New genome editing *ante portas*: precaution meets innovation

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*“To be, or not to be [GMO]? That is the question—
(...)*

*And makes us rather bear those ills we have
Than fly to others that we know not of?
Thus conscience does make cowards of us all;”*

William Shakespeare exert taken from the Hamlet Monolog (Act 3, Scene 1) could easily be transferred into the debate of modern technologies (with my own added GMO = Genetically Modified Organisms). Does today’s fear of potential risks caused by GMO makes us unable to carry out necessary actions for a better life, because we get misdirected ending up as cowards? I am sure Shakespeare would have loved to let Hamlet reflect on the precautionary principle. In these days, human society faces new social, economic and ethical challenges due to the substantial progress made in modern biotechnology. Increasing technical efficacy and decreasing costs revolutionizes the tools that science driven economies will apply to change the availability of genomes as major biological resource. The magic word “CRISPR” (Clustered Regularly Interspaced Short Palindromic Repeats) stands for a quick and deep molecular technology that opens chances and choices for plant and animal breeding, and—more challenging—the medical applications for mankind.

Nevertheless, a substantial group of concerned non-governmental organizations and political parties

is currently hampering a rapid progress in the EU. This became apparent on a high-level conference on behalf of the European Commission on 28 Sept 2017 in Brussels (European Commission 2017).¹ One important question in this respect is whether all genome edited organisms—also those who are not distinguishable from those derived from classical breeding technologies or natural recombination processes—would be classified as GMO. The European GMO legislation is applied in a way that only multinational companies can afford the high costs necessary to deliver comprehensive data packages on the food and feed sector. Only cash crops that would deliver sufficient value harvests make it to the EU market. An application for a single GMO requires regulatory costs worth of several million Euros without guarantee that such organisms could be used in agriculture, since socio-economics and other political demands can be used by EU member states to ban cultivation. There is some hope that a dialogue processes² might break the ice. Major players of the ‘concerned fraction’ also acknowledge the inherent power of the new genome editing technologies. And finally, an actual ongoing EU Court case³ might open the way for a more action than caution orientated interpretation of the law. In this respect, another just finished EU Court ruling

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¹ http://ec.europa.eu/dgs/health_food-safety/events/20170928_modern_biotech.htm (Accessed 10 Oct 2017).

² e.g. the dialogue of the German Federal Ministry of Food and Agriculture (BMEL) https://www.bmel.de/DE/Landwirtschaft/Pflanzenbau/Gentechnik/_Texte/Neue_molekularbiologische_Techniken.html (Accessed 10 Oct 2017).

³ EU Court case GMO definition, <http://curia.europa.eu/juris/documents.jsf?num=C-528/16#>, (Accessed 10 Oct 2017).

clarified the legal interpretation of the precautionary principle.⁴ My favorite paragraph laid down in the statement of the Advocate General: “*The precautionary principle justifies preventive action in order to avert risks that have not yet been fully identified or understood because of scientific uncertainty. Defined in such a broad way, that principle could be construed as encompassing a wide range of risks to a variety of interests, be it the environment, health, public security, social justice, or perhaps even morality. However, if such a broader perception were to prevail, the difficulty then becomes how to determine where to draw the line so that the precautionary principle does not turn into a universal incantation to block innovation. By definition, innovation implies novelty in relation to the extant knowledge*”. It is important to notice that the EU Commission is actually introducing the innovation principle into EU regulation which will interact with the precautionary principle.⁵

Past experiences with GMO demonstrated that authorized GMO are safe for both human/animal health and the environment since no technique-specific risk has been identified within the comparative approach.⁶ Hitting the brakes for a complete ban of genome editing calling upon the precautionary principle is not a realistic option, and we need a concerted action on how modern biotechnologies should be applied in both a cautious and innovative way. It is definitely not only a technological but also a social and ethical debate. For example, the German Ethics Council urgently recommends an international debate on germline interventions in humans in order to establish binding global rules as soon as possible.⁷ For plant and animal breeding, it is time for a reformation of a dogmatic precautionary principle.

Dogmatism is calling the absence of risks before any further action (and progress) might happen. However, there is no riskless activity in human life: Taking no action by avoiding any change or undifferentiated application of strong law interpretation might very likely increase the risk of food insecurity and socioeconomic disasters.

Our environment is constantly changing by the increasing number of humans followed by their impact on physical, chemical and biological resources. Technical solutions will support urgent actions against natural and man-made disasters like global climate change, poverty, epidemic plagues and political conflicts. Our common future can only be guaranteed if we intelligently apply all useful technologies for both, a sustainable and a social secure use of our common water, air, soil, and biological entities. However, changing these entities is an inherent part of human evolution: Conserving a ‘non-human influenced’ nature is an ethical value in itself, but worldly innocent in a context of the free world where *Homo sapiens* are the major force on earth. One brand-new genome editing is ‘Gene Drive’ (see article by Tom de Jong in this issue). This molecular technique is one of the tools currently evaluated to fight malaria.⁸ Although the views of genome editing of innovators and concerned individuals might be diametrically opposed, their goals may be quite similar. Concerned non-governmental organizations are fully responsible for delaying the application of technologies that can be helpful, and I have hope that there is sufficient conscience for courageous solutions and innovative visions that are not poorly driven by fear.

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⁴ EU Court decision Mon810/Italy, see <http://curia.europa.eu/juris/documents.jsf?num=C-III/16#>, (Accessed 10 Oct 2017).

⁵ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017DC0479> (Accessed 17 Oct 2017).

⁶ https://ec.europa.eu/research/biosociety/.../a_decade_of_eu-funded_gmo_research.pdf (Accessed 10 Oct 2017).

⁷ <http://www.ethikrat.org/files/recommendation-germline-intervention-in-the-human-embryo.pdf>, 23 Sept 2017 (Access 9 Oct 2017).

⁸ <https://www.gatesfoundation.org/What-We-Do/Global-Health/Malaria> (Accessed 10 Oct 2017).