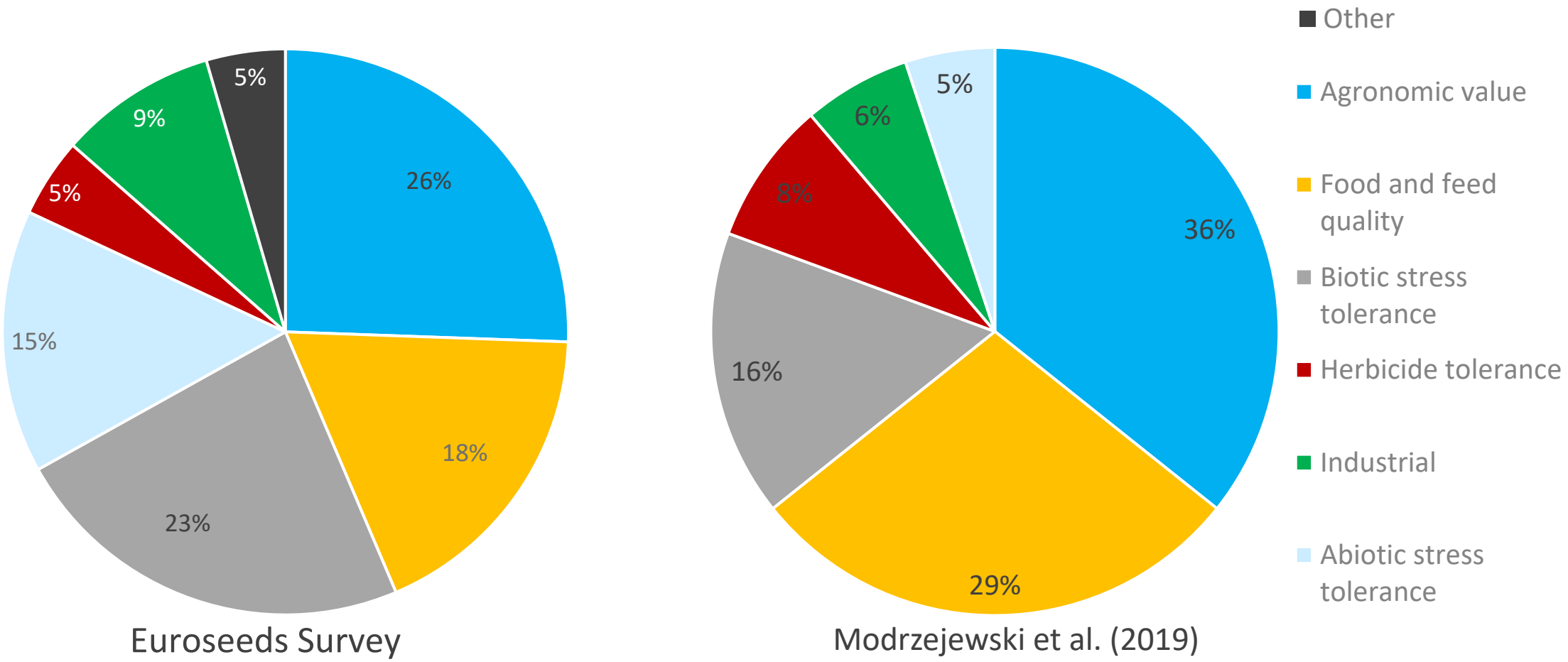


FIGURE 14 | Comparison Euroseeds results as to activity of companies in NBT-related R&D with respective breeding goals compared to the results from Modrzejewski et al. (2019) which shows an assessment of market-oriented applications of crops with nutritionally, agriculturally or industrially relevant traits from published studies between January 1996 and May 2018. Traits mentioned under "other" relate to flavor, shelf-life, digestibility, ornamental value (flower color), and post-harvest quality.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

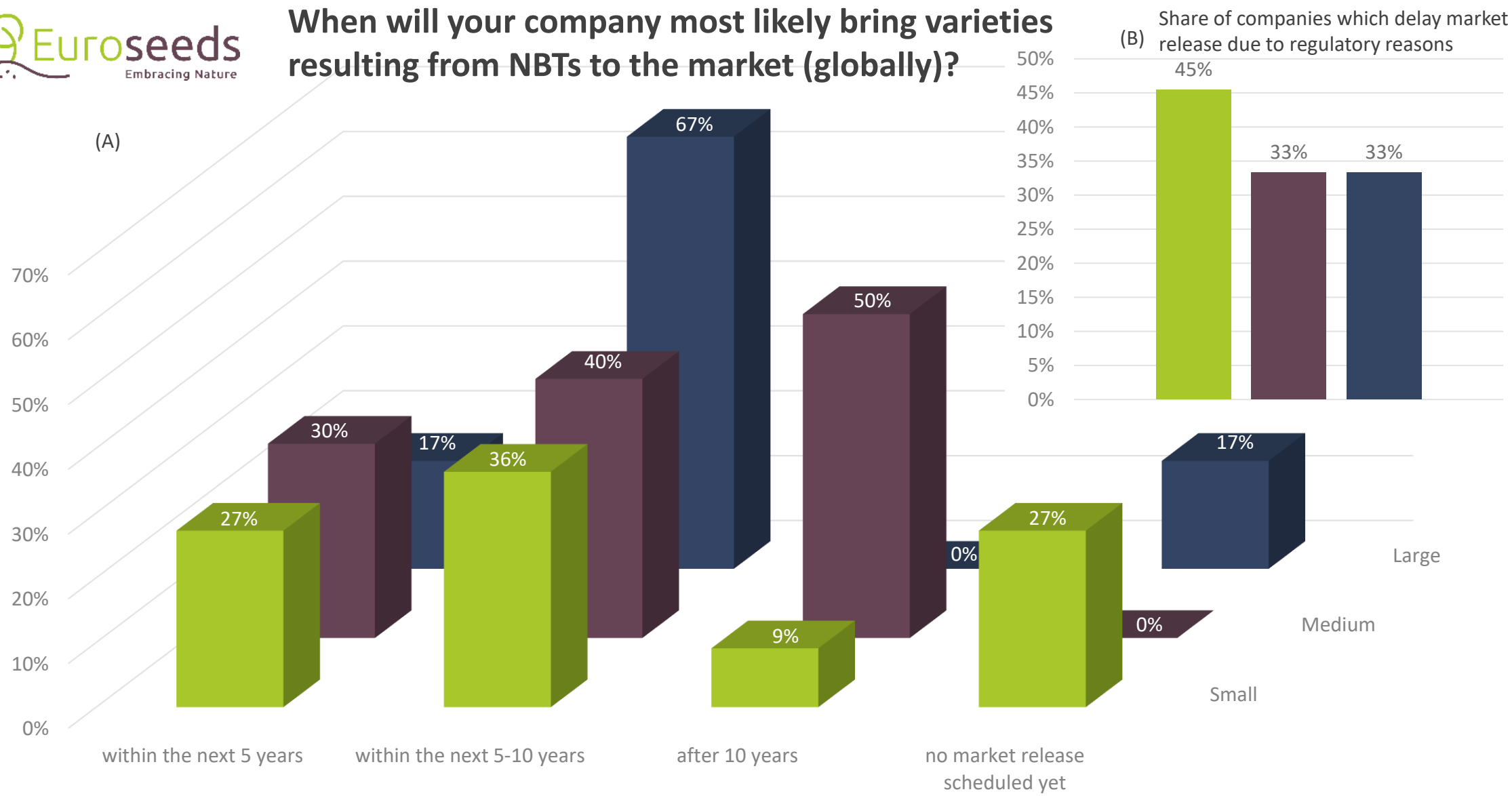


FIGURE 10 | (A) Potential market release (globally) for products resulting from NBT-related R&D activities as to the percentage of replies according to the total number of companies per company size group (multiple answers were possible). Depending on the respective crops companies might envisage different timelines for product releases. (B) Percentage as to number of companies according to size that answered in addition that their intended market releases are delayed due to the current regulatory situation (e.g., GMO regulation in the EU).

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Did your R&D activities for applying NBTs change after the 25 July 2018 ECJ ruling on mutagenesis breeding ?

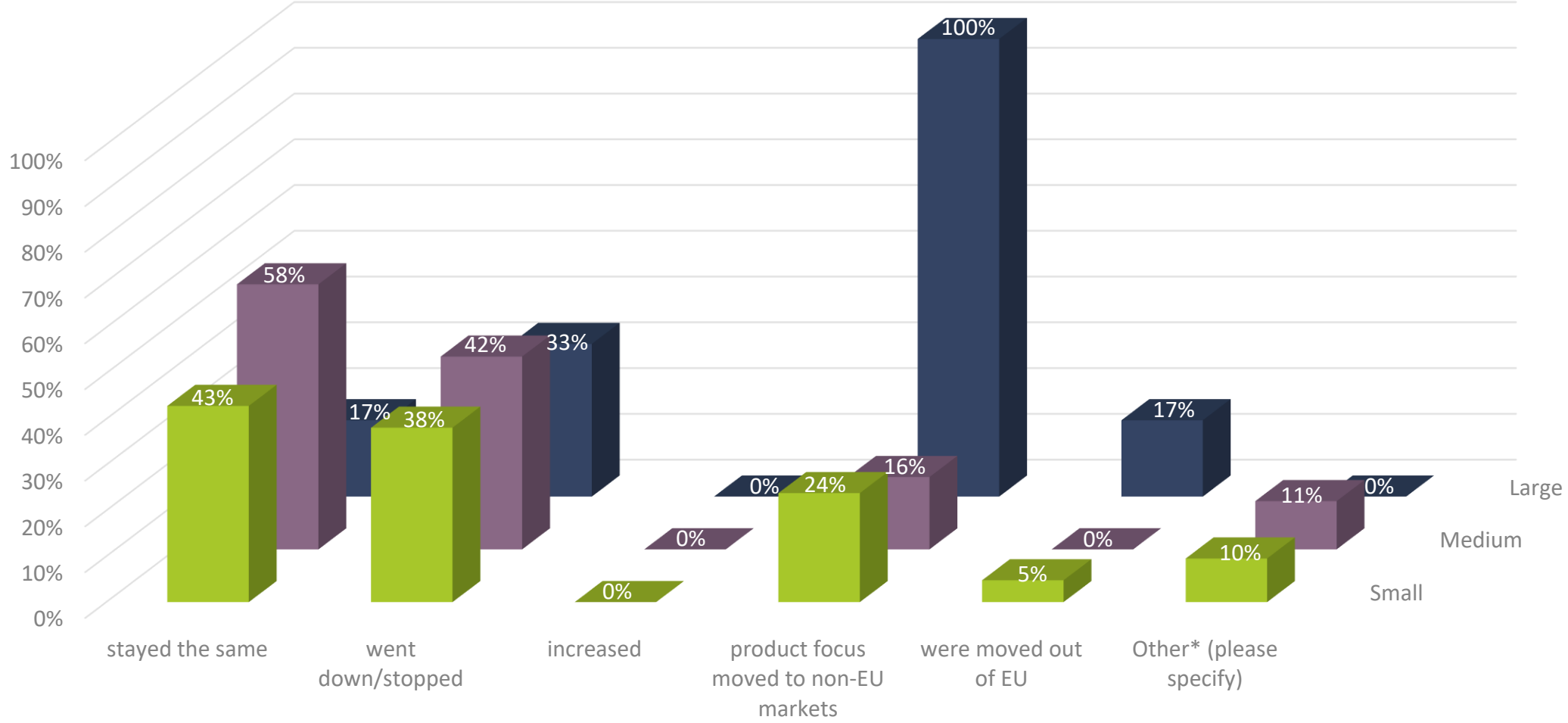


FIGURE 11 | Effect of the ECJ ruling on NBT-related R&D activities of companies. Percentages as to the total number of companies per company size group. Multiple answers were possible, because the situation within companies might differ depending on the crop species and the projects. In addition, and under "other*" companies commented: all projects were re-evaluated, some projects were put on hold and activities were modified in specific cases. These include discontinuation, reduction of scope, change in market focus and re-evaluation of timelines; We will keep watching the future transition in the EU; some programs did not start as a consequence of the ECJ decision; After the decision of the ECJ, we decided to use the technology only for gene discovery and validation and not for product development with partners anymore.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Please indicate the top three factors your company sees as most significant in limiting the potential of the use of new breeding methods?

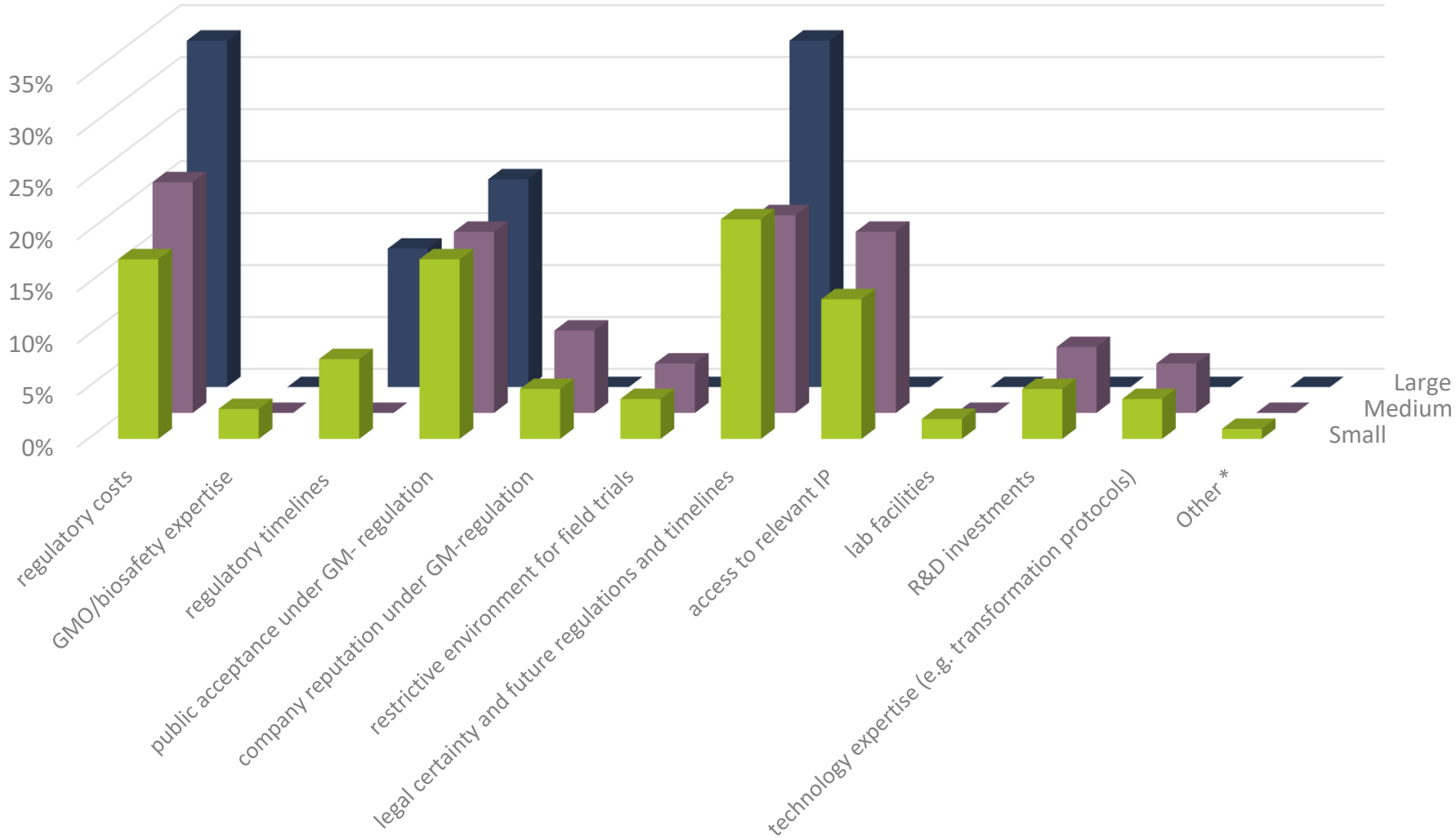


FIGURE 12 | Priority factors that companies regard as most significant as to negatively influence the potential use of NBTs in their breeding programs (3 answers possible). Percentages as to the total number of replies of companies grouped according to company size (multiple answers possible). Total number of replies: small companies, 104; medium-sized companies, 63; large companies, 15. The number of replies for small companies exceeds the number of possible answers (number of small companies multiplied by three) by 2 replies, because 2 companies provided 4 replies without indicating the top three factors. The number of replies for medium and large companies is smaller than the expected. Three medium sized and one large company indicated less than three priority factors. Under "other*" one organic seed company mentioned restrictions due to private organic standards that exclude using NBTs.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Would you invest in product development with NBTs for the EU market, if the varieties would not be regulated as GMO, but as conventional varieties?

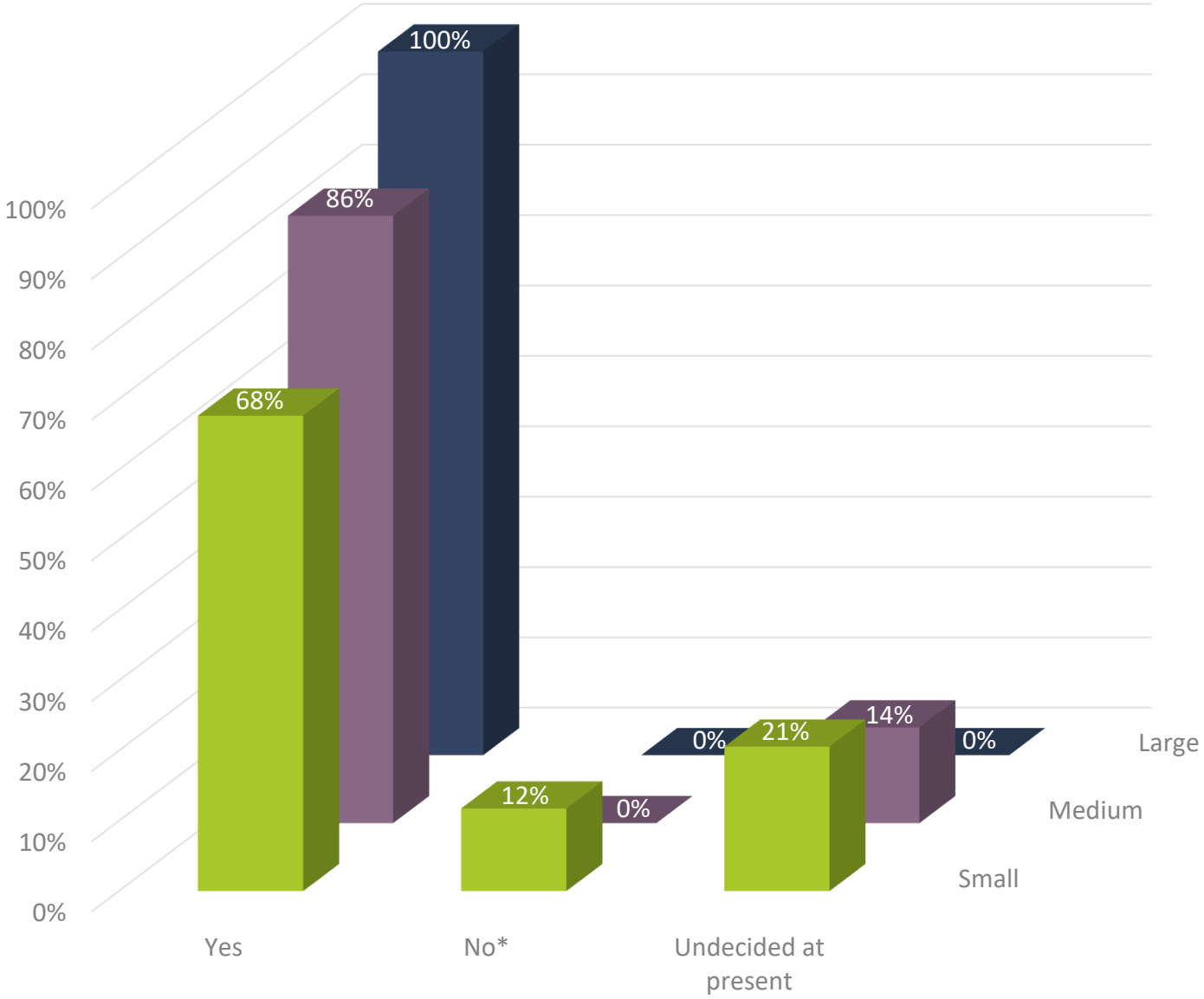


FIGURE 13 | Companies' interest to invest in product development with NBTs for the EU market, if the resulting plants would not be regulated as GMOs, but as conventional varieties. Percentages as to number of companies per company size. Companies that indicated to not be interested in product development (*) were all companies with a main/exclusive focus on the organic seed market.

Source: https://www.frontiersin.org/articles/10.3389/fpls.2020.582011/full

Examples and benefits of (targeted) mutagenesis breeding products

Waxy corn or potato

- Less chemical and energy use during starch processing
- Clean Food Label

Non-browning mushroom

- Less food waste

Fungi - resistant wheat

*Pilot project German Plant Breeders (https://pilton.bdp-online.de/?lang=en)

Gluten-free wheat

- Less pre-harvest losses and less pesticides
- Avoid food intolerance

High Oleic Acid Soybean Oil*

*first product on US-market (http://www.calyxt.com/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on-the-u-s-market/)

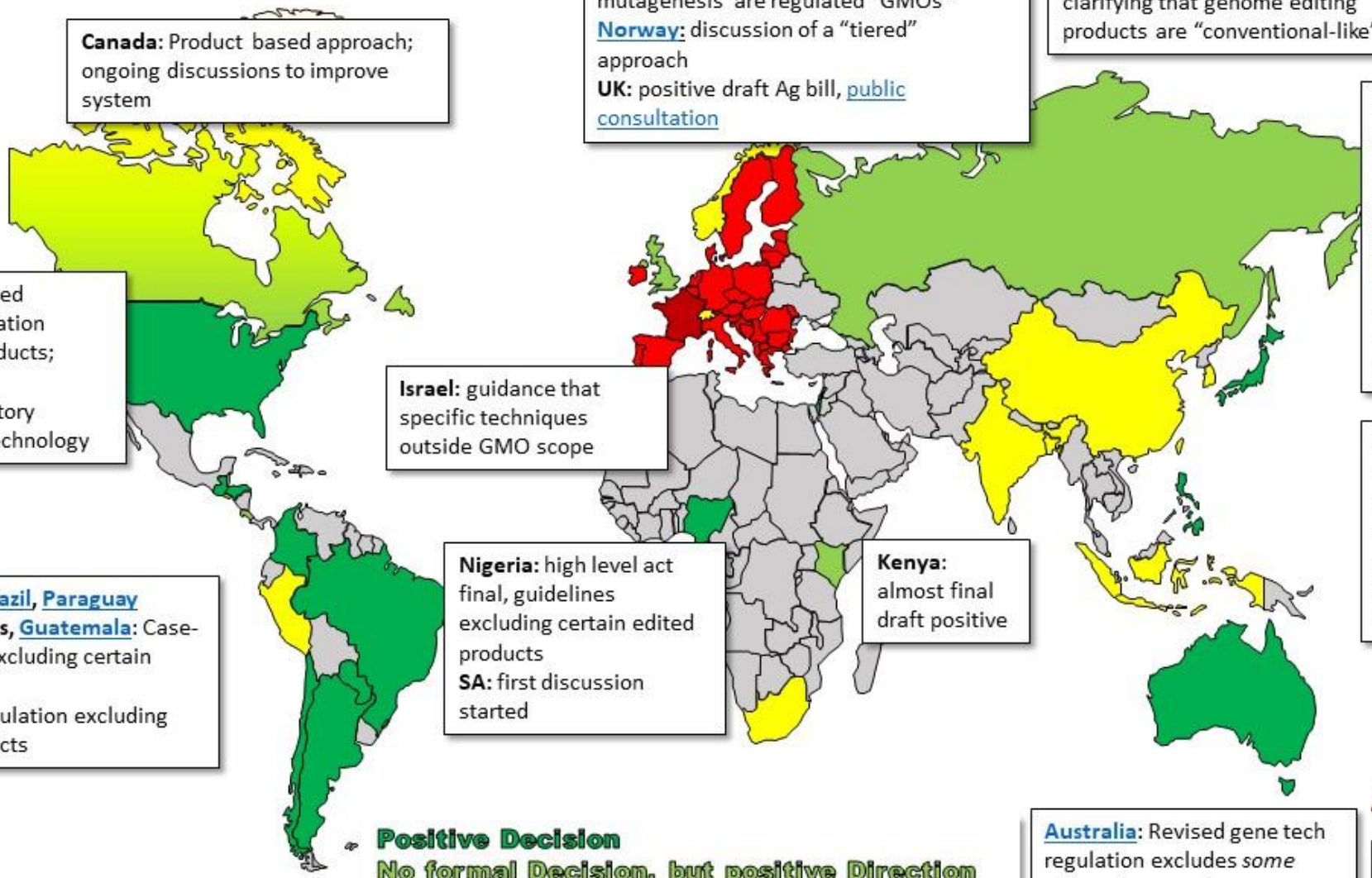
- More stable frying oil

high GABA tomato

*first product approved in Japan (https://sanatech-seed.com/en/20201211-2-2/)

- Lowering Blood Pressure – Food with health effect

Policy developments around the world (01/2021)



Canada: Product based approach; ongoing discussions to improve system

Europe: ECJ decision: all "new" mutagenesis are regulated "GMOs"
Norway: discussion of a "tiered" approach
UK: positive draft Ag bill, public consultation

Russia: decree for R&D program clarifying that genome editing products are "conventional-like"

China: unofficial "GMO-lite" proposal
Taiwan/South Korea: discussion of options
Indonesia: growing consensus to exempt certain gene editing appl.
Singapore: draft proposal to exempt certain edited products under consultation

US: Final USDA revised biotechnology regulation exempts certain products; Executive order on Modernizing Regulatory Framework for Biotechnology

Israel: guidance that specific techniques outside GMO scope

Japan: excluding certain edited products
India: draft guidelines, tiered approach, too excessive info. needs
Philippines: excluding non-transgenic products

Nigeria: high level act final, guidelines excluding certain edited products
SA: first discussion started

Kenya: almost final draft positive

Argentina, **Chile**, **Brazil**, **Paraguay** **Colombia**, **Honduras**, **Guatemala**: Case-by-case approach, excluding certain edited products
Costa Rica: draft regulation excluding certain edited products

Australia: Revised gene tech regulation excludes *some* gene editing applications

NZ: High Court decision that a few specific techniques are GMOs

Positive Decision
No formal Decision, but positive Direction
Discussion started, direction unclear
Restrictive Decision

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