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PROCEEDINGS PAPER

The global need for plant breeding innovation

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Representing National Seed Associations and Companies in 75 countries, the International Seed Federation (ISF) is the voice of the global seed sector and stands for a world where the best quality seed is accessible to all, supporting sustainable agriculture and food security. ISF's mission is to create the best environment for the global movement of seed and to promote plant breeding and innovation.

In view to meet the global challenges like climate change, a growing world population and the need for resource efficient farming systems, plant breeding innovation will definitely need to play a role (Fig. 1). New plant varieties that can better stand pests and diseases with fewer inputs, plants that have stabile yield despite a changing climate and plants with increased productivity, by maximizing resource use efficiency in regard of water, land and nutrients can contribute to meet these goals (Pereira 2016).

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The plant breeding innovation tradition

Plant breeding has a history of innovation (Fig. 2). Since the discovery of the laws of genetic by Gregory Mendel plant breeders have developed improved breeding methods to make the two major steps in breeding a) increasing genetic diversity, and b) selecting the best performing plants, more targeted and efficient.

Starting with intentional cross breeding beginning of the 20th century, the first concepts for hybrid breeding were introduced during the 1920's. One major goal of breeding is to continuously make use of or increase genetic diversity. First attempts to increase genetic diversity by technical means started in the 1930's with using radiation to induce random mutations in the plant's genome followed by intense selection procedures to find valuable new traits.

Since the 1960's new methods for tissue culture improved clonal breeding and wide crosses through embryo rescue technologies as well as speeding up breeding cycles by using microspore cultures by inducing double haploid plants and with that save additional steps in backcross breeding to get homozygous plants were used.

With the new technologies of genome sequencing and the elucidation of gene functions it was possible to introduce SMART breeding methods that improve the selection process by assigning genetic markers to specific traits to more efficiently select for these traits

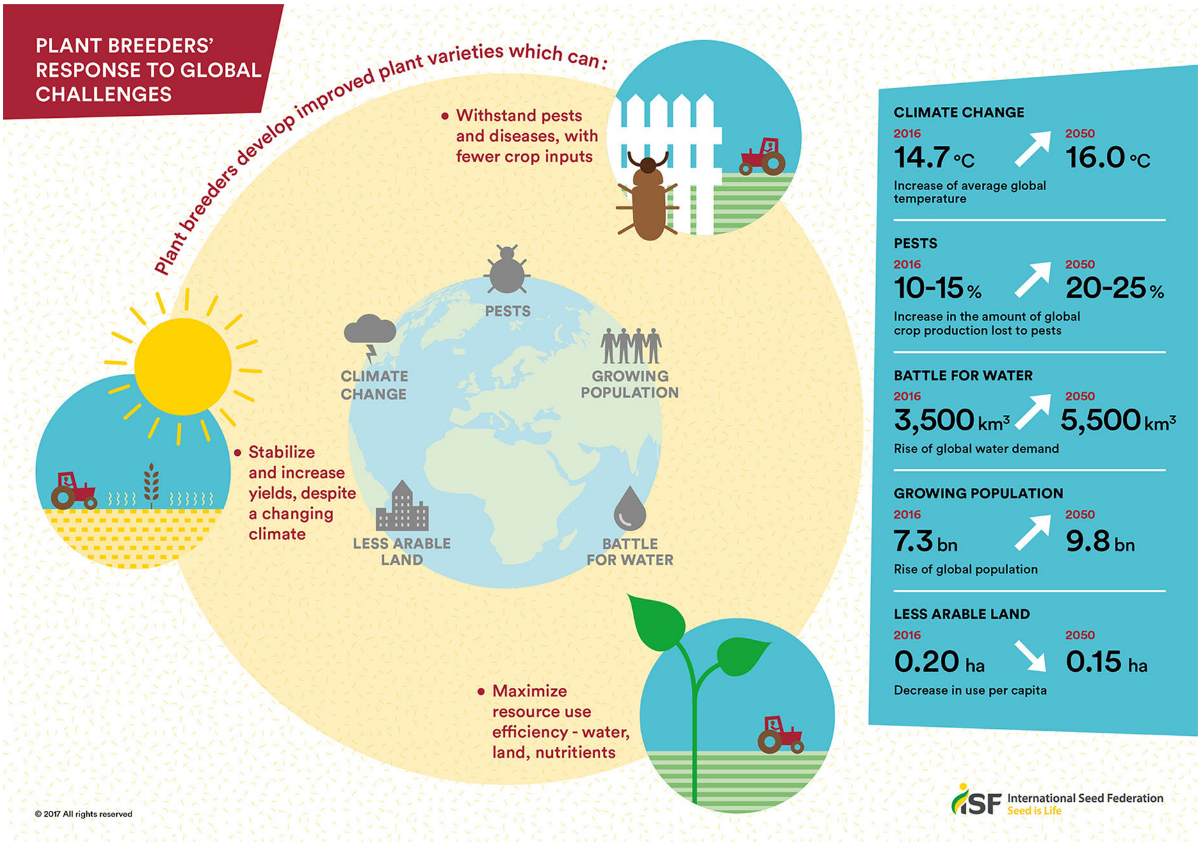

Fig. 1 The role of plant breeding in meeting global challenges

or by using genetic markers to genetically fingerprint plants and select those plants that best combine in cross- or hybrid breeding. Also, the first transgenic plants were developed.

Precision breeding as an integral part of the wholistic breeding approach

New molecular tools of precision breeding help breeders to do their job in an even more precise manner compared to the past. Especially the new tools for genome editing, like ODM (oligonucleotide mutagenesis) or Crispr–Cas provide mechanisms to not only randomly increase genetic variation as it was done by radiation or chemical mutagenesis but also to precisely introduce mutations in genes of known functions to either impair or improve their function. With this, these precision breeding tools can create plants that might also have been produced by conventional breeding methods like chemical or radiation mutagenesis. These plants would in most cases not be distinguishable with respect to the breeding methods that have been used to create these plants (Scientific Advice Mechanism (SAM) 2018). The only difference lies in the efficiency of the process.

All these molecular precision breeding tools can help to improve specific traits, but they need to be integrated into the breeding cycle (Fig. 3). Plant breeding always takes a wholistic approach by looking at all relevant agronomic characteristics. A plant that has an improved pest resistance, but does not perform in yield characteristics or quality, is of no value to the breeder and farmer. This is why -despite the increased efficiency and speed of improving single characteristics by precision breeding methods- it will not release the breeder from testing his candidate varieties in the field over several years and locations to check the

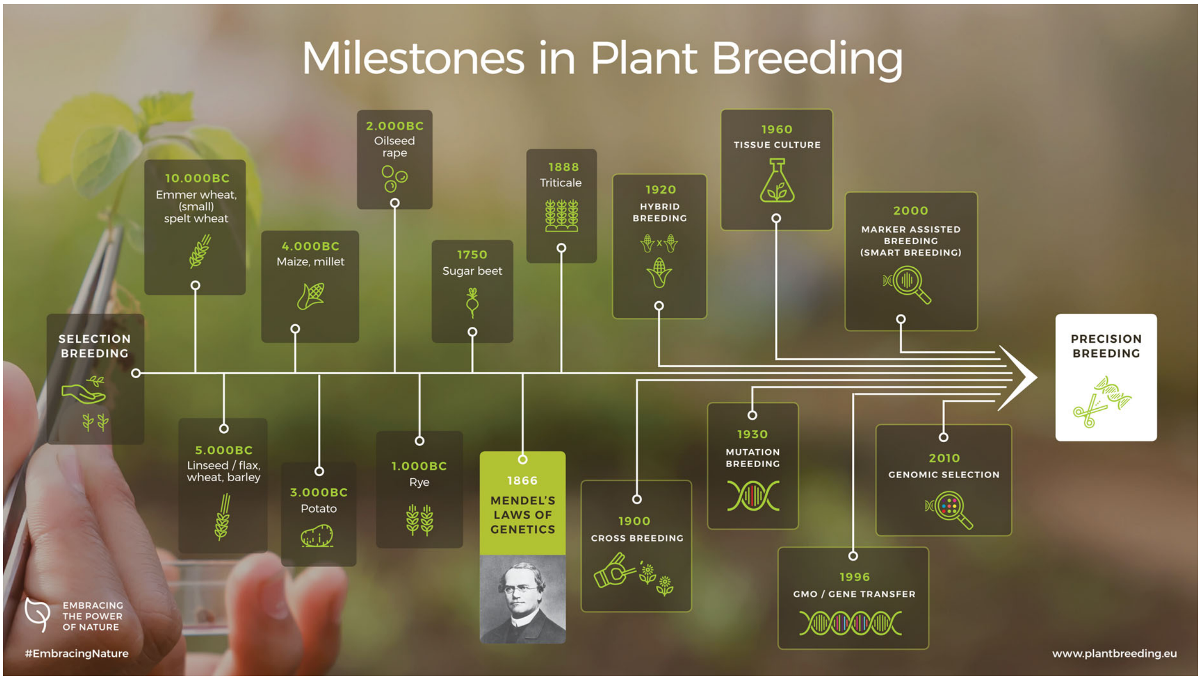

Fig. 2 Milestones in Plant Breeding

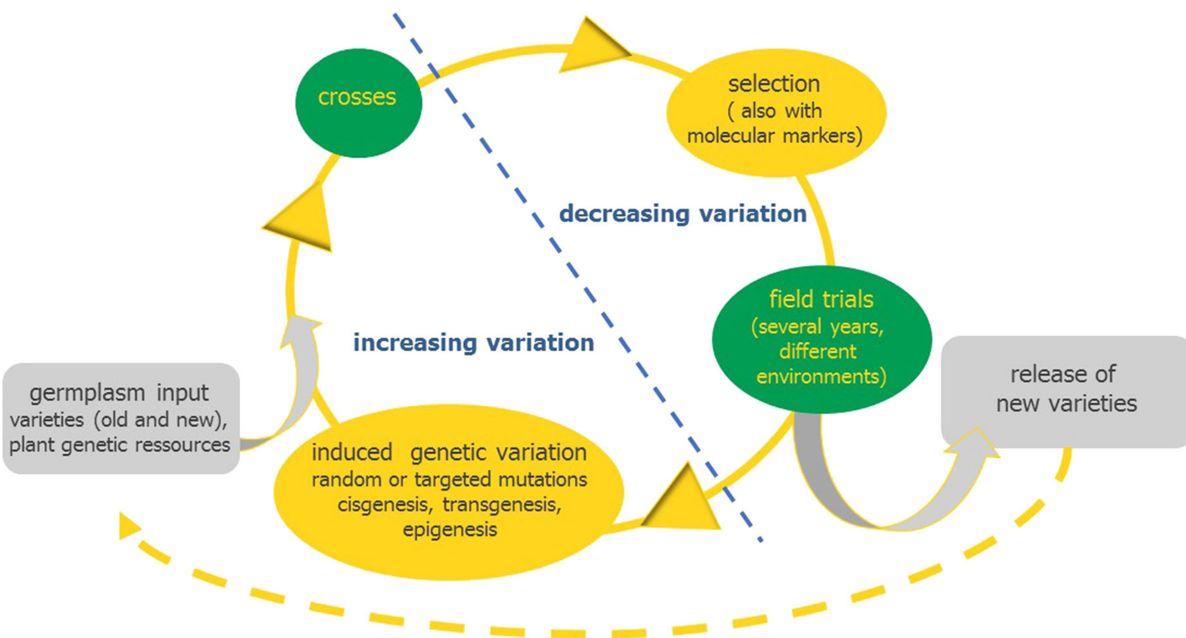

Fig. 3 The Plant Breeding Innovation Cycle

overall agricultural performance of a potential new variety.

The general breeding goals do not change

Despite the use of improved breeding tools, the general goals in plant breeding stay the same. Breeding is about improving and stabilizing yield, quality and resistances against biotic and abiotic stresses. First concrete examples for the application of precision breeding tools from scientific literature show the diversity of characteristics that are addressed: baking quality in barley and gluten reduced wheat (Sanchez-Leon et al. 2018), improved fatty acid compositions in soybean and camelina (Jiang and Henry 2017), improved shelf life and non-browning in potatoes and mushrooms (Waltz 2016); improved starch quality in rice, corn (1DB8FB71-1117) and potato (Andersson et al. 2017); increased corn and biomass yield in corn under drought stress (Shi et al. 2016), canola or rice; drought tolerance in soybean; resistances against viruses and fungi in several vegetables (Chandrasekaran and Brumin 2016) and wheat or potato as well as abiotic stress resistances, like salt tolerance in rice (Duan et al. 2016) to name just a few. A comprehensive overview can be found on the website of the German Federal Ministry of Food and Agriculture (Kohl and Modrzejewski 2018).

The concrete development of commercial varieties, but also the scientific activities in developing and improving precision breeding tools will also depend on the concrete regulatory framework in which scientists and breeding companies must act. The higher the regulatory burden, the more likely that investments in research and development will decrease or moved to more favourable regulatory environments.

Consistent criteria for the scope of regulatory oversight

Countries currently have different systems to evaluate and regulate products entering the market, as for example Genetically Modified Organisms (GMOs). This creates a patchwork of national regulations: some countries regulate specific technologies, while others regulate based on the characteristics of the final product or both. Furthermore, definitions for 'GMO', 'biotechnology','genetic engineering' and 'bioengineering' are not consistent across countries.

If different national regulations are applied to products developed through the latest plant breeding

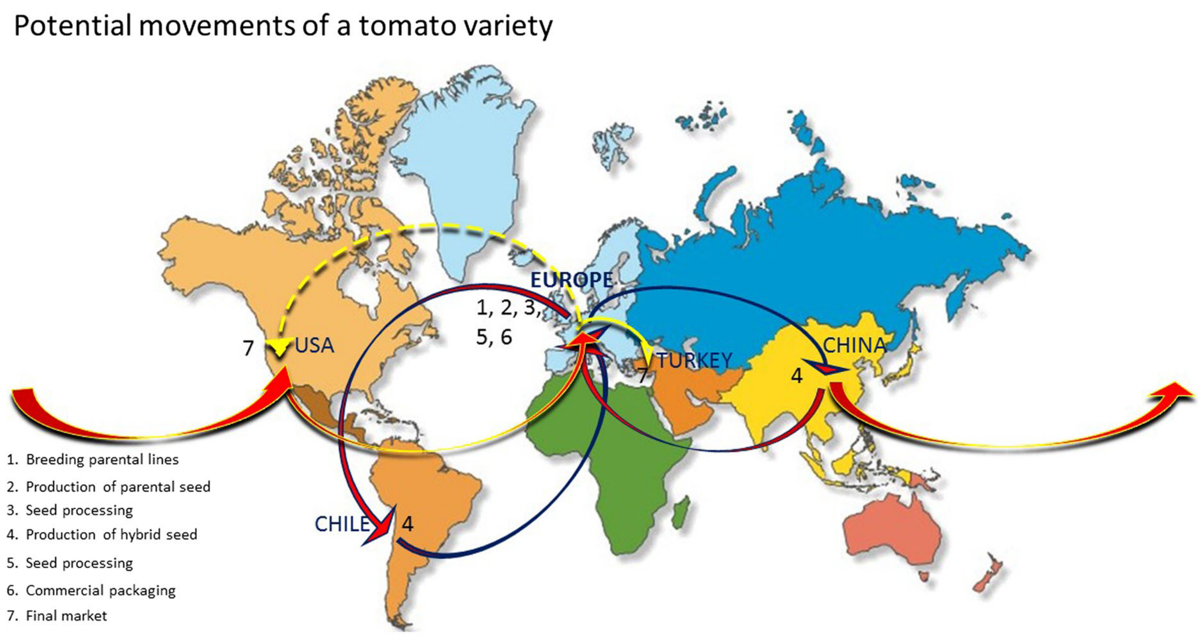

Fig. 4 The typical movement of seeds of a vegetable variety as indicated for tomatoes

methods, such as gene editing, there may be different requirements for pre-market assessments and labelling, for example. This will limit the capacity of the industry to innovate; reduce the diversity of genetic resources; negatively affect research collaborations; and hinder the movement of seed globally (Fig. 4). In addition, commodity trade disruption will occur, and agricultural development and food security will be impeded. Enforcement issues are likely to increase because seeds and commodities developed with the aid of some of the latest plant breeding methods are indistinguishable from those derived from traditional plant breeding methods or naturally occurring genetic variation.

Criteria for the scope of regulatory oversight

When considering the criteria for the scope of regulatory oversight, the question is not whether there is adequate regulation of foods and plants but rather the extent to which a specific pre-market review and clearance process is justified for plant varieties developed through the latest plant breeding methods. An underlying principle for determining these consistent criteria is that plant varieties developed through the latest plant breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier plant breeding methods.

Therefore, the international seed industry proposes the following:

The genetic variation in the final plant product would not be covered under the scope of existing biotechnology/GMO regulations for plants if

a. 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;
b. The final plant product solely contains the stable insertion of genetic material from sexually compatible plant species, or;
c. The genetic variation is the result of spontaneous or induced mutagenesis (International Seed Federation 2018).

Process for determining regulatory status

Once countries agree on the criteria, there may be differences in how they incorporate these

criteria into current policies and regulations. For example, some countries may need to interpret definitions and others may need to redefine regulatory triggers. The second essential factor affecting the predictability of the policy approach is the process used to determine whether a product is within or outside the scope of existing biotechnology/GMO regulations. The process should be predictable and timely, taking into account existing regulatory mechanisms for improved plant varieties, such as variety registration and national seed laws and regulations. Alignment across countries can be facilitated through alignment of:

(a) definitions
(b) standard information requests needed to make determinations
(c) timelines
(d) recognition of other countries' scope decisions

Countries should take into account the global impacts that different processes may have on global seed movement, exchange and access to germplasm globally, agriculture, trade and research collaborations.

Impact of public policy-lessons from the past

The risk is to create another system of patchwork regulations and asynchronous decisions repeating some of the mistakes of GMO regulation. This would create an environment in which only the largest seed companies will have the financial capability to manage the costs related to regulation. Also, only a limited number of crops and traits would benefit from breeding innovations and the accessibility of these tools to the academic community, national agricultural research organizations, and international agricultural research centers e.g. CGIAR centers will be restricted.

The global economic activity in the seed and grain trade will decrease and research cooperation and germplasm exchange for global breeding will become more challenging.

All in all, the intended increase in agricultural productivity in a sustainable way would become more challenging.

The latest breeding methods provide opportunities to target global challenges as well as local needs and can help us achieve sustainable agricultural production and food security. Consistent criteria for a balanced regulatory oversight worldwide are a prerequisite to facilitate these opportunities.

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