2018

Societal benefit and genetically modified organisms

Bioteknologirådet

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Chief Editor: Ole Johan Borge

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Address: Stortingsgata 10, 0161 Oslo, Norway

Web: www.bioteknologiradet.no

E-mail: post@bioteknologiradet.no

The Norwegian Biotechnology Advisory Board is an independent body appointed by the government, first established in 1991. The board is regulated by the Biotechnology Act and the Gene Technology Acts. In addition to providing advice on matters concerning the use of biotechnology and gene technology in humans, animals, plants and microorganisms, the board also facilitates dissemination of knowledge and public debate.

The board shall place particular emphasis on ethical and societal aspects of the use of modern biotechnology in their evaluations.

The Norwegian Biotechnology Advisory Board has 15 members, 5 deputy members and observers from 7 government ministries.

The Norwegian Biotechnology Advisory Board has a budget of 9.5 million NOK for 2018.

Bioteknologirådet

PREFACE

The Norwegian Biotechnology Advisory Board here presents the result of the project "An update of the criterion for societal benefit under the Norwegian Gene Technology Act". The Norwegian Environment Agency and the Board will use the final report as tool during the approval process, and the report contains a model for determining the societal benefit of a GMO (genetically modified organism).

The project was commissioned by the Environment Agency, and the Advisory Board was to use the guidelines on cost-benefit analysis issued by the Norwegian Government Agency for Financial Management (DFØ) in 2014 as a guide. The Board was to elaborate on and supplement the work phases described in the DFØ guidelines so that they specifically addressed the socio-economic assessment of GMOs.

The Advisory Board has on several occasions worked towards operationalising the assessment criteria societal benefit, sustainability and ethics in the Gene Technology Act. The first work was published in a report in 1999 (last updated in 2009). Parts of the report became included in the regulations relating to impact assessment pursuant to the Gene Technology Act. In 2010-2013, the Advisory Board carried out two projects commissioned by the Environment Agency, where the objective was to update the criterion of contribution to sustainable development. The work resulted in two reports on insect-resistant and herbicide-resistant genetically modified plants.

The project on societal benefit is a continuation of previous work, and provides the basis to further define the assessment criteria for societal benefit, sustainability and ethics in the Gene Technology Act. Nevertheless, it is important to realise that the final report does not necessarily provide a complete picture of what should or should not be included when evaluating the societal benefit of a GMO.

The Norwegian Biotechnology Advisory Board would like to thank the external experts Mads Greaker, Ove Jakobsen, Kristin Magnussen, Christian Anton Smedshaug and Oddveig Storstad, the Board's members Ole Kristian Fauchald, Arne Holst-Jensen and Fern Wickson, who have participated in the resource group, as well as collaborators in the Norwegian Environment Agency. We would like to thank senior adviser in the Biotechnology Board Audrun Utskarpen for leading the project, senior adviser Hilde Mellegård for finalising the work, Ida Tarjem for valuable assistance, and the Environment Agency for professional and financial support of the project.

Kristin Halvorsen
Board leader

Ole Johan Borge
Director

SUMMARY

In the report ”Societal benefit and genetically modified organisms”, the Norwegian Biotechnology Advisory Board presents a guide to societal benefit assessments of genetically modified organisms (GMOs) in Norway. The report is the result of a project commissioned by the Norwegian Environment Agency to update the criterion of societal benefit in the Gene Technology Act.

The guidelines provided in the report can be applied when working on GMO-cases, by the Board itself, the Environment Agency and others.

We have used the guidelines for socio-economic analyses issued by the Norwegian Government Agency for Financial Management (DFØ) in 2014 as a starting point. The eight phases of the DFØ guidelines have been supplemented with guidelines aimed at the practical implementation of societal benefit assessment of GMO applications. We have also included control questions that will help identify topics that need more thorough investigation during the socio-economic analyses of GMOs.

An important factor in the assessment of societal benefit is to identify the effects, both advantageous and disadvantageous, that the authorisation of a GMO will have compared to its rejection. Which societal groups that it applies to, and in what way the society in general, such as Norwegian food production, might be affected, are also important.

When evaluating societal benefit, we also need to assess whether the authorisation or ban of a GMO is profitable for society, i.e. whether the benefits are greater than the costs. Effects that are both quantifiable in monetary terms and those that cannot or should not be quantified, should be considered during such an assessment. In this respect, an authorisation or rejection is considered socio-economical profitable when the joint population is willing to bear the cost of the authorisation or rejection. However, some uncertainty is often associated with the consequences included in the assessment. Thus, we must assess which consequences that are important to the overall conclusion, and whether measures can help reduce this uncertainty.

We will also consider how advantages and disadvantages will be distributed among different societal groups. If a GMO is approved in Norway, who receives the benefits and who must bear the costs? We also have to consider whether certain groups are particularly exposed to negative effects.

Finally, after reviewing the steps of the guidance document, we will provide an overall assessment and subsequently recommend whether to authorise or reject a GMO application, based on the criterion of societal benefit.
We have used two examples in this report. The first example is import of genetically modified soy resistant to the herbicide glyphosate, and the other example is a genetically modified potato resistant to late blight. Soy is on the international market today and represents the most widely grown GMO in the world, while the potato is approved and is soon to be released on the US market.

1. Introduction

1.1. The Gene Technology Act and GMO applications

The Norwegian Gene Technology Act of 1993 regulates the production and use of genetically modified organisms (GMOs). In order to be approved in Norway, the law requires that a GMO shall not pose a threat to health or the environment. The production and use of a GMO shall occur in an ethically and socially sound manner. Norway will also place considerable emphasis on whether a GMO provides a societal benefit and contributes to sustainable development. These requirements apply to the deliberate release of GMOs. According to the law, deliberate release constitutes all forms of production and use of GMOs that are not considered contained use (enclosed systems).

To date, no Norwegian stakeholders have applied for permission to cultivate GMOs in Norway or to import genetically modified material. Similarly, no foreign companies have applied for approval directly to the Norwegian authorities. As an EEA Member State, Norway receives applications for authorisation of GMOs via the EU. Norway considers whether a GMO is to be banned or approved after approval by the EU. All applications must be assessed under the Gene Technology Act.

1.2. The Gene Technology Act and the Food Act

The Gene Technology Act regulates living genetically modified organisms such as plants or animals and products from GMOs that contain living material, such as germinating seeds. Food and feed from genetically modified organisms that do not contain viable material is regulated by the Food Act. GMOs containing non-living material, and that is neither food nor feed, are not regulated by laws governing GMOs. Examples include GMOs in cotton fabrics, in packaging materials and in biofuels. The project commissioned by the Norwegian Environment Agency includes living genetically modified organisms regulated by the Gene Technology Act.

1.3. Operationalising the concepts of sustainable development, societal benefit and ethics

The Norwegian Biotechnology Board has a special mandate for assessing sustainability, societal benefit and ethics of genetically modified organisms. In 1999, the Board prepared a report on which considerations to emphasise on during such assessments in Norway. The report contained, among other, a series of control questions. In 2005, parts of the report were included in Appendix 4 in the regulations relating to impact assessment pursuant to the Gene Technology Act. The Biotechnology Board revised the report in 2006 and 2009. In 2011 and 2013, on behalf of the Norwegian Environment Agency, the Board issued reports on sustainability and insect-resistant genetically modified plants, and on sustainability and herbicide-resistant genetically modified plants, respectively. These traits were chosen because such plants currently represents the most widely cultivated GMOs globally. The reports contain suggestions for specific questions that should be directed to the applicants, so that Norway is able to assess if a GMO with these traits contribute to a sustainable development.

Norway was the first country to consider societal benefit, sustainability and ethics in the regulations governing gene technology. Later, other countries have opened up to include similar considerations. Article 26 in the Cartagena Protocol, i.e. the trade agreement governing GMOs under the UN Convention on Biological Diversity, provides states with the option of including socio-economic considerations when deciding on whether or not to allow a GMO. In the EU, Directive 2015/412 allows Member States to prohibit cultivation of a GMO authorised in the EU.[1] Member States may invoke compelling grounds, such as socio-economic impacts, considered in respect to environmental and agricultural policy objectives, town and country planning, land use, avoidance of GMOs in other products, and national policy goals. Both in the EU and under the Cartagena Pro-

[1] Directive (EU) 2015/412 amends Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs on their territory. The amendment is not implemented in Norwegian law yet, but the Norwegian authorities consider such an amendment as unproblematic www.regjeringen.no/no/sub/eos-notatbasen/notatene/2010/nov/endringer-i-utsettingsdirektivet-for-gmo/id2434835/

tocol, work on socio-economics impacts and how to assess these, is in currently in progress.

1.4. Assessments of societal benefit

Neither the Gene Technology Act nor the preamble of the Act provides clear guidelines on how to interpret the concept of "societal benefit". In the preamble, the majority of the select committee for the municipal and the environment of the Norwegian Parliament emphasized that "the authorisation [of deliberate release of a GMO] must depend on its usefulness and the ethical, health and ecological issues that arise during previously conducted controlled trials and impact and risk analyses associated with the deliberate release."[2] It is also emphasised that the assessment of societal benefit should cover more than the applicant`s interests and that societal benefit is not merely an economic criterion. In addition, secondary effects are also relevant, for example changes in pesticide usage.

To date, applications evaluated by Norway rarely contain information that can be used for assessing societal benefit, despite the fact that this is where producers can emphasize positive aspects of the product developed. Still, some published studies on the socio-economic impacts of GMOs exist, which highlights certain questions that should be considered.[3] Some of these questions belong to the assessment of societal benefit, while others are more appropriately addressed under assessments of sustainability and ethical considerations.

Following the mandate, the Biotechnology Advisory Board shall discuss both the positive and negative impacts on society. The Board has previously emphasized that societal benefit not only reflects the advantages or disadvantages that the individual producer, consumer or applicant are exposed to, but also the consequences incurred on third parties.[4] If one considers implications for a second party, e.g. when competition among producers occurs, this should also be done in a broader social context.

Hitherto, the Board has employed a series of control questions (or checklist) from the impact assessment regulation in their assessment of a GMO application. The same approach has been employed by The Norwegian Environment Agency. Control questions are grouped into one of two groups: 1) Product characteristics and 2) Production and use of the product.

The Board has usually employed the questions concerning the characteristics of the product, i.e. whether there is a need or demand for the product, whether the product helps solve a societal problem, if it is significantly better than corresponding products on the market, and if other alternatives exist, which may solve the societal challenge in a better way.

The control questions on production and use of the product, deal with employment in the districts, in Norway and in neighbouring countries. The question also address if usage of GMOs create problems for existing productions that should also continue in the future.

The majority of the Board members have repeatedly stated lack of societal benefit or societal disadvantages as part of the reason for recommending banning of certain GMOs for both cultivation and import. This applies to pesticide- and insect-resistant rapeseed, maize and soy.[5] The Norwegian Environment Agency has also referred to societal demerits as part of their assessment when recommending against cultivation and importation of genetically modified rapeseed.[6] Additionally, the government pointed out the lack of societal benefit when they banned the glyphosate-resistant rapeseed GT73 in 2012.[7]

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[2] Innst. S. nr. 155 (1990–91), s. 8.

[3] Fischer K et al (2015) Social Impacts of GM Crops in Agriculture: A systematic Literature Review. Sustainability 7:8598–8620.

[4] Bioteknologirådet (2006) Bærekraft, samfunnsnytte og etikk i vurderingen av genmodifiserte organismer. www.bioteknologiradet.no/filarkiv/2010/07/2006_05_baerekrafthefte_revidert_BN.pdf

[5] www.bioteknologiradet.no/filarkiv/uttalelser/Sluttbehandling_GMOraps_import_Bioteknologinemnda.pdf
www.bioteknologiradet.no/filarkiv/2013/02/Sluttbehandling_MON810_dyrking_Bioteknologinemnda.pdf
www.bioteknologiradet.no/filarkiv/uttalelser/Sluttbehandling_GMOmais_import_Bioteknologinemnda.pdf
www.bioteknologiradet.no/filarkiv/2017/05/Sluttføring-av-søknader-om-godkjenning-av-genmodifisert-sprøytemiddelresistent-soya-til-import-prosessering-mat-og-fôr.pdf
www.bioteknologiradet.no/filarkiv/2017/01/Genmodifisert-insektresistent-soya-MON87701-sluttbehandling-signert.pdf

[6] www.miljodirektoratet.no/Documents/Nyhetsdokumenter/Helhetlig%20vurdering%20og%20anbefaling%20til%20vedtak%20for%20genmodifisert%20raps%20Ms8,%20Rf3,%20Ms8Rf3.pdf

[7] www.regjeringen.no/contentassets/9e58d02df38542acaf8548d08c2eea17/kgl_res_genmodifisert_gt73_raps_121214.pdf

1.5. The project assignment commissioned by the Environment Agency

In 2016, the Environment Agency commissioned the Biotechnology Advisory Board to assist in updating the societal benefit criteria in the Gene Technology Act. The goal was to "evaluate the societal benefit criterion and update it in accordance with current management practices." The Board was to create a guideline for the assessment of societal benefit of GMOs in Norway, which is to be used by the Board itself, the Environment Agency, and others.

Regulations relating to impact assessment pursuant to the Gene Technology Act of 2005, states that the assessment of societal benefit should be based on the principles of a socio-economic cost-benefit analysis. Socio-economic analyses have become commonplace in public administration. The Norwegian Environment Agency employs the Guidelines for economic cost-benefit analysis issued by the Norwegian Government Agency for Financial Management (DFØ) in 2014 (only available in Norwegian).[8] This is the background for the request from the Environment Agency to update the guidelines on societal benefit assessment of GMOs.

The DFØ guidelines divide the analysis into eight work phases. The Environment Agency wanted to use the phases as a starting point and supplement with guidelines specific to the practical implementation of societal benefit assessment of GMO applications. If necessary, the phases were to be supplemented with control questions providing information about aspects that need more through elaboration in socio-economic analyses of GMOs.

The wish of Environment Agency is that the level and scope of the guidelines will facilitate the ability to carry out assessment of societal benefit of a specific GMO within the current governance framework for budgets and deadlines.

1.6. Limitations of the report

When the Advisory Board and the environmental authorities have previously assessed GMO applications, it has become apparent that the distinctions between the three criteria societal benefit, sustainability and ethics are vague. Aspects that are relevant under one criterion may also be relevant under another. The Advisory Board has earlier recommended that assessment of societal benefit should be limited to Norway and, if necessary, to close neighbouring countries, and that the assessment should apply to the current and near future situation. Both the Advisory Board and the Environment Agency have subsequently used this approach. The criterion of contribution to sustainable development covers more long-term and global assessments. The ethics criterion covers ethical considerations. The ethical considerations can be of short-term and long-term character, and may apply to both Norwegian and global conditions.

Health and environmental risks are separate assessment criteria in the Gene Technology Act, and Norwegian authorities must assess the risks to health and the environment according to certain guidelines.[9] The Act states that a product can only be approved if there is no risk of harm to health or the environment. In the preamble, it is pointed out that this should not be taken literally, but that it is formulated this way to highlight that risk should be assessed beforehand, and that the precautionary principle shall form the basis of the decision. It might be appropriate to approve a GMO if the risk is small and the societal benefit is high, and the cost-benefit analysis may be helpful when weighing such considerations against each other. Thus, health and environmental impacts should also be part of the cost-benefit analysis. There may be both beneficial impacts and impacts associated with risks.

The concept of societal benefit is applied a little differently among various disciplines and laymen, and there are several models and methods that can be employed when assessing societal benefit. An example of a method besides the one used by DFØ, and that has also been applied on GMOs, is multicriteria mapping. In this method, it is emphasized how different people understand and evaluate the consequences of various impacts and uncertainties differently.[10] Other examples are methods based on assessing

[8] Direktoratet for økonomistyring (DFØ) (2014): Veileder i samfunnsøkonomiske analyser. https://dfo.no/Documents/FOA/publikasjoner/veiledere/Veileder_i_samfunns%C3%B8konomiske_analyser_1409.pdf

[9] Forskrift om konsekvensutredning etter genteknologiloven. https://lovdata.no/dokument/SF/forskrift/2005-12-16-1495

[10] www.multicriteriamapping.com/about

several alternative solutions to a problem, such as "PFOA" (problem formulation and options assessment).[11] The assignment given to the Advisory Board was to use the methodology for cost-benefit analysis provided by DFØ as a starting point, and to create guidelines for societal benefit assessment adapted to GMOs. As with other methods, this also has its limitations. In the report, we use the term "cost-benefit analysis" to refer to the type of analysis that DFØ addresses in their guidelines, see chapter 2.1.

In case of applications for import of GMOs, the principles of the cost-benefit analysis can also be used if assessing the societal benefit in the country of production, whereby it would fall under the criterion of sustainability.

In a cost-benefit analysis according to the DFØ model, the time frame is usually longer than near future, often 40 years. However, a GMO is approved for ten years at a time. Therefore, in this reportduring this project, we have recommended that the time frame should be ten years. Yet, in some cases, it may be necessary to have a longer perspective, see chapter 7.1.

1.7. Method of work

The Biotechnology Advisory Board established a resource group consisting of members from the Advisory Board and external experts. The work performed by the resource group forms the basis for this report. The resource group held four meetings: 17th of February, 15th of March, 25th of April and the 1st of June 2017, and the members have commented on the draft report during its development.

The members of the resource group:

- Ole Kristian Fauchald, professor, Dr.juris, University of Oslo and deputy member of the Biotechnology Advisory Board
- Mads Greaker, Ph.D in economics, senior scientist, Statistics Norway
- Arne Holst-Jensen, Dr. Sc., senior scientist, Norwegian Veterinary Institute and member of the Biotechnology Advisory Board
- Ove Jakobsen, professor, Dr. oecon., Nord University
- Kristin Magnussen, Dr. Sc., Menon Economics, Centre for Environmental and Resource Economics
- Christian Anton Smedshaug, Dr. Sc., CEO, AgriAnalyse
- Oddveig Storstad, Dr. Polit., associate professor, Kristiana University College and scientist, NIBIO
- Fern Wickson, Ph.D., senior researcher, GenØk – Center for Biosafety and member of the Biotechnology Advisory Board

1.8. Use of case studies

The resource group discussed two case studies to investigate whether the methodology provided by DFØ for socio-economic analyses could be applied to GMO applications. One example was import of soy resistant to glyphosate, and the other example was potato resistant to late blight. The resource group chose the soy as a case study because it represents a GMO that is currently on the market, it is the most widely cultivated GMO globally, and it may be relevant for import to Norway in the future. The potato was chosen because it might become relevant for cultivation in Norway, research on this type of potato is being conducted in several European countries, and a late blight-resistant potato was recently approved for cultivation in the United States. The report refers to these examples on several occasions. Many of the same aspects will be relevant for other types of GMOs, but there will also be particular aspects applicable to other GMOs, which the group has not addressed.

1.8.1. Case study 1: Import of soy

Genetically modified soy currently represents the largest genetically modified product on the global market, and about 80 percent of all soy available internationally is GMO.[12] This is soy that tolerates certain pesticides, which produces its own insecticide, or which do both. Plants with such traits completely dominate the GMO market. The EU, and thus Norway, receives many applications for approval of various types of GM soy (genetically modified soy) for import, processing, food and feed.

Norway imports over 400,000 tonnes of soybeans a year.[13] It is Denofa AS that imports the soybeans, which are GMO-

[11] Nelson KC, Andow DA, Banker MJ (2009) Problem formulation and option assessment (PFOA) linking governance and environmental risk assessment for technologies: a methodology for problem analysis of nanotechnologies and genetically engineered organisms. Journal of Law and Medical Ethics 37(4):732—748.

[12] www.isaaa.org

[13] www.bioteknologiradet.no/filarkiv/2017/01/Genmodifisert-insektresistent-soya-MON87701-sluttbehandling-signert.pdf

Genetically modified potato is used as an example in the report. Photo: iStock

free. Denofa has developed an entire supply chain from Mato Grosso in Brazil to Fredrikstad in Norway to avoid comingling of GMOs. During recent years, Denofa has also imported from Canada. Thus, Denofa has an international niche with GMO-free products and can subsequently export some of the imported products.

Denofa processes soybeans to soybean oil and meal. The soybean meal is used as feed in the agricultural sector, while soybean oil is used in food. Producers of feed to the aquaculture industry imports over 200,000 tonnes of milled feed in the form of soy protein concentrate and about 40,000 tonnes of soybean meal. Norway also imports some milled soy for use in ready-to-eat foods . Converted to soybeans, imports to fish feed account for around 80 per cent of the soy used in Norway.

1.8.2. Case study 2: Potato for cultivation

Researchers in Europe and the United States are working on the development of genetically modified potatoes with improved tolerance against late blight,[14,15] and the US government approved such a potato for commercial cultivation in 2017.[16] Late blight represents a problem for Norwegian potato breeders, and a late blight-resistant GM potato may be relevant for cultivation in Norway. This is an example of a GMO where the aim of the genetic modification is to solve a disease problem in agricultural crops. Today, Norwegian farmers control the problem of late blight by spraying, and over half of the chemical fungicides used by the agricultural sector goes towards controlling this disease. Late blight-resistance is one of several breeding goals in potato, but it is not of the highest priority. One challenge is that the late blight overcomes the resistance after a few years.

From the year 2000, between 300,000 and 400,000 tonnes of potatoes have been cultivated each annually in Norway.[17] There has been a decline in the number of potato farmers, but these cultivates on average a larger area. Over 70 percent of potatoes are cultivated in Eastern Norway. Approximately 2/3 of what is being produced goes towards raw materials for the industry, e.g. to make flour, chips, alcohol and feed, while about 1/3 is eaten as food.[18]

1.8.3. Other examples of GMOs for cultivation and import

We have also used other GMOs besides soy and potato as examples in the report. These are GMOs that have either been approved for sales or are in the later stages of development, and that exhibit other characteristics that are relevant for the discussion on how to assess the societal benefit of GMO products.

Genetically modified varieties of crops being cultivated to produce plant oils, such as rapeseed and soy, exist on today's market, while similar varieties of sunflower and flax are currently not for sale. Most varieties are genetically

[14] www.bioteknologiradet.no/2016/08/genmodifisering-mot-torrote/

[15] www.bioteknologiradet.no/2013/05/nye-gen-mot-pengesluk/

[16] www.potatopro.com/news/2017/us-government-approved-3-more-simplot-gmo-potato-types-cultivation-and-sale

[17] www.ssb.no/jord-skog-jakt-og-fiskeri/statistikker/jordbruksavling

[18] www.bioforsk.no/ikbViewer/Content/96808/029_NorskPotetproduksjon2011.pdf

modified to tolerate herbicides, but varieties with altered composition of fatty acids are also being developed. In Australia, the company Nuseed has collaborated with the research centre CSIRO to develop genetically modified rapeseed that produces the highly valuable fatty acids EPA and DHA.[19,20] The American company Cargill has also developed such a rapeseed in cooperation with BASF.[21] In both projects, they have tested the rapeseed in feeding trials on salmon, but the plants are not yet commercialised.

One problem with the cultivation of and seeds from rapeseed, is that the plant spreads and crosses easily with other types of cultured rapeseed and rape varieties, and with wild-growing relatives of rapeseed. Norway has already prohibited imports of several cultivars of GM rapeseed due to, among others, environmental risk in Norway. Nevertheless, rapeseed genetically modified to contain a higher amount of valuable and nutritious fatty acids, may have a potential societal value that can affect society's risk acceptance. Therefore, this is an interesting example to discuss when developing guidelines for the assessment of societal benefits of GMOs. Other interesting examples are varieties of soy with a higher content of monounsaturated fat and less saturated fat, which are developed for use in oils for frying and lubricants, and for waxes. Such varieties are approved for import to the EU.

Another GMO that may be relevant in Norway in the future and when discussing the development of guidelines for assessing societal benefit, is gene edited salmon that is sterile and thus, if it escapes, does not produce offspring with wild salmon.[22] This is an example of a GMO that is developed to solve an environmental problem (genetic contamination of escaped farmed salmon) created by an industry important for the Norwegian economy.

[19] www.nufarm.com/assets/36419/1/2017-03NuseedOmega-3.pdf?download

[20] www.bioteknologiradet.no/2015/12/forsok-med-genmodifisert-fiskefor/

[21] www.cargill.com/2016/cargill-developing-new-omega-3-rich-canola

[22] www.bioteknologiradet.no/2016/10/steril-oppdrettslaks/

2. The cost-benefit framework for the assessment

Photo: iStock

2.1. What is a cost-benefit analysis?

According to DFØ, a cost-benefit analysis can be described as a tool for identifying and visualising the effects (impacts) of an action on affected groups in society.[23] By systematically mapping, comparing and evaluating the effects of alternative measures (in this case, to say yes or no to a GMO application), the analysis helps shed light on the advantages and disadvantages of the alternatives and which groups are impacted, and whether the benefits outweigh the drawbacks. The cost-benefit analysis should include an assessment of the economic profitability, an overview of the distributional impacts (i.e. which societal groups that benefit from the authorisation and which that do not) and an assessment of how the authorisation of a GMO corresponds to the overall societal goals.

According to the DFØ guidelines, the fact that a measure is economically profitable indicates that the population as a whole is willing to pay at least as much as the cost of the measure across its lifetime. In addition to calculating such profitability in NOK, we should also consider whether impacts that cannot be quantified in money contribute to making the measure more or less profitable for society. The biggest and most important part of the analysis is to map and quantify the impacts, both those that can be measured in money and those that cannot. In this respect, it is important to be aware of effects that belong to the profitability analysis. There are impacts associated with the use of resources and which, with some exceptions, may have a market effect. Other types of impacts are more naturally assessed against general societal goals.

DFØ divides the analysis into eight steps, see Figure 1. The subsequent structure of the report (Chapters 3 to 11) follows the eight work phases in the DFØ guidelines. We have adapted the names and content of the phases to the assessment of GMOs. DFØ has named phase 1 "Describe the problem and formulate goals". However, should we follow the

[23] DFØ-rettleiaren, kapittel 1.1.

DFØ model, then our task is to assess the consequences of approving a particular GMO application compared to rejecting it. Therefore, we have instead chosen to determine the type of GMO in question and the area of use in the application. It also illustrates one of the limitations of the DFØ method: Using this approach, the objective is not to analyse the pros and cons of alternatives to the genetically modified product as a solution to social or economic problem.

In phase 2, where we, according to DFØ, shall "Identify and describe the relevant measures", it is most natural to identify the various outcomes of the application process: full authorisation, rejection or limited authorisation. For the rest of the work phases, we have used the same names as in the DFØ guidance.

2.2. Simplified or full analysis?

2.2.1. Choosing the appropriate level of analysis

In many cases, we can carry out a simplified analysis with less requirements for documentation compared to a full analysis. DFØ has advised on how to determine the right level of analysis and distinguish between three levels:[24]

1) Minimum requirements for analysis
2) Simplified analysis
3) Cost-benefit analysis

DFØ recommends starting with the minimum requirement and then ask oneself whether this provides adequate information to settle the matter. If not, one can move to the next level, simplified analysis, and then to cost-benefit analysis. The systematic is the same at all levels.

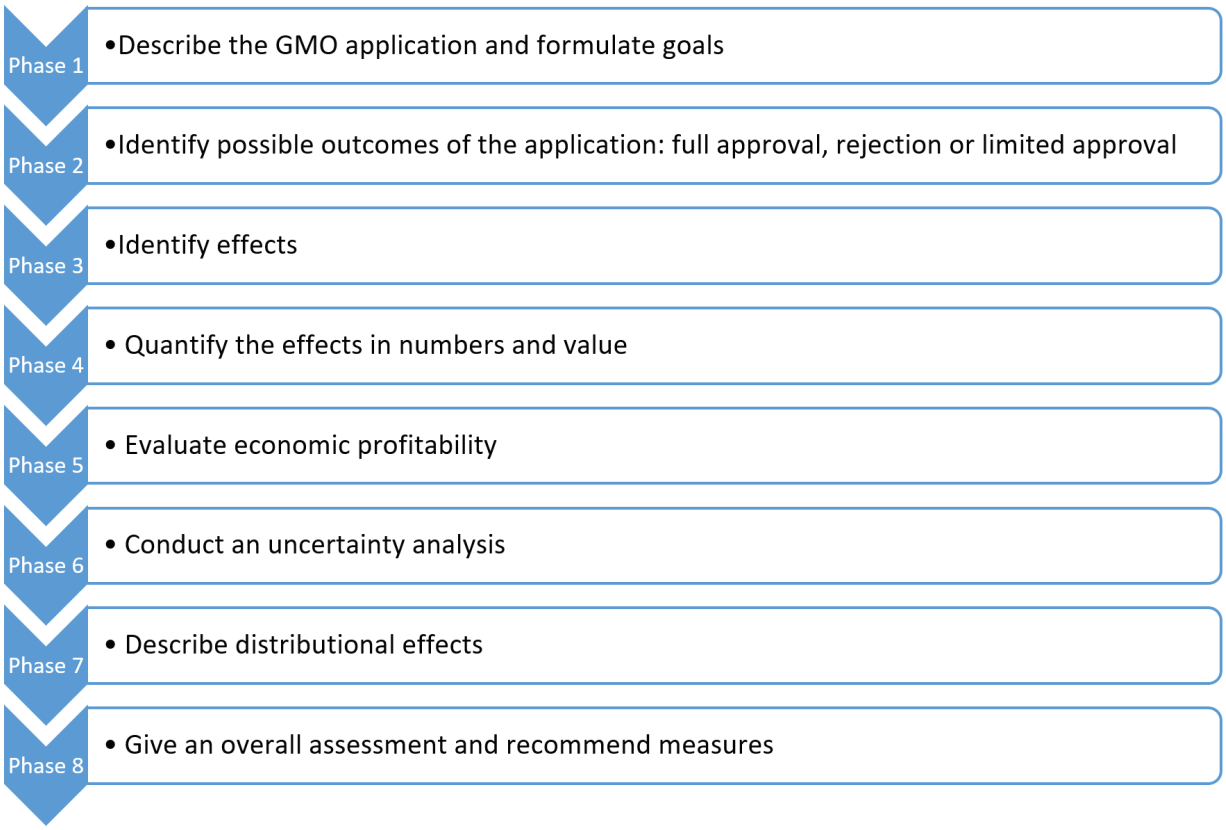

Figure 1. Flow diagram for implementing a cost-benefit analysis according to the DFØ model, adapted to the assessment of GMO applications.

[24] Direktoratet for økonomistyring (2016): Velg riktig nivå på utredningen. Minimumskravene, forenklet analyse eller samfunnsøkonomisk analyse. https://pub.dfo.no/velg-riktig-niva-pa-utredningen/

The minimum requirements constitute answering the following questions:
1) What is the matter of the issue and what do we want to achieve?
2) What measures are relevant?
3) What principal questions arise from the measures?
4) What are the positive and negative impacts of the measures, what is the duration of such measures, who do they affect?
5) What measures should be advised and why?
6) What are the prerequisite for a successful implementation?

”Measures” in this context refer to authorisation, limited authorisation or rejection of the GMO application.

One can meet the minimum requirements by answering the questions in a short and simple manner. However, when a simplified analysis is conducted, it is necessary to provide more thorough answers and additionally follow the guidelines for cost-benefit analyses from DFØ. The main distinction between simplified and full analysis is that in the simplified analysis, the ambitions for quantifying the effects in numbers and value are not that high.[25] In a simplified analysis, it is sufficient to make quantifiable measurements only when this information is readily available.

According to DFØ, we should adjust the scope of the description according to the size of the measure. In the case of GMOs, a simplified analysis would be sufficient when the authorisation has minor impact on small groups in society, while a full analysis is needed when the effects have large and serious - and potentially irreversible - consequences for large societal groups. A high level of uncertainty about the impacts also suggests that it is necessary to increase the level of analysis. It may also be reasonable to have different levels of analysis based on whether it is the first time a GMO of a particular type is being assessed, or if similar products have been considered previously.

2.2.2. First or nth GMO?

No genetically modified organisms are currently approved for food or feed in Norway. Going from GMO-free to approving the first GMO is a big step. The precautionary principle also constitutes a central pillar in the GMO regulations and the assessments of GMOs. Unless there are clear reasons for doing an analysis according to the minimum requirement or a simplified analysis, one should therefore perform a full analysis. If it is the first time approving a GMO, it is unlikely that the minimum requirement would be enough to recommend authorisation.

The authorisation of several GMOs may have larger consequences than approving a few, whether it is the same type of GMOs or different types. Before settling on an analysis based on the minimum requirement or a simplified analysis, one should consider whether there may be cumulative effects (accumulation effects) of approving more GMOs, which would speak in favour of a full analysis.

When a similar product has been fully analysed previously, it may be expedient to perform a simplified analysis or to meet the minimum requirement for analysis. At the same time, one should consider whether changes or uncertainties might have changed. One example is the potential approval of a genetically modified pesticide-resistant or insect-resistant soy for import and use in food and feed. In this case, it may be useful to perform a full analysis once, while for similar applications for the same species, a simplified analysis might suffice.

2.2.3. Differences according to area of use

Applicants apply for approval of a GMO for certain uses, such as cultivation, import, processing, and use in food and feed or for other purposes. It may be relevant with a full analysis for certain types of use, while a simplified or minimum requirement analysis might suffice for others, if the area of use have already been approved for similar GMOs before.

2.2.4. Other criteria are decisive

If it is appropriate to prohibit the GMO based on other criteria, such as health or environmental risk, it may suffice with a simplified analysis or a minimum analysis. One

[25] Chapter 2.1 and 2.2 with tables showing the three levels of analysis, in Direktoratet for økonomistyring (2016): Velg riktig nivå på utredningen. Minimumskravene, forenklet analyse eller samfunnsøkonomisk analyse. https://pub.dfo.no/velg-riktig-niva-pa-utredningen/

example would be if the GMO easily spreads and crosses with other crops and wild relatives. This is evaluated during the environmental risk assessment.

2.2.5. GMOs with particular traits

If the GMO contains a gene for antibiotic resistance, it will not be approved for use in food and feed because it is prohibited according to Norwegian regulations. The Norwegian Parliament has asked the government to ban genetically modified products with genes for antibiotic resistance and to work to promote prohibition of such products internationally. The government has banned several GMOs containing antibiotic resistance genes, under the Gene Technology Act. Therefore, for such GMOs, it should be sufficient to meet the minimum requirement for analysis. In this case, one can provide brief answers to the questions to explain the matter at hand.

If we receive applications for approving the cultivation of GMOs developed to be used in conjunction with pesticides that are prohibited in Norway, it may also be adequate to meet the minimum requirements. The same applies to GMOs that produce insecticides against insect pests that do not exist in Norway. For GMOs with multiple traits, it would be the product as a whole that is decisive, which would require a more complete assessment.

2.2.6. Control questions for determining the appropriate level of analysis

Below are some relevant control questions to help assess whether one should perform a simplified or full cost-benefit analysis of a GMO:

- Is this the first GMO to be allowed in Norway?
- Have similar GMOs or GMO products been assessed previously?
- If similar GMOs/GMO products are already allowed: Have changes in terms of impact or uncertainty occurred since the authorisation?
- Are there or will there be cumulative effects (accumulation effects) of allowing more GMOs?
- Is it applicable to perform different levels of analysis for different areas of use?
- Is there a large degree of uncertainty about the effects of an authorisation?
- Is it appropriate to ban GMOs according to other criteria, such as health or environmental risks, for example if the GMO easily spreads and crosses with other crops and wild relatives?
- Does the GMO contain antibiotic resistance genes?
- Is the GMO developed to be used in conjunction with pesticides that are banned in Norway due to health and environmental hazards?
- Does the GMO produce insecticides against insect pests that do not exist in Norway?

2.3. Who should perform the analysis and when?

When Norway receives an application for authorisation of a GMO, the Biotechnology Advisory Board has a special mandate for assessing societal benefits, sustainability and ethical aspects. The Norwegian Environment Agency coordinates the Norwegian assessment of all criteria in the Gene Technology Act and recommends a decision to the Norwegian Ministry of Climate and Environment. The final decision is made by the government.

Performing a full cost-benefit analysis according to the DFØ model requires several resources. It is possible that one could first perform a minimum or simplified analysis of societal benefit, and then consider whether it is necessary to do a more thorough assessment. In order to do a more complete analysis, it would require socio-economic and other types of specialist competencies, as well as contributions from stakeholders that might be affected. Expert groups who may be commissioned to perform the analysis will collect information from different sources and stakeholder groups. The project assignment may specify particular groups that need to be contacted and aspects that one needs to consider more carefully. Regardless of whether external competencies have been recruited during the process, the Biotechnology Advisory Board and/or the Environment Agency shall make an overall assessment of societal benefit and be responsible for the final analysis.

There is a requirement for public hearings of all GMO applications, where everyone who wishes has the right to submit their views to the Environment Agency in writing. According to the routine proceedings of the Ministry of Climate and the Environment, the hearing will be arranged after the Norwegian Food Safety Authority, the Norwegian Scientific Committee for Food and Environment (VKM) and the Biotechnology Advisory Board have completed their assessments.

3. Describe and elaborate on the GMO application and alignments of objectives (work phase 1)

3.1. Describe and elaborate on the GMO application and the characteristics of the GMO

This work phase includes a description of the GMO application that Norway will consider, the characteristics of the GMO, and what it will be used for in Norway. Common uses of plants are feed for fish or livestock, cooking oil or ingredients in ready-made food for humans. Currently, typical traits are insect-resistance or herbicide-resistance. A few GMOs with other properties are on the market, but several are under development, see chapter 1.8.3.

When living GMOs are imported to Norway and used to make the final product here, one should monitor the organism up until the final product, even if the end product is non-living and thus no longer regulated by the Gene Technology Act. It is the area of use that is interesting, not the importation itself. One example is when soybeans, which are living, are imported to Norway and used to make soybean meal and other products. In this case, the soy is monitored all the way until it is processed into food or feed, even if the end product is regulated by the Food Act and not by the Gene Technology Act. In other cases, it can be sufficient to only analyse the living GMO. This applies to, for example, genetically modified fish or cut flowers. Nevertheless, waste and by-products might also need to be considered.

The DFØ guidelines on cost-benefit analysis is based on the fact that one should assess measures that will solve a societal problem. However, it is often a matter of assessing the consequences of a measure without it necessarily solving a problem. Still, the measure may have socio-economic benefits or costs. When the public administration evaluate GMO applications, they assess whether to allow or ban a GMO, regardless of whether the GMO is solving a societal problem or not. Opinions are divided on whether the Gene Technology Act should be interpreted in a way where the GMO must make a positive contribution to society in order to be approved, or if it is sufficient that it does not contribute negatively. In any case, the cost-benefit analysis will shed light on the pros and cons of rejection or authorisation, in order to provide the government with a sound basis for making a decision.

During this phase, one shall elaborate on the need, the use or the potential problem, for which groups it is important for, the scope, the severity, which factors that will affect it over time, why it potentially needs to be resolved now, and the explanatory factors for why it arose.

Control questions:

- Why was the GMO developed?
- What are the characteristics of the GMO?
- What are the areas of use of the GMO in Norway (cultivation, import, processing, food, feed, other purposes)?

3.2. Compile a reference alternative (null alternative)

The consequences of allowing a GMO will be compared with a reference alternative. According to the DFØ guidelines, the reference alternative constitutes the present day situation and the expected development in the absence of new measures (i.e. 'business as usual'). For a specific application, it is reasonable to make a comparison with the plant or animal that the GMO is to replace, or with the common farming or livestock system in the area.

When status quo is used as a starting point, one should also ask whether it is likely that the situation will change, or whether Norway has societal or political objectives that facilitate changes in a certain direction. One should therefore assess the reference alternative in the context of the alignments of objectives (see chapter 3.3) as these will affect one another, and preferably develop these concurrently. Especially when determining what is most emphasized when formulating the reference alternative, it is necessary to see this in the context of the overall societal objectives.

The reference alternative should include the expected development of external factors, but also how consumers, businesses, governments and political groups will adapt to such changes. Such factors may entail altered demands or whether it is possible to obtain a non-genetically modified product. What should be included in the reference alternative, beyond the current situation, must be something that

have already been initiated or planned, or that is realistic to take place.

If there are currently several different types of production - for example, both organic and conventional cultivation - one should consider to include both in the reference alternative. This is important if they are affected in different ways.

The DFØ guidelines emphasises the importance of considering the available time and resources when choosing the required precision level of the reference alternative. In addition, DFØ points out that it is important to document and determine the prerequisites upon which the reference alternative is based.

For example, in the case of late blight in potatoes, it might be advisable to examine whether other varieties of potato that tolerate late blight will be developed, whether other measures will be developed to prevent late blight in the field, whether losses due to late blight will be reduced during subsequent years, and if consumption of potatoes is expected to increase or decrease. If no particular measures have been implemented or planned during the last ten years, it is reasonable to assume that the situation will remain as is.

EXAMPLE OF IMPORT OF GM SOY:

Example of import of GM soy: In this case, a natural reference alternative would be non-genetically modified soy, which is currently imported from Brazil as soybean, processed and used for livestock feed in Norway. Research projects have been initiated to develop alternative sources of protein for feed, for which little research has been conducted previously.

Soy plants. Photo: iStock.

Control questions:

- Is it important for the effects that we are going to analyse, to distinguish between different forms of production?
- Has research and development been initiated or planned, for example new plant varieties or breeding projects, and is it reasonable to say that it will produce results that are of importance to the reference alternative?
- How will changes in other external factors, such as demand for the product and access to non-GM products, affect the reference alternative over time?
- Is there a high level of uncertainty in factors that are very important to the reference alternative?
- Are there societal objectives that are relevant for the reference alternative (see chapter 3.3)?

3.3. Alignments of objectives

The DFØ guidelines state that one should formulate objectives, where a future scenario or a result one wish to achieve, is described. The objectives must relate to the measures in question and shall contribute to defining alternative measures. It should include both societal objectives, that express a preferred state of the future society, often formulated at an overall level, and impact goals or action goals, which shall reflect a preferred state of the target group(s).

With GMO applications, it is not necessary to formulate objectives in order to identify the appropriate measure, as the measure (i.e. to approve the application) and the reference alternative ('business as usual', i.e. if the application is dismissed) are determined beforehand. Nevertheless, it is useful to formulate objectives to investigate whether the decision contributes to developing society in the preferred direction. Under societal objectives, it is important to address overall objectives within for example agriculture and aquaculture, and the values one wish to build upon. The objectivess must be something that the GMO can contribute positively or negatively to. General societal objectives should be available in official documents, and they should be applicable for several GMO assessments, even if the objectives are not relevant in all cases.

Overall political objectives are described in the budget propositions of the Norwegian Parliament, and such objectives are also available in parliamentary reports, such as the agricultural report " Endring og utvikling " (St. mld. 11 2016-2017). In St.prp. 1S 2016-2017, four main objectives with

sub-goals for the agriculture and food policy are stated. Proposition.[26] St.prp. 1 S also contains national objectives for the climate and environmental policy within the six areas of natural diversity, cultural heritage and cultural environment, outdoor and recreational life, pollution, climate and polar areas,[27] and objectives for the industry and fisheries policy.[28]

In the case of GMOs, relevant environmental policy objectives could include, among others, that ecosystems should be in a good state and provide ecosystem services, that pollution should not harm health and the environment, that emission of health and environmentally hazardous pollutants should be stopped, that no habitats become destroyed or species become extinct, and that the situation for endangered species and habitats are improved. Examples of relevant agricultural policy objectives are to ensure food safety for the consumers, to ensure good animal and plant health and good animal welfare, to produce and ensure access to food that consumers demand, competitive production of raw materials and food industry, to safeguard the agricultural landscape in agriculture, including conservation and sustainable use of the genetic resources, and the sustainable use and protection of the area and the resource basis in agriculture. In the business and fisheries policy, the overarching objective is to maximise value creation in the Norwegian economy within a sustainable framework.

Action-specific goals are goals that apply to the specific GMO and that should be achievable for the target groups if the GMO is approved.

Both action-specific goals and general goals will influence what is emphasised both in the projections in the reference alternative and in the scenario where the GMO is approved. One should therefore consider all of this in context.

The overall goals are not to be quantified and calculated, as they are overarching and general, but shall be addressed at the start of analysis, and revisited during the final phase to assess whether the decision contributes to moving the particular politics in the direction preferred by society. Action-specific goals should be more concrete and should express the desired socio-economic effects of a GMO approval. One should investigate whether these effects can be quantified or not during the analysis, see chapter 6 for more information.

EXAMPLE

In the case study of late blight-resistant genetically modified potato, general objectives may entail good plant health and to decrease release of health and environmentally hazardous substances. Action-specific goals may be that the farmers use less pesticides during potato cultivation and less production losses due to reduced late blight.

Control questions:

- What overarching objectives for the environment, agriculture or fisheries policy can be expected to be affected if the GMO is approved?
- What specific objectives should the target groups achieve if this particular GMO is approved?

[26] St.prp. 1S 2016–2017 www.regjeringen.no/contentassets/1f5292dede5a486081e79a14b15c5800/nn-no/pdfs/prp201620170001lmddddpdfs.pdf

[27] www.regjeringen.no/contentassets/c2c15072d804414d8f9147c74916c72c/nn-no/pdfs/prp201620170001kldddpdfs.pdf

[28] www.regjeringen.no/contentassets/ac47537d9db24b3e87e0fc84e33feb80/no/pdfs/prp201620170001nfddddpdfs.pdf

4. Identify possible outcomes of the application: authorisation, rejection or limited authorisation (work phase 2)

The outcome of a GMO application addressed directly to Norway or via the EU is that Norway either authorise or ban the GMO, or potentially allow only some of the areas of use applied for, or authorise some areas of use on certain conditions. It is difficult to assess whether to restrict an authorisation before having conducted the cost-benefit analysis. Thus, one should return to this work phase during the final phase of the work. To begin with, one should consider the impacts on the areas of use that are applied for. This could entail cultivation, importation or processing of a GMO, and use for food and feed or other purposes. If the results of the analysis speak in favour of authorisation, then we should assess if certain aspects of the analysis indicate that approval should be limited to certain uses. It may also be necessary to restrict the authorisation within the areas of use, for example only approving the GMO for certain types of feed.

In the past, a GMO could be approved in the EU for feed and not for food. However, because there were several cases where GMOs only approved for feed unintentionally commingled with the food production chain, a GMO must today be approved for both feed and food. It is hardly realistic that such a distinction between food and feed will be introduced again. Therefore, it may be more realistic to only approve processed food or feed such as oil, meal, fibre or ready-made food (according to the Food Act) and not living/germinating GMOs (according to the Gene Technology Act). This may lead to a GMO only being applied in fish farming, where much of the feed is imported as meal or oil. In Norway, there are other stakeholders who import and produce feed for fish farming than for agriculture, and this could make it easier to authorise a GMO for fish farming, but not for the agricultural sector. Anyway, one should analyse the impacts on agriculture and aquaculture separately as they will be different.

Control questions:

- What areas of use are being applied for?
- Does the results of the cost-benefit analysis indicate that the GMO authorisation should be limited to some of the areas of use being applied for?
- Does the outcome of the cost-benefit analysis indicate that the potential authorisation should be restricted within the areas of use being applied for?

5. Identify effects (work phase 3)

Identifying groups and areas that are affected by approval or ban of a GMO, is part of an economic profitability analysis. Photo: iStock

5.1. Identify and elaborate on cost-benefit effects

Identifying and elaborating on the positive and negative effects is the most important and extensive work phase. One shall determine the effects of authorising a GMO compared to the reference alternative. It is crucial for a good analysis that the most important effects are identified at this stage - and to understand which effects that are relevant for an analysis of economic profitability. A good starting point for analysing the impacts is to identify all the effects that manifest themselves in a market. Not all effects will affect the markets and such non-monetised impacts must be assessed in an appropriate manner. Resources are not only natural resources or means of production, but also for example labour, capital and ecosystem services. Some effects, such as environmental effects, do not always impact a market. In order to determine if the effect is to be included, one may ask what the alternative use of the resource may be and whether it is a real economic effect.

EXAMPLE

In the example of import of genetically modified soy, there may be effects in the market for salmon feed, the market for animal feed and the food market. In this case, we can briefly elaborate on which stakeholders are present on these markets and the turnover in kilograms and monetary value. Subsequently, we have to make an assumption of the potential market share of GM soy. This will depend on, among other, the price of GM soy compared to the alternative and the number of consumers that would want to buy the product. The amount saved will constitute a beneficial effect.

Additionally, it is important to keep the effects separate from each other and to avoid counting the effects more than one time. Some effects are outcomes of preceding ones, and the effects will often intervene with each other, but each effect must be assessed separately to make it possible to carry out the analysis. To determine whether the

effects have been adequately concretised, one can ask whether the authorisation of a GMO for certain purposes will influence the suggested effect, in each case.
According to DFØ, a beneficial effect constitutes an increase in the welfare of one or several groups in society or for the society as a whole. Examples of beneficial effects in a market are economic savings in the form of cheaper imported raw materials, reduced production costs, and less expensive end products for consumers. According to DFØ, costs entail all uses of resources following a decision, in our case a GMO authorisation. For example, costs may include environmental impacts such as loss of biodiversity, costs of separate production lines, loss of farmer and consumer choice, investment costs and costs to prevent spread of GMOs.

5.1.1. Identify groups and areas that are affected by approval or ban of a GMO

In the cost-benefit analysis, one will usually take into account the effects that affect one or more markets. Still, DFØ recommends identifying the societal groups that would be affected by the decision on whether or not to authorise a GMO. This may help map the potential effects, but is not carried out as a way of limiting the necessary considerations. It is particularly important to assess whether there are effects that affect a third party, and whether there are groups at risk of being overlooked. Examples of such groups are farmers that practise less common methods of cultivation, such as organic farming, and people who are concerned with buying organic food. Another group is future generations, but this is less relevant within a ten-year perspective. Furthermore, this is taken into account when assessing whether the GMO contributes to sustainable development.

In general, one can distinguish between groups that become affected economically, i.e. production, distribution, consumption or redistribution (waste/reuse), and other groups. Other groups may be groups that do not participate in the analysed markets. Potential groups can also be identified through the consultation list that the Environment Agency uses for the public consultation in Norway held in association with the GMO application. The groups can be both directly and indirectly affected, and the effects can be both small and large. The natural environment is not considered a separate group, but an area that society has decided to take care of, thus environmental effects must be included.

Control questions:

- What groups will be affected within the analysed markets, i.e. production, distribution, consumption and redistribution (waste/reuse)?
- Which other groups, interests or areas are affected?
- Are there any groups that affected that are particularly vulnerable?

5.2. Special considerations that applies to the effects of a GMO

In order to identify the effects, one can follow the chain of production, and for every step (i.e. production, distribution, consumption and redistribution (waste/reuse)) ask whether the GMO would impose any changes. One should also investigate whether there are different effects for the various uses that have been sought approval for (cultivation, import, processing, food, feed, uses other than food and feed).

One should also be aware of differences between industries. There are great differences between how the Norwegian agriculture and aquaculture is organised and regulated. The feed production for agriculture and aquaculture is divided. Most of the production from agriculture is for domestic use, while most of what is produced by the aquaculture industry is exported. Therefore, one should distinguish between effects towards agriculture and aquaculture, and effects that incur in Norway and in export markets. In addition to feed, there is the use of GMOs in food. Some effects may be the same, but may vary in their extent according to the area in question. Within agriculture and aquaculture, it is important to distinguish between effects that impact the part of the industry or the market that may use the GMOs, and the part that does not.

In Norway, the agricultural policy, especially through customs and government budget subsidies, has a great impact on what is being produced and where, the amount being produced, and the price of input factors and the end products.

Since there are currently no GMOs used in Norwegian food production, the authorisation of the first GMO will entail breaking a barrier. Consequently, there is an important distinction between the effects of approving the first GMO and the effects of approving additional GMOs if GMOs are already in use.

To determine the market share of a GMO, one must estimate how many that will adopt the GMO if authorised. This will depend on the demand for the GMO and the GMO-free product. Someone may choose to retain GMO-free as a niche, considering that Norway up until now has promoted itself as GMO-free; others may choose to change fully or partially to GMOs; or novel stakeholders that employ GMOs may appear. If someone has started using GMOs, this can provide information about the demand. We do not have much practical experience from Norway. However, between 2005 to 2014, four producers of feed for farmed fish were given dispensation by the Norwegian Food Safety Authority to use ingredients from 19 genetically modified plants in fish feed, though they did not use such feed.[29]

Even though the government performs their own, standardised assessments of health and environmental risks, health and environmental effects can also be included during the cost-benefit analysis. Moreover, health and environmental risk assessments involves identifying hazards connected to the GMO, not whether there are benefits. As a result, there may be health and environmental impacts of a GMO that is not included in the risk analysis. Still, these should be included in the cost-benefit analysis.

5.3. Control questions to identify effects

There are certain questions we should ask, which may apply to several effects. If we have included certain assumptions in the reference alternative, e.g. changes in external factors, then the same assumptions must form the basis for assessing the consequences of authorising a GMO. Here are some general control questions:

- Is this the first GMO to be approved in Norway?
- Is this the first GMO with this trait to be approved in Norway?
- Is this the first GMO to be approved on the relevant markets ?
- How large is the market share of the product, and what is the difference in economic value between the GMO and the reference alternative?
- How many, and what type of stakeholders, e.g. farmers or processors of food and feed, will make use of the GMO, and how many and what type of stakeholders will not?
- In what area of the country will stakeholders use the GMO?
- Is it important for the analysed effects to distinguish between different production methods, such as organic and conventional production?
- What impact will changes in external factors, for example demand for the products themselves (genetically modified or not) and access to non-genetically modified products, have on the effects over time?
- What prerequisites have been included in the reference alternative that should also apply to a scenario where the GMO is approved?
- Does political priorities, such as support in the form of subsidies and tariff protection, impact on the effects?
- Examples of control questions to map specific effects:
- Will the price of the raw materials or the processed product change with use of GMO?
- If the price of the raw materials or the processed product change, will sales increase, decrease or remain as is?
- How will the price of the raw materials and processed food and feed change in the short and long term?
- Which manufacturers will choose to have separate production lines and which producers will adopt solely either GMO or GMO-free products?
- Will there be additional costs of labelling, monitoring and controls, and if so, who will cover the cost?
- Can the GMO establish itself in Norwegian habitats or cross with wild relatives and other crop plants, thus spreading the trait in Norwegian nature?
- How is the population affected by different environmental impacts?

This is how a table of effects may look like:

Effects	Monetised Effects		Non-monetised effects	
	Benefit	Cost	Benefit	Cost

[29] www.mattilsynet.no/planter_og_dyrking/genmodifisering/bakgrunn_for_avslag_om_aa_bruke_genmodifisert_fiskefor.16613

5.4. Examples of effects that may be included in the analysis of economic profitability

Below are some examples of potential effects of authorising a GMO, that may be included in the economic profitability analysis. Because the effects may vary, it is necessary to identify the specific effects and elaborate on them individually for each specific GMO application.

5.4.1. Effects associated with the production and the product

Here, it is useful to distinguish between the effects that apply to those using the GMO and those that do not, and between primary producers (farmers, breeders) and secondary producers (processors).

5.4.1.1. Changes in the price and quantity of raw materials for import

In some cases, GMO raw materials will be cheaper than the equivalent non-genetically modified raw materials, but they may possibly also be more expensive. If so, there will be a benefit or a cost to the importer. Generally, to shed light on this, one must quantify the price of the raw material on the current market and the expected price of the GMO raw material. When mapping effects, we need to make an estimate of the number of people who would want to switch to GMO raw materials and the number that would remain GMO-free. Based on this, one can calculate the volume expected to be sold at a different price than earlier. If the raw material becomes less expensive, it usually leads to an increase in demand and thus sales, and one must determine if this is likely in this particular case.

How many that will make use of the GMO product will depend on, among others, the way in which the product is perceived. For example, a GMO product may contain approximately the same nutritional content as a GMO-free product and exhibit no proven risk to health and the environment. Nevertheless, for ethical or other reasons, it may be perceived as different. Those who employ the product will, if it is less expensive, receive a benefit in the form of saved expenses. However, not everyone will adopt the product, and the savings will only be relevant to parts of the market.

5.4.1.2. Production costs

Adopting a GMO can result in increased or reduced production costs if the use of input factors changes. Input factors are resources used during the production process. In agriculture, this includes labour, natural resources such as soil and water, or capital, i.e. concrete and physical things like machinery, tools, planting materials, fertilisers, pesticides and irrigation technology. One or more of these costs may change when adopting GMOs and one must account for these individually. We should also differentiate the production costs between all the segments in the value chain: farmers, the food and feed industry, retailers and consumers. If a cost at one point of the value chain is counterbalanced by a profit in another, then the end benefit for the consumer will be zero, which might indicate that no distinction is necessary in that particular case. However, the cost and profit are not necessarily of the same magnitude, and one should nevertheless distinguish between separate effects as it will be of value when assessing the distributional effects.

One should also consider whether others besides the ones adopting the GMO, such as farmers who do not grow GMO, will have reduced or increased production costs. Additional costs may incur if they must pay for measures to avoid GMO comingling, e.g if they have to sow at later stages or with other varieties, or if they have to cover expenses for testing the crops for GMO. In that case, it will be a separate effect.

If a GMO is approved, then the producer is required by law to have a surveillance plan to monitor health and environmental impacts, and the products must be labelled as GMO. Costs for labelling and monitoring that are imposed on the producers through the regulations, must be covered by the producers themselves, and will, as a result of this, be part of their production costs. The same applies to expenses associated with separation of GMOs and non-GMOs on the producers' own fields, or to prevent GMO from spreading to neighbouring fields. If others have extra costs for labelling, monitoring and measures for coexistence, it will be considered an effect of its own, see chapter 5.4.1.5 and the previous section.

Production costs may be affected if farmers are able to increase production without expanding the area used for cultivation. Thus, one must investigate whether this is a likely scenario, and if they produce more of the same crop or employ some of the area for cultivation of other varieties, and how this will develop over a ten-year period.

EXAMPLE

In the example of late blight-resistant potato, reduced production costs may be less use of pesticide to prevent late blight. If the farmers do not have to spray as often, they also reduce expenses on wear and tear of machinery, fuel and labour. We should also investigate if there is an increase in production per unit area due to less waste, and whether the remaining area can then be used to cultivate more potato or other crops. Whether such effects arise, and the possible magnitude of such effects over a ten-year period, will depend on, among others, how long the resistance lasts and the cost of seed potatoes. Sooner or later, the resistance will normally disappear, but it is uncertain how long this takes.

5.4.1.3. Changes in the price and amount of the end product

One must be aware that a GMO product may exhibit a different price than an alternative that is not GMO. However, it may be difficult to predict the price. One of the reasons is that the price of agricultural products is also a result of the agricultural policy. Another reason is that it is difficult to know the market's perception of the product, the influence of potential market campaigns, and the willingness to pay, and thus the demand. This should be included in the uncertainty analysis, see chapter 8.

One must avoid counting a saving or cost twice, both in this section and in 5.4.1.1. However, it may be important to have the price and amount of the end product as a separate effect as it might influence the distributional effects. In this respect, it will be of interest whether it is the producer or consumer that is exposed to the effect.

5.4.1.4. Effects from separate lines within processing and distribution

To avoid commingling of GMO ingredients with GMO-free food and feed, it is often necessary to establish separate lines. This section refers to costs of separate lines during processing, packaging and distribution.

The effects of separate production and distribution lines can be quantified (monetised), but this requires knowledge on how many that will adopt the GMO wholly or partially and how many that will remain GMO free. Today, it is less common for a feed producer to exhibit several lines. We need to investigate whether introducing two lines makes the capacity of the production lines less suitable, and how big the investment and operating costs will be. This will again influence how many that will choose to introduce two lines. At present, the effects of separate lines can be determined accurately, while this becomes more uncertain further on in time.

EXAMPLE

In the case study of import of genetically modified soybeans, it would not be sufficient to clean the production lines after using GM soy following the current requirements for GMO-free products. Thus, it would be necessary to introduce permanently separate production lines. A similar example comes from feed production, where it is allowed to use fishmeal in feed for pig and poultry, but not for sheep and cattle. Because it is impossible to clean the production lines for fishmeal, the feed will not be made at the same factory.

EXAMPLE

In the example of genetically modified potato, we need to investigate whether the costs vary depending on the type of potato, whether it is a potato meant for industrial applications or consumption. For example, production lines for potato meal from industrial potato are difficult to clean and must therefore be separated. Packaging lines, which are used for potatoes for consumption, are easy to clean and we should investigate if there may be less stringent requirements for these types.

5.4.1.5. Monitoring and labelling costs for others than producers and processors/distributors

If the authorities or others than the producers and processors/distributors experience increased costs due to monitoring and labelling, it should be assessed as a separate effect. If we presuppose that the producers must cover the expenses of additional monitoring/controls and labelling, it falls under section 5.4.1.2 or 5.4.1.3. When assessing societal benefit, we must clarify who will cover such costs.

Additional costs may for example be relevant if the government has to introduce additional monitoring of pesticide residues. Moreover, those that do not adopt GMOs have to test for GMOs in their production lines. This applies to both organic and conventional producers. In other countries, this has resulted in additional expenses for those who do not use GMOs, and we need to investigate how this would play out here.

Today, Norway has no regulations for coexistence, i.e. if and how genetically modified and GMO-free crops can be cultivated in neighbouring fields. Developing such regulations will incur a cost on the government. Some stakeholders may demand that GMO producers and processors/ distributors have to cover the expenses, but it is uncertain how this will play out.

To put a figure on potential costs of monitoring, we need to know which are the most prominent solutions, or calculate the costs of different alternatives.

If producers choose to label their products as GMO-free, it is uncertain whether this should count as a socio-economic cost. Rather, it can be perceived as a marketing cost for the individual producer. So-called "negative labelling", i.e. including a label that states what the product does not contain, is considered misleading by the Norwegian Food Safety Authority.
If it is required to have a labelling scheme for meat from animals fed with GMOs, the authorities may have costs when establishing such a system, but it is uncertain who will have to pay for this once it is established.

5.4.1.6. Market harmonisation with the EU

Different regulation of a GMO in the EU versus Norway may give rise to effects due to unsufficient market harmonisation. This is of particular concern if there are plans to import or export to or from Norway. In this case, we should investigate whether such effects may arise, and avoid counting the price and quantity of raw material for import in section 5.4.1.1 twice.

5.4.2. Societal effects besides GMO production

5.4.2.1. The reputation of Norwegian food production

By reputation of Norwegian food production, we mean the way in which consumers perceive certain aspects of food production, such as environmental impact, animal welfare, food security, conditions of production, etc. We should investigate the current perception and whether this may change with GMO adoption.

If it is a matter of authorising the very first GMO for cultivation, food or feed in Norway, it may be advisable that the authorities ensure that a study on the potential reputational effects is carried out.

The reputational impacts may differ in Norway and in the export markets. The effects of authorising the first GMO will also differ from effects appearing if GMOs have already been approved. If only a single stakeholder choose to adopt GMOs, then everyone else would still have to deal with any potential effects on reputation.

One possible reputational cost by using the GMOs available today, is the potential loss of support for Norwegian agriculture among the population and the political will to set aside money in the governmental budget for this industry. [30] If a GMO exhibits many positive aspects compared with the alternatives, it may be a different scenario.

In the cost-benefit analysis, one should consider whether the stakeholders themselves have taken into account the potential reputational effects and as a result taken into account that they will receive a decrease or increase in the product price, or whether it is an external effect. In the former case, we should not consider it a separate effect, while it would be necessary for the latter case. Because the agricultural sector is so well organised with a joint GMO policy, one could argue that they themselves will take into account the reputational effect. On the other hand, the reputation also applies to other products besides agricultural ones, and other parts of society should have a say when it comes to the reputation of Norwegian food production. This speaks in favour of it being an effect in its own right.

Generally, reputational costs are difficult to quantify in monetary terms. The reputation impacts on the achievable price that the producer gets for the products. When quantifying the effect of reputation for a product, one can measure whether the competitive ability weakens or strengthens over a long enough time frame. One should distinguish between the effects on the reputation of the agricultural sector, the processing industry and the production site itself.

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[30] Storstad O (2007) Naturlig, nært og trygt. En studie av hvordan forbrukertillit til mat påvirkes av produksjonsmåte og matskandaler. Doktorgradsavhandling, NTNU.

5.4.2.2. Costs of the consumers to orient themselves in the market

If GMOs are approved, it may be considered a cost that consumers have to get familiar with the labelling scheme and how the GMO is employed in the value chain, and that there is more to consider when buying food. It is very challenging to put a monetary price on such a cost.

5.4.2.3. Health effects

The GMO regulations in Norway and the EU require an assessment of health risks before any GMO may be approved. Impacts on health shall be included in the cost-benefit assessment, although some of the effects are evaluated during the health risk assessment. Information can be retrieved from such evaluations, in addition to investigate if there are any health effects that are not included there. Health risk assessment is about assessing risk and not, for example, whether the GMO is healthier or less healthy than the alternatives. The latter is relevant if it concerns a GMO with altered content of fatty acids, vitamins or other nutrients. If certain health impacts are already identified as separate actions in the cost-benefit analysis, one must avoid duplicating the effects.

In Norway, VKM conducts the risk assessment, while the European Food Safety Authority (EFSA) is the responsible authority in the EU. The same requirements for assessment applies for both. EFSA has prepared guidelines for risk assessment of food and feed for both genetically modified plants and animals, in addition to guidelines for assessing health and animal welfare for the genetically modified animals.

According to the EFSA guidelines, the following should be considered during the health risk assessment of genetically modified plants:[31]

1. Characteristics of the recipient plant and of the organisms from which the genetic material originates
2. The genetic modification and consequences for the functionalities of the plant
3. Agronomic and phenotypic characteristics of the GM plant, i.e. characteristics of cultivation and observable traits of the plant
4. Characteristics of the composition of the GM plant and food and feed from the plant
5. Potential toxic and allergic effects of the gene product (protein, degradation product) and of the whole GM plant and products thereof
6. Intake through the diet and if it is possible that the nutritional content of the food is affected
7. Impact of processing and storage on the properties of the product

5.4.2.4. Environmental effects

According to the regulations in Norway and the EU, environmental risk must be assessed before any GMO may be approved. Environmental impacts shall be included in the socio-economic assessment, and one can retrieve information from the environmental risk assessment and assessment of sustainability. Since the objective of the environmental risk assessment is to determine whether the GMO poses a risk to the natural environment, there may be environmental effects that are not associated with risks and as a result are not considered during such assessments. These may be environmental impacts with beneficial effects. If certain environmental impacts are already identified as separate effects in the cost-benefit analysis, we must avoid duplicating the effects. Some environmental effects can be quantified in monetary terms, such as reduced use of pesticide, while others cannot. An example of the latter is ecosystem services like biological diversity.

EXAMPLE

An example of an environmental effect that we should avoid duplicating is less use of pesticides. The price of a pesticide includes an environmental fee. If reduced pesticide has previously been identified under effects as a saving in monetary terms, then the environmental benefit has in principle already been accounted for.

In Norway, VKM conducts the environmental risk assessment, while EFSA is the responsible authority in EU. The same requirements for assessment applies for both. EFSA has prepared guidelines for risk assessment of food and feed for both genetically modified plants and animals. The

[31] EFSA (2011) Guidance for risk assessment of food and feed from genetically modified plants. www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2150.pdf

impacts are not necessarily quantified during the risk analysis.

According to the EFSA guidelines, the following should be considering during the environmental risk assessment of genetically modified plants:[32]

1. The level of persistency and invasiveness of the plant and the relatives it can cross with (for example, whether the plant can readily establish itself in a certain habitat and outcompete other species)
2. Gene transfer from the plant to microorganisms (for example, antibiotic resistance gene)
3. The interaction between the GM plant and target organisms (i.e. organisms the plant is intended to affect, for example certain insect pests)
4. The interaction between the GM plant and non-target organisms (i.e. organisms that the plant is not intended to affect, for example other insects besides the insect pest), including choosing appropriate species and relevant functional groups (for example, organisms in a particular place in the food chain) for risk analysis
5. Impacts of the special type of cultivation, management and harvesting techniques used (this also covers production systems and the environment surrounding the cultivation site, for example pesticide-use)
6. Effects on biogeochemical processes (e.g. CO2-uptake by the plants, formation of living material in the soil, evaporation of water and conversion of nitrogen compounds)
7. Effects on the health of humans and animals

Some environmental impacts will be of major importance for members of the society, while others will be of less importance. Whether the plant can establish itself in Norwegian nature, cross with wild relatives and spread in nature, are of particular importance for the severity of the effects. If the method of cultivation changes, it can also have major environmental consequences. Effects on ecosystem services can be indirect, for instance if the GMO affect the flora or fauna in a way that enhances or weakens the ecosystem services associated with the plants, such as flood control and contribution to the quality of the air, soil and waters.
If the approval of a GMO results in less expensive animal grain feed, then for instance this may replace roughage, which may affect the use of grass resources in Norway. This may in turn affect the biological diversity in the cultural landscape and ecosystem services. If less outfields are exploited, this may also affect the biodiversity.

If livestock grazes less, animal welfare may be affected. Another possible consequence is altered composition of the products.

[32] EFSA (2010) Guidance on the environmental risk assessment of genetically modified plants. www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1879.pdf

6. Quantify and valuate effects (work phase 4)

6.1. Monetised effects

DFØ recommends monetising effects in physical quantities and to use market prices from the private sector to quantify them in NOK as far as possible. According to the DFØ guideline, chapter 3.4.2, the main principle of valuation is that the benefits are to be equated with what the population as a whole is willing to pay to achieve these effects. Costs should be equal to the value that such resources have in the best alternative area of use (the alternative cost). The prerequisite for quantifying an effect is that it provides meaningful information about the effect. One should elaborate on the underlying prerequisites and the level of uncertainty about the numbers, see chapter 8.

In many cases, market research will be useful, for example to determine the willingness to pay for a GMO product, and consequently if the price will change. The Norwegian authorities should conduct their own investigations for specific products, or we can refer to previously conducted and general surveys to make a generalisation. The price and willingness to pay will not necessarily be decisive for the assessments of GMO products.

See the DFØ guidelines, chapter 3.4, for a review on how to quantify and valuate effects.

6.2. Non-monetised effects

Some effects cannot be quantified in monetary terms, and it may also be undesirable to quantify certain effects in NOK. This may include effects on the natural environment, biodiversity or other types of environmental impacts in addition to the effects on culture, well-being, safety, etc. Even if there are certain things in nature and society we cannot valuate in money, such services might still be of value to people.

The DFØ guidelines mention the plus-minus method as a way of assessing non-monetised effects. First, the impact that authorisation of a GMO has on different areas of society is assessed, for example on a three-part scale: small, medium, large. Subsequently, the scope is evaluated, for example going from large to medium and small, and by distinguishing between a positive and negative scope on a seven-part scale. Finally, the consequence is identified using a consequence matrix. See the DFØ guidelines, chapter 3.4.8, for review on how to assess non-monetised effects and using the plus-minus method.

7. Assessing economic profitability (work phase 5)

Photo: iStock

According to the DFØ guidelines, an effect is economic profitable when the population is willing to pay at least the cost of the effect across its entire lifetime. In others words, that the total benefits exceed the total costs. When assessing economic profitability of approving a GMO, we first calculate the sum of all the monetised effects. Subsequently, the non-monetised effects are evaluated. If the monetised and the non-monetised effects point in the same direction, the assessment of profitability is obvious. On the other hand, if the monetised and the non-monetised effects diverge, the assessment is more ambiguous. In these cases, we must elaborate more closely on how we assess the proportions between the monetised and the non-monetised effects.

Chapter 3.5 of the DFØ guidelines outline how to assess economic profitability, including how to choose the discount rate, period of analysis and residual value. We have looked specifically at the analysis period, see chapter 7.1.

7.1. Period of analysis

In the EU, a GMO is authorised for ten years at a time, and the GMO producer must apply to prolong the authorisation before the end of the ten-year period. Consequently, ten years is a natural period of analysis for the cost-benefit analysis.

Most GMOs are replaced by new ones after a few years. Patents are given for 20 years at a time and plants are rarely sold after the patent has expired. Issues related to resistance of weeds and insect pests may also necessitate replacement of GMOs with new ones. Thus, the lifetime of the products also speaks in favour of employing a ten-year period of analysis.

In other cost-benefit analysis, 40 years is often used as the analysis period, and 10 years is considered short. This is often due to a high cost of initial investments, where a positive yield is not obtained until several years later. There may also be effects that do not appear until after ten years

time, such as environmental effects. In some cases, the initial benefits eventually disappear. Thus, one should consider whether it is necessary with a longer time frame for certain GMOs.

One alternative might also be to postpone the authorisation of the GMO if one expects to acquire more information that can facilitate a better decision-making after a few more years.

Control questions to determine whether the analysis period should be more than ten years:

- What is the expected service life of the GMO?
- Will approval of the GMO result in significant investments that will not yield a positive return the first ten years?
- Can approval of the GMO lead to advantages or disadvantages that are not noticeable before more than ten years have passed?
- Is there a large degree of uncertainty associated with the assumptions made concerning the reference alternative or the approval alternative?
- Is there a large degree of uncertainty about important effects and how these will evolve over time?

8. Conducting an uncertainty analysis (work phase 6)

The objective of the uncertainty analysis is to identify uncertainty and to demonstrate how to deal with this uncertainty. The uncertainty factors for monetised and non-monetised effects will be registered, both the uncertainty about what the effects will be and the uncertainty associated with the quantification and valuation. In addition, the uncertainty related to the scenario associated with the reference alternative and the alternative of authorising a GMO need to be determined.

It is important to define what we mean by uncertainty. Examples of different types of uncertainty include when the outcome is known, but not the likelihood; when there are unknown aspects, but research can help elucidate these; and when there are unknown aspects, but research cannot provide answers. Another type of uncertainty is when different research groups arrive at different results or have different interpretations of the results.

Furthermore, it is important to determine which uncertainty factors are important for the conclusion, and to analyse or calculate these factors in order to determine their relevance to the economic profitability. Finally, we will consider if measures can be implemented to reduce the uncertainty.

There is a fundamental difference between monetised and non-monetised effects. Models for calculating the uncertainty related to monetised effects exist, such as sensitivity analysis. Non-monetised effects cannot be quantified, but models exists which map the magnitude and severity of the uncertainty. DFØ has a model for classifying non-monetised uncertainty factors, where the probability of deviations ranging from very small to very large, and the effect on profitability ranging from insignificant to very large, are assessed.

See the DFØ guidelines, Chapters 3.6 and 4.4, for further advice and methods on how to conduct uncertainty analysis.

EXAMPLE

In the example of herbicide-resistant soy, the most important effects will be: the price of the raw materials (quantified and valuated, low degree of uncertainty), costs for separate production lines (quantified and valuated, low degree of uncertainty) and impact on reputation (non-monetised, high degree of uncertainty).

Example: The potential market share of GM soy is uncertain, which is decisive for several effects. Another factor in the uncertainty analysis is if and how consumer behaviour will change depending on the type of information they receive about the product. Consumer behaviour does not always coincide with the information they provide during surveys, nor is it certain that the information reaches the consumers. Consumer perceptions are relevant to assess effects on reputation. For example, a GMO with marine omega-3 fatty acids or a late blight-resistant potato can result in a positive reputation. Nevertheless, it is necessary to consider whether information about, for instance reduced use of pesticides and how long this advantage will last, actually reaches the consumers.

9. Determine distributional effects (work phase 7)

During this work phase, we will determine how the costs and benefits distribute themselves among different societal groups - who gets the benefits and who bears the costs if a GMO is authorised for production or import? Are there any groups that are especially negatively affected This will constitute an additional analysis to the economic profitability assessment. It is the effects identified through the economic profitability analysis that will be assessed. Potentially novel and relevant effects that become apparent through this work must also be included. We will then perform an additional assessment to the original economic profitability assessment before making an overall assessment of distributional effects.

Distributional effects must be assessed on a case-by-case basis. We should investigate whether there are large negative effects for some of the groups identified in chapter 5.1.1, i.e. groups that fall within the economy (production, distribution, consumption or redistribution (waste/reuse)) and other groups. Examples of groups that are adversely affected may be: all consumers or certain groups of consumers, producers of organic or other GMO-free commodities, and geographical regions in Norway. Redistribution between generations is less relevant assuming a ten-years perspective.

Distributional effects can, for example, be related to public and private ownership, structural changes in a business, and redistribution of power in the food and feed production chains. One example includes consumers that want GMO-free food production and that may become negatively affected if there are no requirements for labelling of meat from animals that have been fed GM feed, as they no longer exhibit freedom of choice. Additionally, conflicting consumer interests may arise if certain consumers desire a GMO product that is not authorised.

10. Overall effects that should be assessed against the general societal objectives before we make a final assessment and provide specific advises

During the economic profitability analysis, we try to include all relevant socio-economic effects. It also includes non-monetised effects, such as certain environmental impacts. Other effects are not relevant for the cost-benefit analysis, but may for example be associated with political priorities and still be relevant as part of the basis for the decision-making (work phase 8). Therefore, one should discuss whether these effects contribute positively or negatively to the general social objectives (see chapter 3.3 and 11). It may also be appropriate to consider other effects than those mentioned below against the general societal objectives.

10.1. Food security

Food security relates to access to enough, safe and nutritious food.[33] Norway has a goal of being self-sufficient to some extent with self-produced food. In addition, Norway aims for a robust food supply, which is part of the supply security. We should consider how a decision to approve a GMO may affect these goals. We should also investigate whether introduction of GMOs may contribute to a change in power relationship in the food chain, for example by shifting power from the producer (the farmer) to other levels along the chain, or if power is concentrated in monopoly.

The level of self-sufficiency is closely linked to political priorities in the food policy. For instance, even though it becomes cheaper to cultivate a GMO variety, it is still not certain that the total cultivation of the species will increase.

If we import a GMO of a plant species that is not cultivated in Norway, it will basically not affect the level of self-sufficiency. On the other hand, one should investigate whether it could make a difference if the GMO replaces something else, for example grains that can be cultivated in Norway. In theory, the grain can be used for producing something else. But because there is a distinction between grains that can be utilized for food and grains that can be utilized for feed, it is not necessarily that easy to make a shift.

Supply security of food can be measured as our ability to cover the nutritional needs in Norway in the event of a war or crisis. This is achieved through the production of food, the restructuring of production if necessary, food storage and the best possible trade relations. If it is cheaper to import GM food or feed, it may result in increased imports, which in turn may result in slightly reduced supply security, but it is not given that imports will increase.

The effects on self-sufficiency and supply security are challenging to quantify and are often characterised by uncertainty, but high and constant production is generally considered a prerequisite for the best possible food security.

EXAMPLE

Regarding GMO-free soy, the demand for this has contributed to keeping the world production at around twenty percent of total soy production in the past eight years.[34] GM soy is not that much cheaper than GMO-free soy so that it will change the big picture, so it is uncertain whether it will have much impact on Norwegian agriculture and aquaculture. If it becomes difficult to obtain GM-free soy, it is quite possible to authorise GM soya if necessary.

10.2. Share of organic food production

According to the agricultural report "Endring og utvikling" (St. mld. 11, 2016-2017), a quantified goal on organic food production is no longer in place. The production development is instead determined by the demand for it. The cultivation or import of GMOs in itself will not increase the cultivation of organic food, since GMOs are not allowed in

[33] According to The Food and Agriculture Organization of the United Nations (FAO), food security exists when «All people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life.» www.fao.org/economic/ess/ess-fs/en

[34] www.isaaa.org

organic production. In Spain, organic production of maize has faced great difficulties and is more or less non-existent in areas where GM maize is cultivated.[35] Thus, we should consider whether GMO approval may make it more difficult to reach the goal of organic food production in Norway, whether it will not make a difference, or whether it will be be a positive contribution. Good opportunities for coexistence between GM plants and organic plants will be important in this case.

10.3. Access to genetic resources in crops and livestock

If a GMO is adopted in Norway, we should consider whether it may affect the rights to plant varieties and livestock. There are often different types of rights, typical patent rights, associated with GMOs compared to ordinary plants, for which plant breeders' rights is the most common. There will be a difference between the impacts associated with the importation of a GMO and a GMO developed by Norwegian breeders, as plant breeders' rights is the most common in Norway.

In other countries, patent right has often provided companies that sell GM plants the right to impose restrictions on further breeding and on farmers' rights to retain seeds from their own crops. This may affect the diversity of cultivars in the long term. We should clarify which rights the patent holders have over primary producers in Norway, and which agreements Norwegian seed and planting material businesses will make in terms of reciprocal licenses.

Can a GMO affect the rights to genetic resources in plants and animals, if approved? Photo: iStock

10.4. Knowledge and technology development

10.4.1. Changes in the composition of food and feed

Changing the relative price of input factors can contribute to a change in ingredients employed in food and feed. In practice, it is uncertain what impact this may have, and it will vary with the type of GMO.

EXAMPLE

In the example of herbicide-resistant soy, the composition of feed will not change. In fish farming, the current cost of feed is small compared to the value of the fish. For example, in Norwegian agriculture, the content of pig feed has already been optimised based on feed cost and the pig's growth, concurrently as having to exploit a certain part of Norwegian raw materials for feed.

10.4.2. Novel, unintended areas of use

When the price of a product changes, it may result in new areas of application for the product that may be challenging to predict. The product can replace a totally different product in a different industry, which can be considered both positive and negative. One example is if soy or rapeseed becomes so cheap that it is beneficial to use as biofuels.

10.4.3. Changes in the breeding volume in Norway

If a large number of farmers start cultivating a genetically modified plant variety, the volume that is not genetically modified may fall below a critical mass, so that breeding activities of non-genetically modified cultivars are no longer good enough. This can negatively impact traditional breeding and the conservation of cultivar diversity. We should investigate whether the approval of a GMO may have such effects.

10.4.4. Incentives for innovation

If Norway rejects or approves a GMO application, it may both increase and decrease the incentives for innovation in food and feed production, but the effects cannot be quantified. If GMOs are authorised, it may result in insufficient

[35] Herrero A, Binimelis R, Wickson F (2017) Just resisting is existing: The everyday struggle against the expanison of GM crops in Spain. Sociologia Ruralis. DOI: 10.1111/soru.12166 http://onlinelibrary.wiley.com/doi/10.1111/soru.12166/abstract

research on alternatives to GMOs. On the other hand, banning a GMO could result in less research to develop other GMOs because developers consider it difficult to obtain authorisation. It is also possible that the use of GMO technology can contribute to increased breeding activity to develop varieties adapted to cultivation in Norway. Potentially, authorising a GMO may contribute to reduced breeding activity by encouraging the agricultural sector to focus on properties that are developed by companies or institutions outside of Norway.

EXAMPLE

In the example of soy, approving the import of GM soy, which is cheaper than ordinary soy, could weaken the incentive to develop substitutes for soy in feed. However, if the GM soy results in less expensive fish feed, it can lead to an increase in fish production, which will increase the demand for marine ingredients which, together with increased margins, can result in more innovation.

11. Give an overall assessment and recommend a decisive measure (work phase 8)

The Biotechnology Advisory Board is responsible for assessing the societal benefit of a GMO, while the Environment Agency provides an overall assessment and recommends a decisive measure for the Ministry of Climate and Environment. It is the government that make the final decision whether to authorise or reject an application. All authorities must take into account the result of the cost-benefit analysis and make political assessments. The more thorough the cost-benefit analysis is required to be, the more important is it to acquire specialist expertise from economists and others, who can then be commissioned to conduct an analysis, see chapter 2.3.

Those commissioned to conduct such an assignment, shall submit the results of the economic profitability analysis. In addition, they must discuss distributional effects, i.e. who receives the benefits and costs when a GMO application is authorised, and how the authorisation of an application meets the objectives and societal goals. The economists shall not recommend authorisation or rejection, but should clarify the consequences of choosing one option over another, for example by stating that if we choose this option, the outcome of the economic profitability analysis and distributional effects will be this, without making a proposition on whether this is bad or good. The economist shall also consider how the authorisation of the GMO may affect societal goals, but without considering which goals that should be prioritised.

Economic profitability measures how much people are willing to pay over the lifetime of the measure, but this does not necessarily imply that it is better than measures with less willingness to pay. One challenge is that monetised and non-monetised effects cannot be directly compared. Besides, the monetised effects in the analysis are managed at the same level, but it may be that there are figures that are not directly comparable, even though they are quantified in money. . If so, one can take into account that certain financial consequences should be more heavily weighed than others when making a decision.

The Biotechnology Advisory board, the Environment Agency and the government should also ask if there are certain prerequisites that trump all others. Thus, if these are met, this alone is reason enough to ban a GMO. It can constitute a value that cannot be quantified in money, and that is related to for instance nature or culture. The requirement that a GMO shall not cause any environmental or health hazards may constitute such a prerequisite. Nonetheless, the work leading up to the Gene Technology Act states that this should not be considered an absolute requirement, to leave room for weighing it against great societal benefit or contribution to sustainable development.

Subsequently, based on political assessments and valuations, the Biotechnology Advisory Board, the Environment Agency and eventually the government must decide what they will place most emphasize on. They must also take into account that different sections of the population have different understandings and interpretations of the impact of the effects and the uncertainty they hold.

The Norwegian Biotechnology Advisory Board
Stortingsgata 10
0161 Oslo, Norway

Ph: +47 24 15 60 20
e-mail: post@bioteknologiradet.no
www.bioteknologiradet.no

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