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Gene technology in a sustainable future

Summary

Genetic techniques are developing at a high speed, both in Norway and internationally. New methods and approaches are continuously advancing and are becoming increasingly relevant in various areas of society. This includes products and organisms used in pharmaceuticals, and increasingly in food and feed. At the same time, the Norwegian Gene Technology Act has largely remained unchanged since 1993. The Norwegian Public Committee on Gene Technology (hereafter the Committee) was tasked with updating the knowledge base by carrying out a broad review across various disciplines to answer questions related to the production and use of genetically modified organisms in different areas of society. The Committee had a broad composition spanning various professions and sectors in society, and as such, represents different views on gene technology. The Committee has looked at how current and future policies and regulations regarding gene technologies, health and environmental technologies, food production and industry, can be adapted in line with today's knowledge base and the new opportunities posed by advances in gene technologies.

The Committee agrees that any new proposal for regulating products developed with gene technology should include all living organisms, i.e. plants, animals and microorganisms. Furthermore, the Committee believes that the regulation should promote the development and use of sustainable products, include assessment of the properties of the product or the organism, take into account consumer interests and transparency, and stimulate research and innovation. Although the Committee agrees that these are all central considerations for gene technologies, there is disagreement on several points related to how to implement these considerations in future policies and regulations.

The entire Committee supports the assessment of sustainability, benefit to society and ethical justifiability as an important part of the assessment of living GMOs under the current Gene Technology Act. However, the Committee concluded that the assessment of these criteria should be adapted. In a consensus recommendation, the Committee proposes that ethical justifiability be understood as an overarching concept that includes sustainability and societal utility. Furthermore, they propose that ethical justifiability is assessed according to four central principles; utility, sustainability, fair distribution and transparency. The Committee recommends that this assessment should apply to both living GMOs and products derived from GMOs. In order to contribute to increased innovation, the Committee recommends that field trials under the Gene Technology Act be exempted from this assessment.

There are thus several points on which the Committee is relatively in agreement, but there are also key differences in the views of the majority and the minority of the Committee on what should be regulated and how. This relates to what types of genetic modifications should be covered by the GMO regulations, and the type of assessments to be carried out. The points of agreement as mentioned in the section above on ethical justifiability, therefore apply to organisms and derived products that both the majority and the minority believe should be covered by the GMO regulations. As for how much emphasis is to be put on ethical assessments for imported products, the Committee is divided.

For assessments of GMO medicinal products for human use, the Committee members are largely in agreement. The members unanimously recommend that the main responsibility for clinical trials of GMO medicinal products for human use should lie with the Norwegian Medicines Agency and that some regulatory streamlining should be introduced. The Committee's assessments here largely correspond to the current regulation, which was changed during the Committee's term. The Committee is divided in its recommendations regarding changes beyond the current regulation, including issues of public consultation and certain aspects of the regulation and management of clinical trials of GMO medicinal products for animals, and what legislative framework should cover GMO medicinal products. The recommendations on GMO medicinal products are elaborated in chapter 12 of the report.

Discussions about the risks posed by organisms developed with gene technologies and how risks should be assessed and handled during regulatory decision-making, have both been an engaging and time consuming topic for the Committee. In particular, the discussions have focused on organisms developed with new genomic techniques (NGTs) intended for environmental release and food production, which

include targeted genetic changes within the species or with species capable of interbreeding. The Committee members have different opinions on how risk aspects of gene technology and new genomic techniques should be understood and what types of knowledge should be emphasized. The majority of the Committee members believe that the risk primarily depends on the product's characteristics, and that the risk of a product produced with gene technology does not differ from the risk of a corresponding product produced using conventional techniques if the genetic changes can be considered to be similar or identical. A minority among the Committee members believe that there is not a linear relationship between the technique used, the magnitude of a genetic modification, and the potential corresponding change in the organism's risk profile. This means that even small genotypic changes can have significant phenotypic or environmental consequences, and vice versa. These different perceptions of risk can be said to have been an important reason for the Committee's two separate recommendations to how to regulate and manage products developed with gene technology.

The recommendations that the whole Committee supports are referred to as recommendations from the *Committee*. Where the Committee is divided in its recommendations, these are presented as recommendations from either the *majority* (seven members: Anna Wargelius, Muath Alsheikh, Sigrid Bratlie, Trygve Brautaset, Espen Gamlund, Arne Holst-Jensen and Camilla Tøndel) or the *minority* (four members): Aina Bartmann, Ingvild Ulrikke Jakobsen, Kaare Magne Nielsen and Fern Wickson.

The whole Committee recommends changes in the regulation of organisms and products developed using gene technologies, and none of the members wish to retain the baseline option, which is defined as the current regulation and management practice. The proposals of both the majority and the minority can be regarded as a modernization of the current regulations. However, the majority proposal goes significantly further in proposing changes to the current regulatory system. The majority proposal represents a significant restructuring of current regulation and administration, while the minority's alternative represents an adaptation and updating of current regulations and practice. Both proposals are presented in their entirety in chapter 10 and are summarized below.

Recommendations of the majority

Gene technology can contribute significantly to a more sustainable future. However, today's regulations and their implementation create too many obstacles to realize its potential. The majority believes that it is ethically most proper to facilitate increased use of gene technology, and therefore proposes a significant change of direction that will provide a more predictable, risk-proportional and resource-efficient path from research and innovation to market, for products and organisms developed with gene technology.

The majority's model is intended for all types of organisms (plants, animals and microorganisms) and involves different levels for approval requirements, based on two main criteria. The first criterion is the type of genetic change, where changes within the species' gene pool - which are considered by the members to be similar to the ones that can be achieved by the use of conventional breeding methods - are classified as precision breeding (PB). The supply of new genes that are not part of the species' gene pool will still be considered genetic modification (GM) - transgenesis. Another criterion is knowledge of the trait or property that the change provides. If the trait or property has a long history of safe use or there is existing knowledge that gives a predictable low risk, the requirements for risk assessment are reduced. The majority proposes four levels of regulation, two for PB and two for GMOs. At the lowest level (PB with a known trait) only a very simplified approval procedure is required, while for the highest level (GMO with a new trait) the proposed regulation is very similar to the current regulatory regime. Ethical justifiability must be assessed for all levels.

Because the model largely equates PB with conventional breeding methods, the conditions for market access are adapted accordingly: PB products will not have special requirements for labelling, traceability or coexistence, nor will they trigger access to patent rights for the developer. Except for organisms with temporary genetic changes that have been proposed to be specifically exempted from the scope of the Act, all organisms are kept within gene technology-specific regulation to safeguard the need for regulatory review, transparency and consumer confidence.

The majority also proposes several measures to make administration more efficient and to harmonize regulations and practice with the EU: All food and feed should be managed by the food authorities and

regulated in the Food Act in line with the sector principle, as is also proposed to be applied to GMO pharmaceuticals. Furthermore, a distinction should be made between import and national production, so that rules and policies follow international trade policy obligations. Measures should also be taken to implement the EU's GM food and feed regulation in the EEA agreement. In the period prior to implementation, regulations under the Food Act should be changed so that Norway can have access to genetically modified products that have been approved in the EU. Pending full implementation, Norway can presumably modernize rules for PB faster than the EU, and thus set the standard for responsible use of gene technology in Europe. The majority also proposes a number of incentives to stimulate more socially beneficial and sustainable innovation.

Recommendations of the minority

The minority recommends maintaining the purpose of the Gene Technology Act to "ensure that the production and use of genetically modified organisms takes place in an ethical and socially responsible manner, in accordance with the principle of sustainable development and without health and environmental harm". Following this purpose, the minority places particular importance on the regulation working to ensure that nature's diversity and ecological functions are maintained prior to any deliberate release of a living GMO. To ensure this, these members believe that the environmental authorities should maintain regulatory and management responsibility for all living GMOs. The minority also proposes updating the current GMO definition in line with recent technological developments.

The minority recommends a modernization of the current regulatory system. This means that the main features of the Gene Technology Act are maintained, however a number of legal clarifications and updates, as well as simplifications of regulatory and administrative practice are suggested. The purpose of the modernization is, among other things, to better facilitate research and innovation that can contribute to sustainable products.