Current and future market applications of new genomic techniques (NGTs)

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Advisory Group Meeting-DG SANTE , May 19, 2021

JRC Study on NGTs - Background

- In **July 2018**, the Court of Justice of the European Union (CJEU) clarified that organisms from new mutagenesis techniques fall within the scope of the EU GMO legislation.
- In **November 2019**, The EU Council requested the Commission (Council Decision (EU) 2019/1904) to submit, by **30 April 2021**, a study on the status of NGTs.
- The **JRC** was requested to provide, as part of the EC study, “An overview of current and future scientific and technological developments in New Genomic Techniques as well as of new products that are, or are expected to be marketed”.

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Links to report

https://op.europa.eu/en/publication-detail/-/publication/8940fa16-a17e-11eb-b85c-01aa75ed71a1/language-en

Scope

Sectors:

- Agriculture
- Bio-based industry
- Medical

Organisms:

- Plants (& mushrooms)
- Animals
- Microorganisms
- Human cells

Uses of NGTs:

Within the scope:

- Product/variety development (traits)
- Use as breeding tool (e.g. reproductive characteristics)

Outside the scope:

- Technology development (e.g. new/improved genome editing tools)
- Gene discovery research

Market applications review - Methodology

NGT APPLICATIONS DATABASE

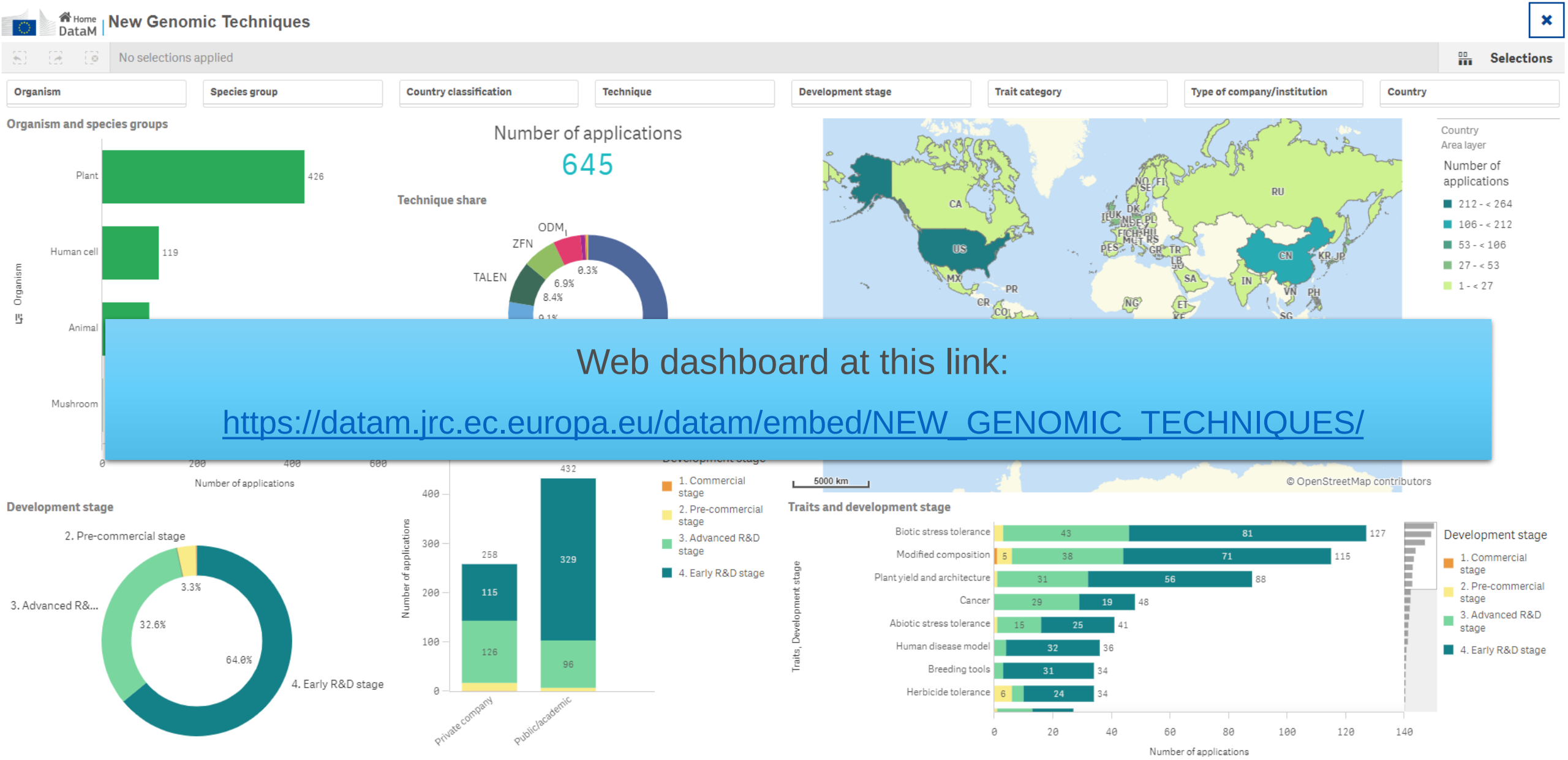
- Screening of public authorities' databases of different countries
- Search in scientific literature and datasets, including clinical trials databases worldwide
- Identification of companies/institutions developing NGT products and screening of their websites and press releases
- Expert consultation: More than 20 videoconferences with regulators and public/private technology providers from several countries worldwide
- Survey of public and private technology developers: 47 organisations participated (37 private companies and 10 public/academic organisations)
- Integration and cleaning of the data from different sources in the database

Market applications review - Methodology

The NGT applications identified were classified, using the information available, as being at the following development stages:

1. Commercial stage	NGT applications currently marketed in at least one country worldwide
2. Pre-commercial stage	NGT applications ready to be commercialised in at least one country worldwide but not yet on the market
3. Advanced R&D stage	NGT applications at a late stage of development and likely to reach the market in the medium term
4. Early R&D stage	NGT applications at proof of concept stage (i.e., testing gene targets for trait enhancement of commercial interest).

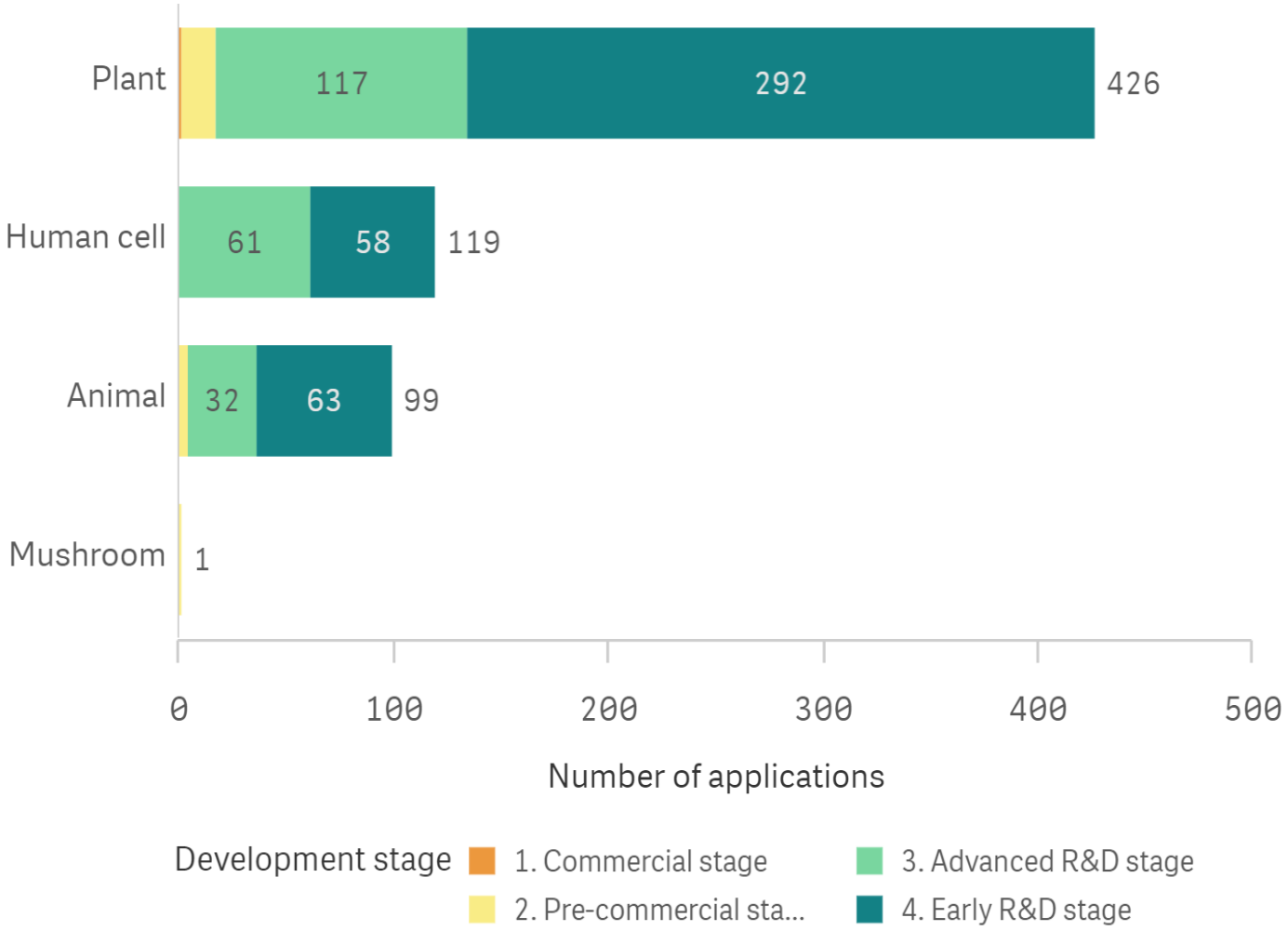
Results : web dashboard

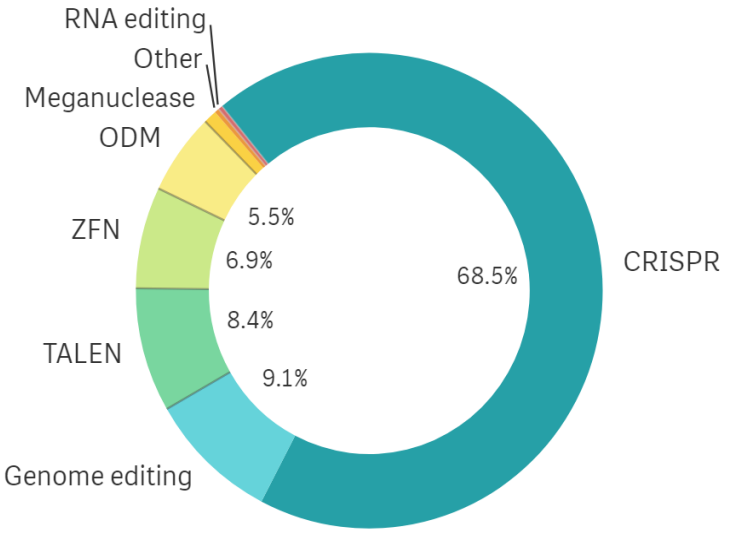


Web dashboard at this link:

https://datam.jrc.ec.europa.eu/datam/embed/NEW_GENOMIC_TECHNIQUES/

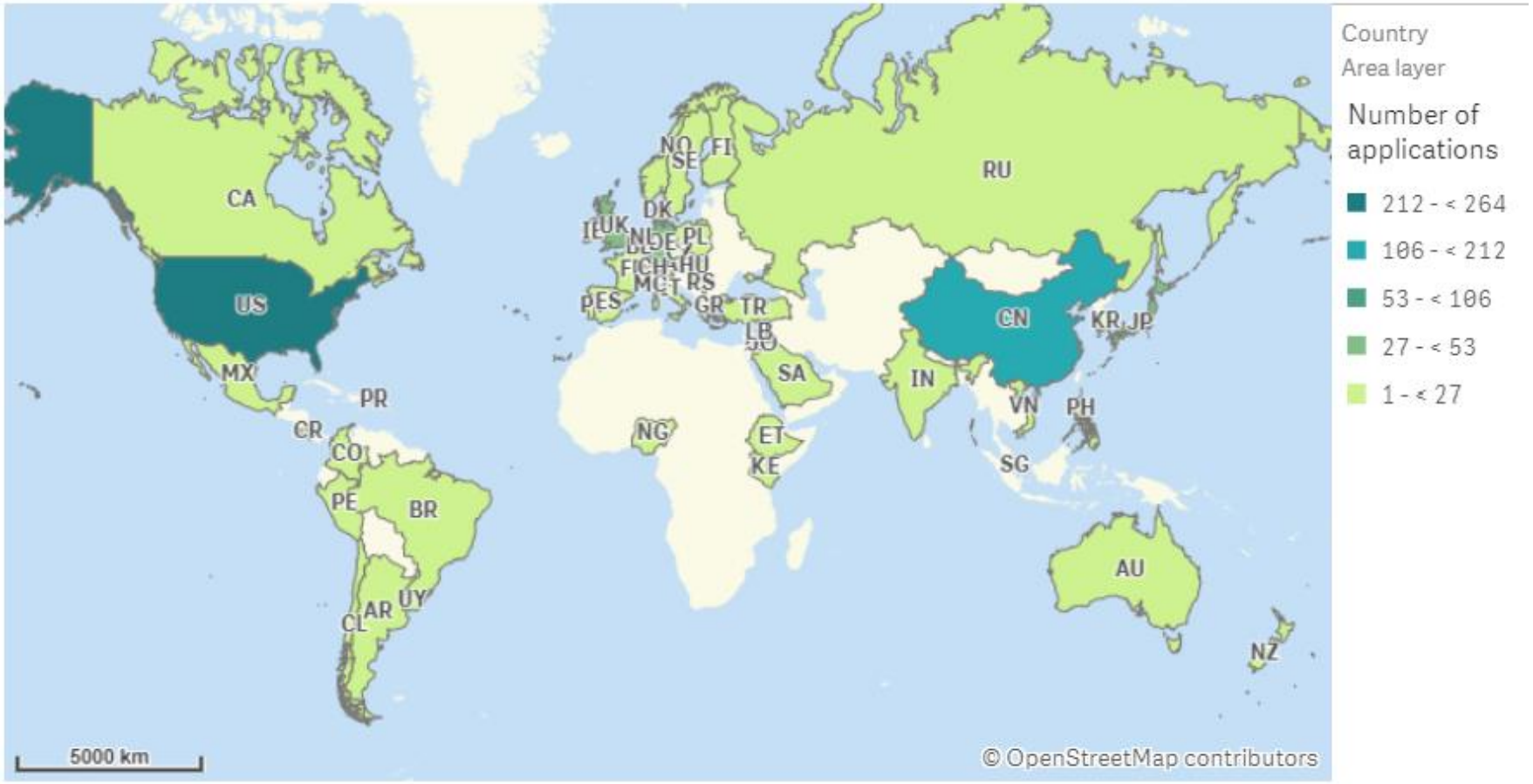
General overview of results

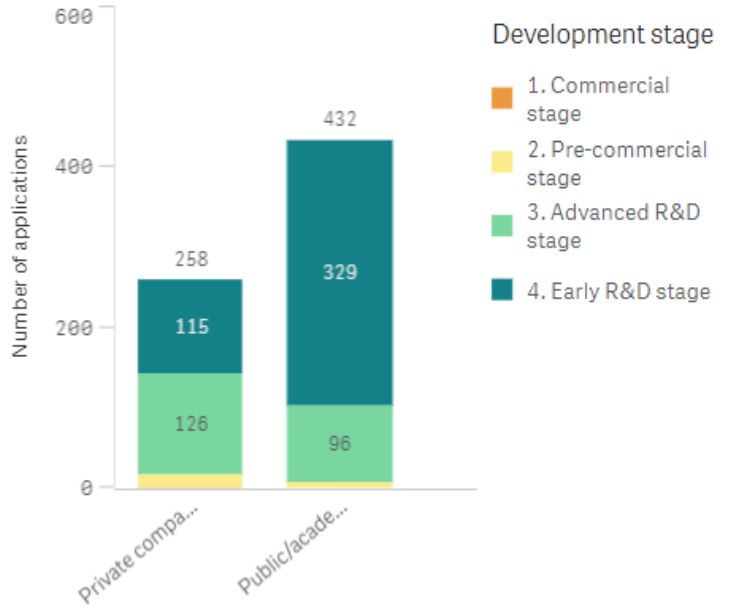




NB: Data on **microorganisms** were not aggregated in the same way, because of a different data structure and more limited availability

Breakdown by countries and public/private developers





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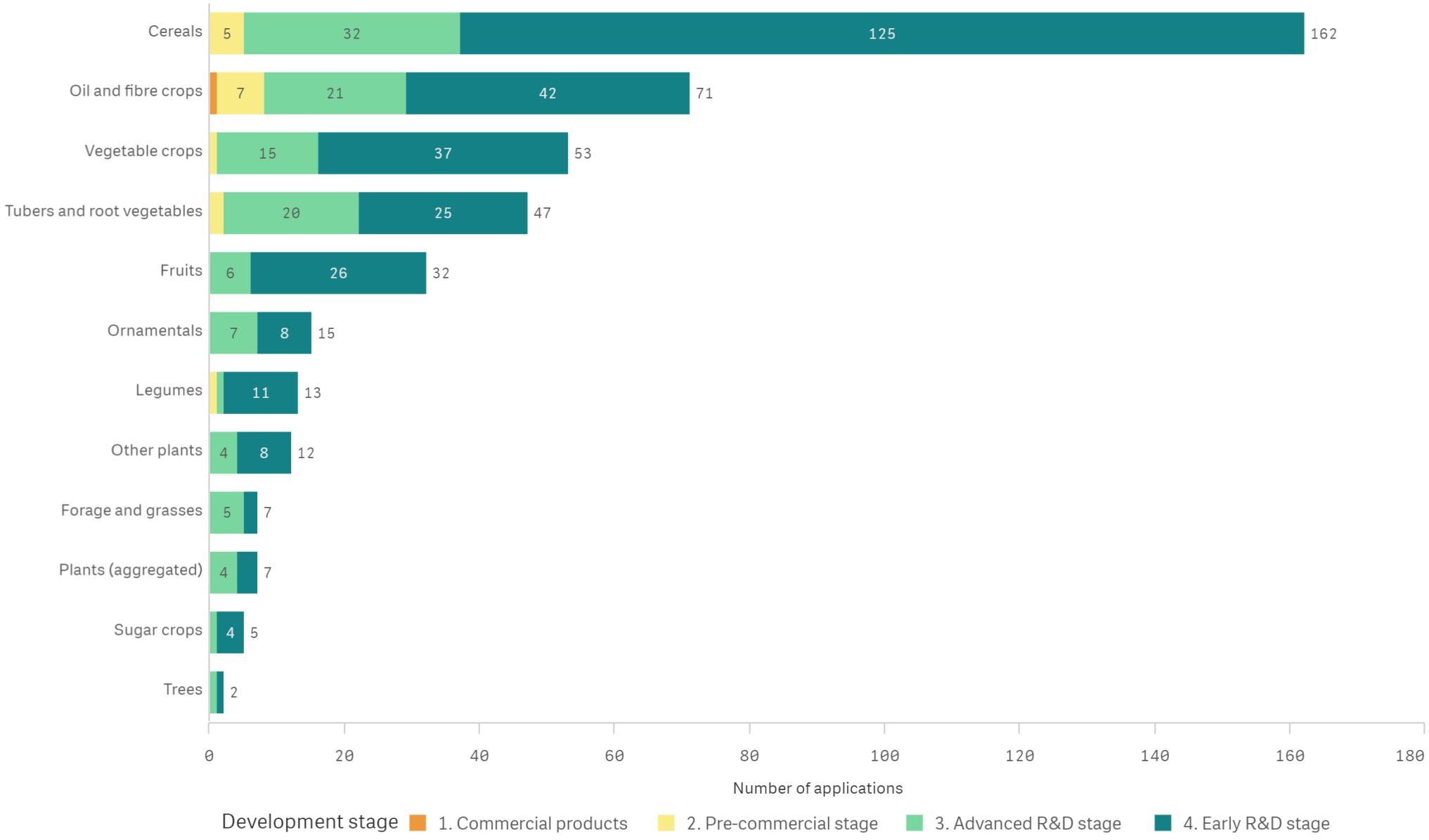
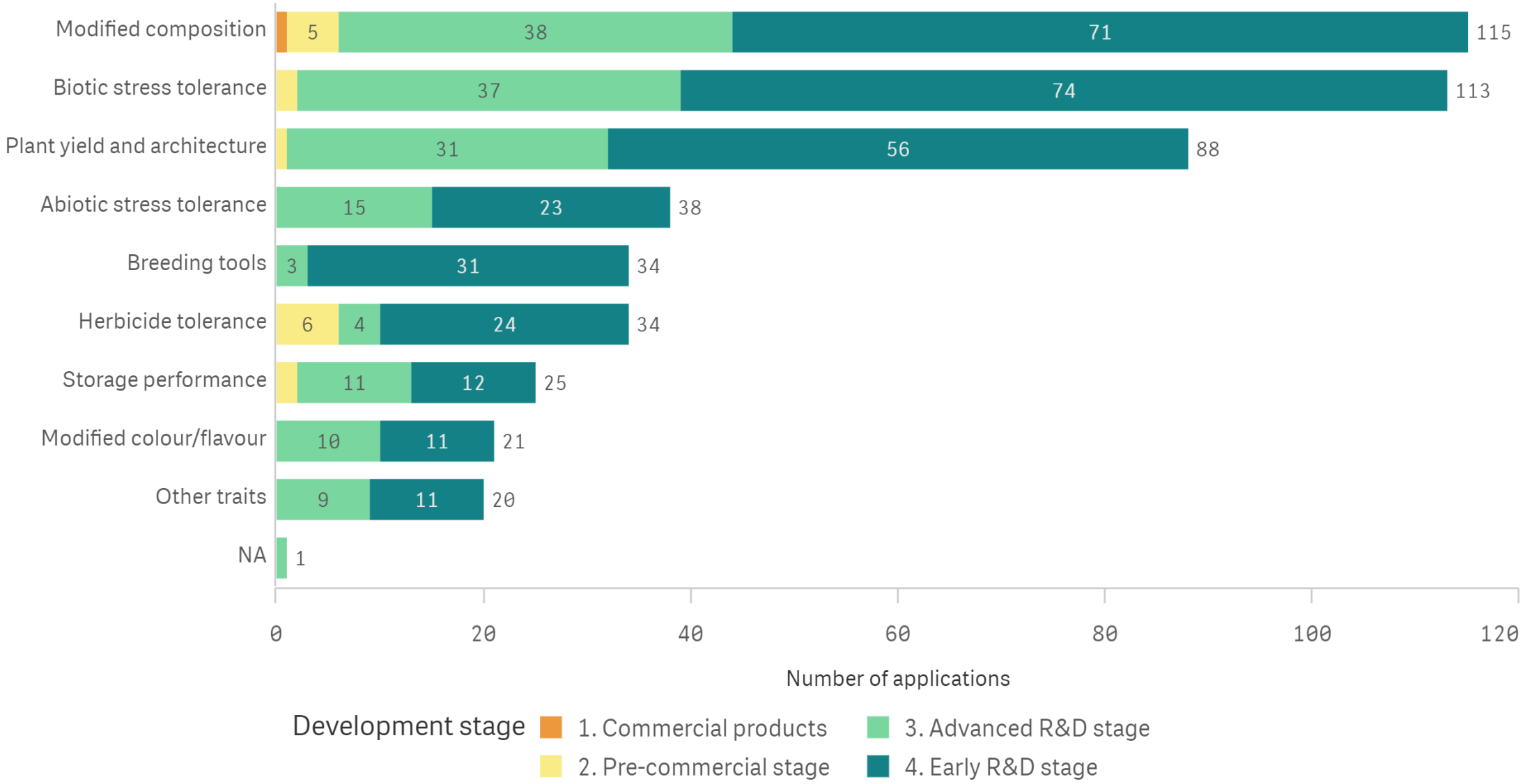
NGTs -Plants –breakdown by crop groups



NGT -plants – breakdown by traits



SOYBEAN- High Oleic Calyno

Stage: COMMERCIAL

Technique: TALEN

Trait: High Oleic (Calyno oil)

Developer: Calyxt (US)

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TOMATO- Enhanced GABA (“Sicilian rouge”)

Stage: COMMERCIAL

Technique: CRISPR

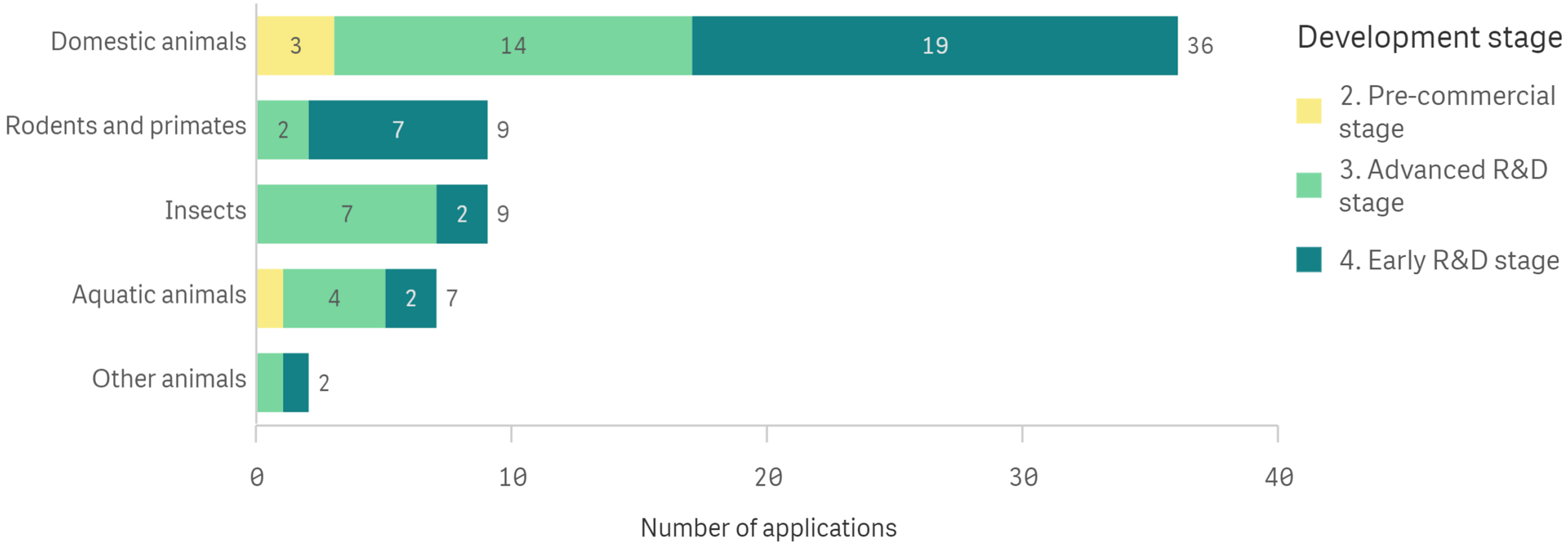
Trait: high GABA content (low blood pressure association)

Developer: Sanatech (Japan)

Results in plants/animals – developing countries

Research centre	Species	Trait category	SDN type (1, 2, 3)	Development stage
IITA	Banana	Biotic stress tolerance	SDN1	4. Early R & D stage
IITA	Banana	Biotic stress tolerance	SDN1	4. Early R & D stage
IITA	Banana	Biotic stress tolerance	SDN1	4. Early R & D stage
CIAT	Beans	Modified composition	SDN1, SDN2	4. Early R & D stage
CIAT	Cacao	Modified composition	SDN1, SDN2	4. Early R & D stage
CIAT	Cassava	Haploid techniques	SDN1, SDN2	4. Early R & D stage
ICARDA	Chickpea	Abiotic stress tolerance	SDN1	4. Early R & D stage
ICRISAT	Chickpea	Modified composition; plant yield and architecture	SDN1, SDN2	4. Early R & D stage
CIMMYT	Maize	Biotic stress tolerance	SDN1, SDN2	3. Advanced R & D stage
CIMMYT	Maize	Biotic stress tolerance	SDN1	3. Advanced R & D stage
ICRISAT	Millet	Storage performance	SDN1, SDN2	4. Early R & D stage
ICRISAT	Pigeon pea	Reproductive/flowering characteristics	SDN1, SDN2	4. Early R & D stage
CIP	Potato	Biotic stress tolerance	SDN1, SDN2	4. Early R & D stage
CIAT	Rice	Biotic stress tolerance	SDN1, SDN2	3. Advanced R & D stage
CIAT	Rice	Plant yield and architecture	SDN1, SDN2	4. Early R & D stage
IRRI	Rice	Plant yield and architecture	SDN1	4. Early R & D stage
IRRI	Rice	Modified composition	SDN1, SDN2, SDN3	4. Early R & D stage
IRRI	Rice	Reproductive/flowering characteristics	SDN2	4. Early R & D stage
IRRI	Rice	Biotic stress tolerance	SDN1	4. Early R & D stage
ICRISAT	Sorghum	Biotic stress tolerance	SDN1, SDN2	4. Early R & D stage
CIMMYT	Wheat	Biotic stress tolerance	SDN1	4. Early R & D stage
CIMMYT	Wheat	Biotic stress tolerance	SDN1	4. Early R & D stage
ILRI	Cattle	Biotic stress tolerance	SDN3	4. Early R & D stage

NGT -Animals – species breakdown



NB: NGT-derived animals are also used as disease models for gene therapy research (most common in mice) or production of human-compatible organs (most common in pigs)

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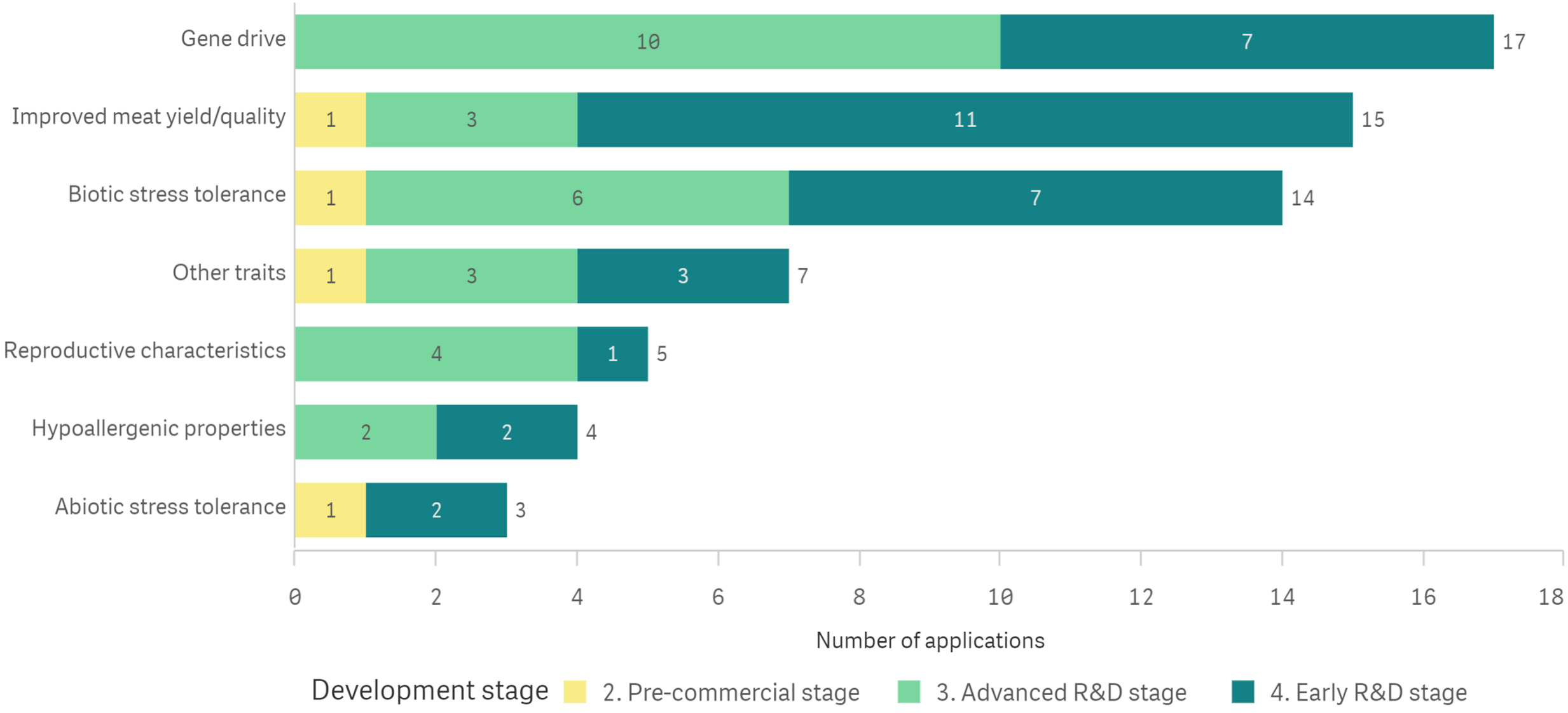
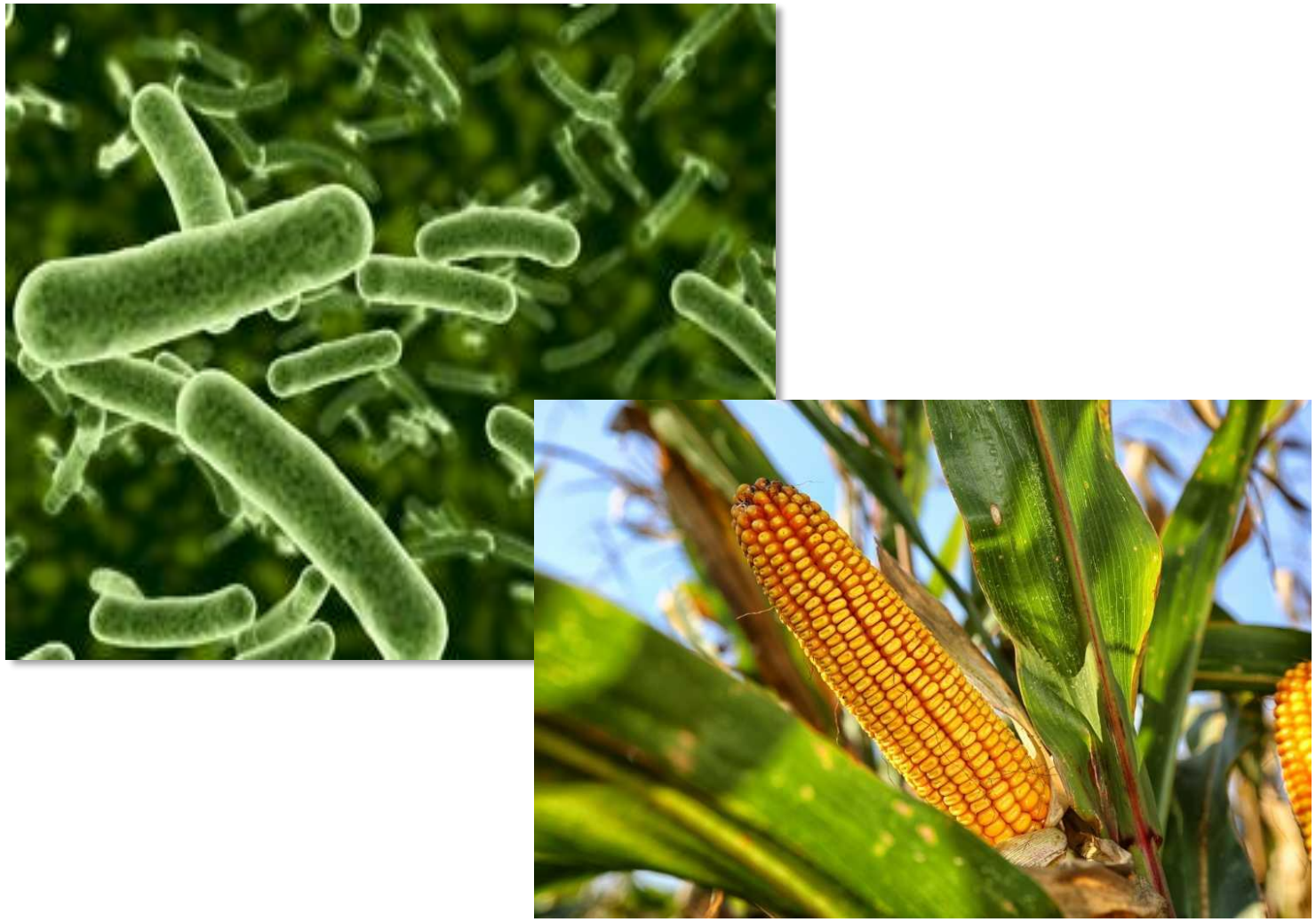
NGT- Animals- Traits under development



NGT- microorganisms for contained use

- NGTs are already applied commercially in microorganisms for the bio-production of industrial molecules and the R&D pipeline is active
- Technology developers continuously use genetic techniques (including both established and new) to improve microbial strains
- NGTs (CRISPR) are becoming standard tools in some cases
- NGTs are mainly used to knock out unfavourable genes (e.g. toxins, intrinsic antibiotic resistance or by-products)
- It is difficult to estimate the current share of microorganism strains used by bio-industry worldwide that have been improved with NGTs.
- Sectors: biofuels, bio-based enzyme production

NGT microorganism for deliberate release PIVOT-BIO- SOIL BACTERIA-N fixing



Stage: COMMERCIAL

Technique: Gene editing

Trait: Nitrogen-fixing-bacteria associated to maize/sorghum seeds

Developer: Pivot Bio (US)

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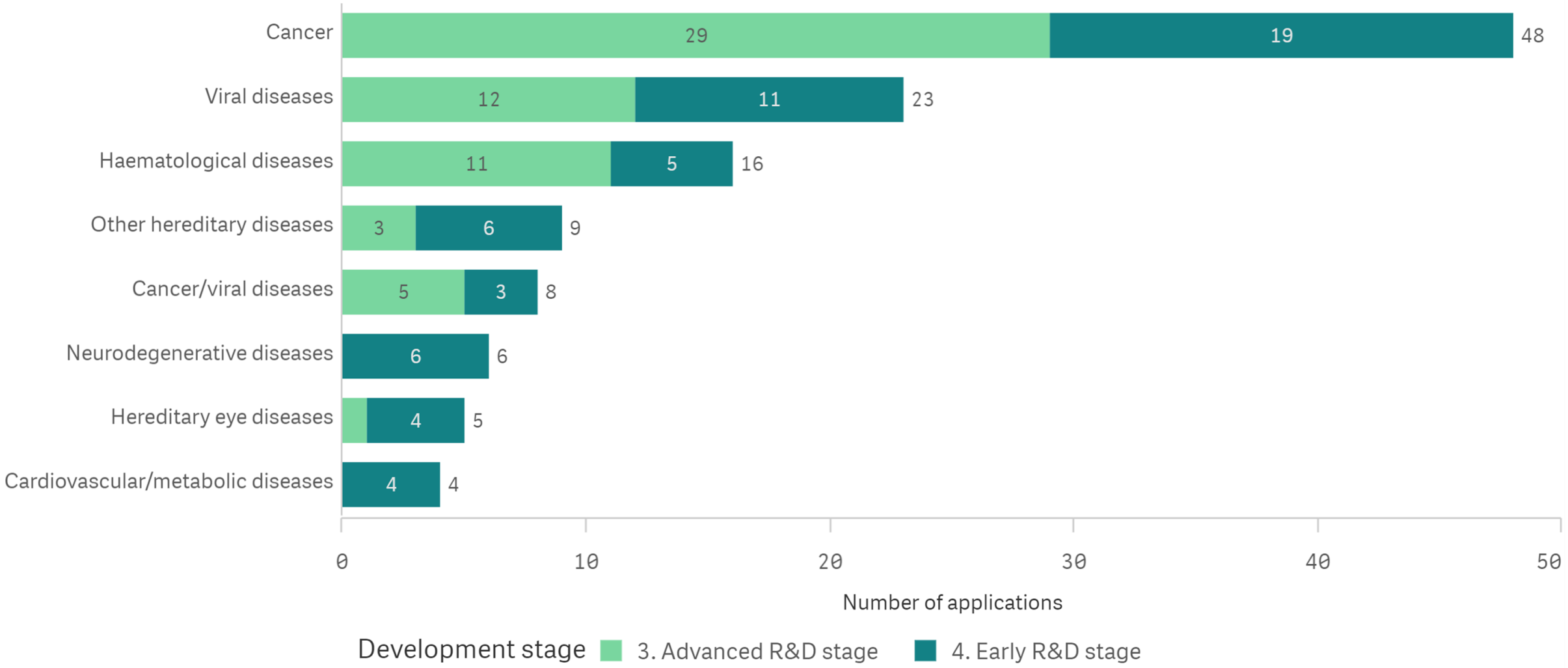
Results in human health applications - conditions



Conclusions I

- NGTs Group I (mainly CRISPR) are actively and increasingly used in agri-food, industrial and medicinal applications (over 600 items identified)
- NGTs Group I used in >90% of cases
- Few applications are marketed worldwide (two crop plants, one microorganism for release and microorganisms for contained production of industrial molecules)
- Plants the largest pipeline (>400), composition and resistance to pests and diseases the largest pipelines
- Soybean oil (high oleic) and functional (high GABA) tomato commercial
- Animals (>50 items) abundant pipeline, farm and non-farm applications

Conclusions II

- NGT now incorporated in toolkit for improving strains of microorganisms for contained use commercial (biofuels/enzymes) . Share of commercial strains w/NGT difficult to estimate
- NGT microorganisms for agricultural soil commercial (N fixation) Pipeline active
- NGTs actively used to tackle several human diseases, and many applications have already reached patients (phase I and phase I/II clinical trials).
- CRISPR/Cas is already being applied to the search for solutions for rapid detection of COVID-19 and in some therapeutic options against the disease
- United States and China are the most frequent countries of origin, particularly in the stages closest to market. The EU, particularly Germany and France, is also active in the use of NGTs. Several developing countries very active, mostly in the agricultural sector.
- Private and public sector both source of applications

Thank you

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