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REPORT

Herbicide-resistant genetically modified plants and sustainability

Bioteknologirådet
The Norwegian Biotechnology Advisory Board

CONTENTS

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The Norwegian Biotechnology Advisory Board is an autonomous body that was first appointed by the Norwegian Government in 1991. The legal basis for the Biotechnology Advisory Board consists of the Act relating to the application of biotechnology in human medicine, etc. and the Act relating to the production and use of genetically modified organisms, etc. In addition to providing advice in matters relating to the use of biotechnology and gene technology in connection with humans, animals, plants and microorganisms, the Board is charged with disseminating information and promoting debate.

In its assessments, the Board shall attach particular importance to the ethical and social consequences of employing modern biotechnology.

The Board had 21 members in the period 2008–2013. In addition, seven ministries participated as observers. The Board's secretariat is located in the centre of Oslo. The Norwegian Biotechnology Advisory Board had a budget of NOK 8.7 million for 2013.

Bioteknologirådet
The Norwegian Biotechnology Advisory Board

PREFACE

In this report, the Norwegian Biotechnology Advisory Board presents the results of the project "Herbicide-resistant genetically modified plants and sustainability". The project was commissioned by the Norwegian Environment Agency, formerly the Directorate for Nature Management. The Agency wanted a document containing guidelines that could be used by administrative staff to process applications for approval of genetically modified organisms (GMOs) pursuant to the Gene Technology Act. The objective was to arrive at parameters that could be used to determine whether a plant that was genetically modified to resist a herbicide contributed to sustainable development.

The Biotechnology Advisory Board has endeavoured on a number of occasions to operationalise the concepts of sustainable development, social benefit and ethical and social considerations in the Gene Technology Act. The results of the first endeavour were published in a report most recently updated in 2009. Parts of the report were included in the Regulations on Impact Assessment (see 1.1.4) pursuant to the Gene Technology Act. In 2010/2011, the Biotechnology Advisory Board conducted a project on insect-resistant genetically modified plants. The project on herbicide-resistant plants in 2012/2013 is a continuation of the other endeavours. The project forms the basis for further work to translate the concepts of sustainable development, social benefit and ethics in the Gene Technology Act into concrete terms.

The Biotechnology Advisory Board would like to thank those external experts and Board members who have participated in the *ad hoc* group, and our partners in the Environment Agency. We would also like to thank the Agency for financial support for the project, and senior adviser Audrun Utskarpen of the Biotechnology Advisory Board's secretariat for directing the work.

Lars Ødegård	Sissel Rogne
Board Chairperson	Director General

Summary

The Norwegian Biotechnology Advisory Board carried out the project "Herbicide-resistant genetically modified plants and sustainability" in 2012/2013. The objective was to find relevant parameters that could be used to determine whether a plant that was genetically modified to tolerate a herbicide contributed to sustainable development in the areas of environment/ecology, economy and society. Using the parameters as a basis, we formulated questions that must be answered to enable the evaluation of applications for approval of these plants. In addition to the questions for applicants, there are questions the Norwegian authorities should reply to. We also discuss knowledge gaps.

The questions concerning environment/ecology are grouped into three blocks. The first concerns the herbicide-resistant plant itself, and the topics are:

- characterisation of the plant
- interaction between plant and environment
- gene flow
- preservation of biodiversity
- comparison with control plants

The second block concerns the herbicide the plant has been modified to tolerate, and covers the following topics:

- characterisation of the herbicide
- effects of a change in the spraying regime on
  - preservation of biodiversity
  - the time when spraying takes place
  - drifting of the herbicide with the wind
  - the type and amount of herbicide that is used
  - the effects of using more than one herbicide in the same area
- resistance of other plants to the herbicide

The last block concerns soil, water, energy and climate.

The questions on sustainable development in the areas of economy and society are grouped into the following main topics:

- the right to sufficient, safe and healthy food
- animal health and welfare
- living conditions and profitability for the farmers who cultivate herbicide-resistant genetically modified crops
- living conditions and profitability in the production area
- rules for use of herbicides
- plant genetic resources for food and agriculture
- independent risk research
- free choice of agricultural system in the future

The questions the authorities should answer are grouped under the following topics:

- freedom of choice for Norwegian consumers
- ecological, economic and societal consequences in Norway
- plant genetic resources for food and agriculture
- independent risk research
- the consequences of approving many different genetically modified organisms
- Norway's North-South policy, work to protect biodiversity and international role
- prioritisation of the most important issues

Finally, we discuss factors that we believe to be particularly important for deciding whether herbicide-resistant genetically modified crops – hereafter called HR crops – can be said to contribute to sustainable development.

1 Introduction

1.1 The Gene Technology Act and sustainable development

The Norwegian Gene Technology Act of 1993 regulates the production and use of genetically modified organisms (GMOs). The Act requires that for a genetically modified plant to be approved in Norway, it must not be harmful to health or the environment. Norwegian authorities must also consider whether the production and use of the genetically modified plant

- contribute to sustainable development
- are of benefit to society
- are ethically justifiable

1.1.1 Sustainable development

The 1987 report *Our Common Future* of the World Commission on Environment and Development (the Brundtland Commission) defined sustainable development as development that

> meets the needs of the present without compromising the ability of future generations to meet their own needs.[1]

The concept of sustainable development is based on the notion that people must be able to meet their needs without this being at the expense of future generations, and that the basic needs of the world's poor must have priority. The capacity of the environment to meet our needs now and in the future depends on technological development and the organisation of society. To make it easier to determine what sustainable development must mean in practice, the concept has usually been divided into three main areas, also known as the three pillars:

- environmental (ecological) sustainability
- economic sustainability
- social sustainability

The perspective is global, and extends across several generations.

1.1.2 The precautionary principle

The preliminary works to the Gene Technology Act stress that the objective is to assess the risk to health and the environment in advance, and avoid potential adverse effects, and that the precautionary principle must be applied. The precautionary principle is employed when there is lack of scientific understanding or when there is scientific uncertainty. If there is reasonable doubt as to whether serious harm is a likely result, or reasonable doubt as to serious consequences, the absence of conclusive evidence must not preclude the use of the precautionary principle, for example for not approving the cultivation or import of a genetically modified organism.[2] The precautionary principle is one of the principles embraced by the concept of sustainable development. With regard to sustainability, the Biotechnology Advisory Board has counselled that the precautionary principle should only be used in connection with risk to health and the environment. If the precautionary principle is used in assessing sustainability, the perspective is more long-term and global than in traditional health and environmental risk assessments.

1.1.3 Responsibilities of the Biotechnology Advisory Board

The Biotechnology Advisory Board is responsible for making a holistic assessment of genetically modified plants, and has a special responsibility for assessing sustainability, social benefit and ethical factors. Genetically modified plants can contribute both positively and negatively to sustainable development. The developers of genetically modified plants tend to market the benefits of this technology. The Biotechnology Advisory Board is also required by its mandate to consider challenges and weigh up the benefits against the possible drawbacks and risks. Assessing risks means considering which harmful effects may ensue, how likely they are, and what the consequences would be. The Biotechnology Advisory Board also gives advice on the management of potential risk, i.e. what the authorities and the community should do to mitigate documented risk. This also entails managing scientific uncertainty, lack of consensus and knowledge gaps. Risk and uncertainty must then be weighed up against the benefits of approving a genetically modified plant.

1.1.4 Operationalisation of the concepts of sustainable development, societal benefit and ethics

The work of the Brundtland Commission formed the basis for the inclusion in the Gene Technology Act of the requirement that contribution to sustainable development must be

FACT BOX

Herbicide-resistant genetically modified plants – HR crops

Plants that are genetically modified to tolerate herbicides are also called herbicide-resistant crops (HR crops) or herbicide-tolerant crops (HT crops). One or more genes that code for new proteins that cause the plant to counteract or bypass the effects of one or more herbicides have been inserted into the DNA of these plants. The purpose is to kill weeds with herbicides that the cultivated plants have been made resistant to, while the cultivated plants remain in the field unharmed. Most HR crops are resistant to herbicides containing glyphosate, glufosinate or both, but in recent years HR crops that tolerate herbicides such as 2,4-D and dicamba have been developed.

Herbicide-resistant plants are cultivated in over 80 per cent of the area worldwide that is used for genetically modified plants.[7] HR plants that are also resistant to pest insects are cultivated on about one third of the area devoted to HR plants. The herbicide-resistant plants that are most widely cultivated today are soya, maize, cotton and oilseed rape. The most common is glyphosate-resistant soya (Roundup Ready soya). The countries that cultivate the most HR soya are Brazil, Argentina and the USA. HR sugar beet is cultivated in North America, and HR alfalfa has been cultivated in the USA. The company Monsanto has also developed rice and wheat that are resistant to glyphosate, but these plants are not on the market. A number of HR plants have been approved for import into the EU. One variety of HR maize has been approved for cultivation, but has never been used.

considered. But what is required for the production and use of a genetically modified plant to be regarded as sustainable, and how the various considerations should be weighed up against one another, are by no means self-evident. In order to find answers to these questions, the Biotechnology Advisory Board drew up a report in 1999 on the factors to which Norway should attach weight when assessing the ethics, sustainability and social benefit of genetically modified organisms (GMOs).[2] Parts of this report were included in 2005 as Appendix 4 to the Regulations relating to Impact Assessment pursuant to the Gene Technology Act. The report was revised in 2006 and 2009. In 2011, the Biotechnology Advisory Board published a report on insect-resistant genetically modified plants and sustainability. The report proposed parameters that should be used to assess whether insect-resistant genetically modified plants contribute to sustainable development.[3]

1.2 The assignment from the Directorate for Nature Management

In late 2011, the Directorate for Nature Management commissioned the Biotechnology Advisory Board to write a report on factors of relevance to an assessment of the Gene Technology Act's criterion of sustainable development in the light of contemporary knowledge. This time, the assignment concerned plants that were resistant to herbicides. In 2012, the Biotechnology Advisory Board appointed an *ad hoc* group consisting of members of the Advisory Board, Norwegian researchers and other experts (see p. 10). The tasks of the *ad hoc* group were to

1. identify important parameters of relevance for assessing the sustainability of herbicide-resistant genetically modified plants:
   a. ecological parameters
   b. economic parameters
   c. social parameters
2. identify important knowledge gaps associated with the parameters identified
3. formulate general questions to be put to applicants in connection with applications for release of GMOs

The concept "release of GMOs" covers cultivation in addition to imports of food and feed and other products that contain viable material.

1.3 Working methods

The work of the *ad hoc* group forms the basis for this report. Dr Audrun Utskarpen of the Biotechnology Advisory Board's secretariat has coordinated the work and drafting of the report. The *ad hoc* group has held three seminars: 10–11 May 2012, 10–11 September 2012 and 28 May 2013. The Biotechnology Advisory Board also organized public meetings with international guest speakers in connection with the first two seminars.[4] The aim was to be updated on new knowledge, learn from the experience of others in translating the concept of sustainable development into concrete terms, and identify knowledge gaps.

In an assessment of sustainable development in the areas of environment, economy and society, relevant topics and questions in one area will also affect the two others, and there will also be some overlapping of all three areas. Many questions could be classified under both economy and society, and we therefore chose to combine these two areas.

The *ad hoc* group evaluated the following for each of the main areas of environment/ecology and economy and society:

- Must any special requirements be met in order for development to be sustainable?
- What sort of questions should be asked in the sustainability assessment?

With the aid of the *ad hoc* group, the Biotechnology Advisory Board arrived at a set of questions that the Advisory Board regards as the most important for determining whether a herbicide-resistant genetically modified plant contributes to ecological, economic and social sustainability compared with comparable, non-genetically modified plants. The report contains explanations of the questions. Parts of the contents of this report are based on the report on insect-resistant plants.

The thoroughness with which various issues and hypotheses have been investigated through research varies. In some cases, there is no published research. In others, a few studies have been published, but some of the findings of these studies may indicate a need for further investigation. We have therefore provided a brief account of knowledge gaps in the report. On p. 61 we have considered other possible ways of determining whether GMOs are sustainable, on the basis of international conventions or certification schemes. Some researchers are also using algorithms to try and determine whether GMOs are sustainable. The challenge, however, is that many of the answers to the questions we are asking cannot easily be quantified. Nor will sustainability assessments yield one unambiguous answer; they will also be built upon value-based conclusions where political choices must be made. It is therefore advisable to use lists of questions, such as the ones we have drawn up, as a means of assessing contributions to sustainable development.

1.4 Use of the report

The report is intended to be an administrative tool and provide a better basis for deciding on applications for approval of the import or cultivation of herbicide-resistant genetically modified plants. The report has been written with the intention that it should be possible to consult individual chapters without reading the whole report.

Up to the present, no Norwegian institutions have applied for permission to cultivate in Norway or to import genetically modified viable material. Nor have any foreign companies applied directly to the Norwegian authorities for permission to do so. However, as a member of the EEA, Norway receives applications for approval of genetically modified plants through the EU. In connection with applications from the EU, the Norwegian authorities ask questions via the European Food Safety Authority (EFSA), but also address themselves directly to the applicants.

11.4.1 Questions that can be used to assess sustainability

We have arrived at main and sub-topics in the areas of environment/ecology and economy and society that represent material and ethical values that it is important to safeguard and develop in a sustainable manner. The questions we have formulated express in more concrete terms the aspects that we consider pertinent for determining whether HR crops can contribute to sustainable development. For each topic/question in the table there is a reference to a chapter in the report with further explanations.

HR sugar beet is cultivated in North America. Photo: Scanstockphoto

The questions for applicants seeking approval of an HR plant are compiled in Table 1, p. 12 (environment/ecology) and Table 2, p. 15 (economy and society). It is the applicants' responsibility to ensure that an impact assessment is carried out.

In addition to the questions to the applicants, we also have a list of questions for Norwegian authorities; see Table 3, p. 17. The reasons for this are: first, it is not the responsibility of the individual applicants to consider all issues relating to sustainable development, nor can they reasonably be expected to resolve them. Second, when the concept of sustainability is split up into environmental, economic and social sustainability, and then broken down further into a number of individual questions, there is a risk of losing the holistic approach that lies at the heart of the concept. For example, the consequences of approving many genetically modified organisms may be different from approval of a few. Among other things, it should be taken into account that synergistic and cumulative consequenses may arise. The authorities must assume the responsibility for assessing this. The authorities must also evaluate the documentation from the applicants and compare it with other available documentation.

What we are asking for can in many cases be formulated in an alternative way as parameters, i.e. variables that may have different values. For example, under topic 7a, *Effects of a change in spraying regime, preservation of biodiversity,* a number of health effects, a change in the biodiversity of weeds, damage to microflora and microfauna in the soil and hormone-mimicking and -inhibiting effects can be regarded as parameters. In some cases, it may be necessary to break down a question further into sub-questions with sub-parameters to make it possible to answer.

The term "indicator" is widely used in connection with sustainable development. An indicator measures the state of a particular factor or phenomenon. Indicators can also be formulated on the basis of a number of the questions. As part of the follow-up of the work of the Brundtland Commission, each country undertook through Agenda 21 to establish indicators of sustainable development.[5] Norway obtained its set of indicators in 2005.[6] On page xx we provide an account of the Norwegian sustainability indicators and how the sustainability of genetically modified organisms can be assessed in accordance with these.

Some of the questions contain clear criteria for HR crops contributing to sustainable development; i.e., certain requirements that must be met. Examples of such criteria are that the HR crop must not contain genes for resistance to antibiotics, and that it must be available for independent risk research.

The questions can be used both to assess cultivation of genetically modified herbicide-resistant plants in Norway and the import of such plants for use in food and feed. If the application is only for permission to import, the questions on cultivation conditions and ecology relate to the country of cultivation. Not all the questions are equally relevant to all applications, and some are more relevant if the plant is to be cultivated in countries other than Norway.

Although the assignment from the Norwegian Environment Agency covers food and feed with viable material that is regulated by the Gene Technology Act, the sustainability assessments will also be relevant for assessing the import of food and feed without viable material. However, some questions are most relevant for viable material.

1.4.2 Answers to sustainability questions

In order to make it easier to assess a plant's contribution to sustainability, we have formulated most questions in such a way that the answer must be either "yes" or "no", "increased" or "reduced", "more" or "fewer" etc. One possible risk is that the answers we receive do not provide enough information. We therefore stress that the applicants must document and substantiate their answers to all questions.

Some questions only have two possible answers, such as the question of whether the HR crop is resistant to more than one herbicide. Other questions allow for different answers and assessments along a sliding scale. We have provided more details in the report on what we believe it is important to take into account in the assessments.

The quantifiability of what we ask about varies, and there may or may not be methods for measuring what we want to know. However, the fact that something cannot be quantified, or that no method has been developed for measuring something, is not indicative of the importance of the question, and does not justify dismissing the question. Knowledge gaps should be followed up with research.

In several questions a particular answer clearly counts in a particular way. For example, a "yes" reply to the question of whether the HR crop in the form of food or feed has harmful effects on health, will count negatively. If, on the other hand, the use of herbicide is reduced, which is beneficial for the health of the community, this counts positively. The answers to other questions, such as whether ownership in the area is changing, do not automatically count positively or negatively. In other cases, it counts positively if the plant meets one condition, but it does not count negatively if the condition is not met. For example, it is positive if the HR crop is to be used for food and/or feed, but it does not count negatively if it is to be used in other ways, for example in manufacturing. An HR crop that is not intended to be used for food or feed may contribute to sustainability in other ways.

A number of the questions, particularly on environment/ecology, are arranged so that the respondent and risk assessors must first decide whether there are differences between the HR crops and the crops or cultivation system with which a comparison is being made. Then they must consider whether the differences may result in adverse effects, and finally, they must assess the risk, i.e. how probable and how serious potential adverse effects would be.

1.4.3 Basis for comparison

All agriculture has consequences for the environment, the economy and society, and different agronomic methods may be more or less sustainable. In order to determine whether the HR crop contributes to sustainable development, a comparison must be made with some kind of benchmark: either an existing plant or practice, or a standard that is higher than the existing one. It is this benchmark that decides how stringent the requirements we make will be in practice. In the area of environment/ecology, we recommend comparing the HR crop with its closest genetic relative under the same ecosystem conditions. In the individual application, it will be most correct in the area of economy and society to make a comparison with the plant the HR crop is replacing, or with the cultivation system commonly used in the area. A particular effect that is accepted under the usual agricultural system will then also be accepted if this effect ensues from an HR plant.

If the cultivation practice with which we are making the comparison cannot be regarded as sustainable, this may nonetheless present a dilemma. We might then approve an HR crop with the same effects, but which will also not be sustainable, or an HR plant that is a little better, but still not sustainable. At the same time, there might be other alternatives that actually would be sustainable. Questions of this nature should be discussed in light of the goals of food policy and the consequences of allowing many different genetically modified plants. In order to bring about the developments desired by society, the authorities are responsible at all times for setting general agricultural standards, and adopting food policy goals.

1.4.4 Basis for further work

This project on herbicide-resistant genetically modified crops, in conjunction with the project on insect-resistant genetically modified crops, provides a basis for continuing the work of operationalising the concept of sustainable development in the Gene Technology Act, and for revising the Regulations on Impact Assessment. The project also forms a basis for further work on assessing the sustainability of other types of genetically modified organisms, in addition to ethical factors and social benefit.

Members of the *ad hoc* group:

- Professor Stein W. Bie, PhD, Imsa Knowledge Company AS, Koppang
- Mads Greaker, PhD, head of research, energy and environmental economics, Statistics Norway
- Knut A. Hjelt, Cand.real., member of the Biotechnology Advisory Board and Technical Director Aquaculture, the Norwegian Seafood Federation
- Professor Eline Hågvar, Dr.agric., Norwegian University of Life Sciences
- Valborg Kvakkestad, PhD, research scientist, NILF – Norwegian Agricultural Economics Research Institute
- Elisabeth Magnus, Dr.scient., Nordic Area Coordinator, the Foundation for Ecolabelling (participated in 2013)
- Anne I. Myhr, Dr.scient., Acting Director, GenØk – Centre for Biosafety
- Jan Netland, Dr.scient., research scientist, plant health and plant protection, Bioforsk – Norwegian Institute for Agricultural and Environmental Research
- Professor G. Kristin Rosendal, Dr.polit., Fridtjof Nansen Institute
- Even Søfteland, Cand.mag., member of the Biotechnology Advisory Board and general manager of CapMare
- Bell Batta Torheim, Cand.polit., member of the Biotechnology Advisory Board and adviser, the Development Fund
- Professor Terje Traavik, Dr.philos., member of the Biotechnology Advisory Board and senior adviser, GenØk – Centre for Biosafety
- Marte Rostvåg Ulltveit-Moe, Cand.scient., project worker of the Norwegian Society for the Conservation of Nature and former member of the Biotechnology Advisory Board (participated in 2012)
- Toril Wikesland, Siv.agric., member of the Biotechnology Advisory Board and head of organisation, Akershus Farmers' Union

2 Characteristics of sustainability: questions for applicants and the authorities

The questions we need answers to in order to determine whether a herbicide-resistant genetically modified plant contributes to sustainable development are presented in Table 1 (environment/ecology), Table 2 (economy and society) and Table 3 (questions for Norwegian authorities). Tables 1 and 2 propose questions that applicants seeking approval of an HR crop for import or cultivation should answer. Table 3 contains questions that Norwegian authorities, and not the applicant, should answer when making a holistic assessment of the application.

Large-scale agriculture. Harvesting soybean in Brazil. Photo: Yasuyoshi Chiba / Scanpix

Table 1. Sustainable development environment/ecology: questions for applicants The questions are grouped under main topics and in some cases sub-topics. For each topic or question, there is a reference to a chapter explaining in more detail the point of the question and why it is relevant.

The genetically modified plant	1. Characterisation of the HR plant* See chapter 3.1.1.	a. Has the HR crop been thoroughly phenotyped and genotyped?
		b. Are the genome, gene expression and properties of the HR crop stable over time and through several generations?
		c. Is the HR crop substantially equivalent to the unmodified parent plant with the exception of the inserted gene and the protein it expresses, and does the answer apply irrespective of cultivation site and conditions?
		d. Is the HR crop resistant to more than one herbicide?
		e. Does the HR crop have a gene for resistance to antibiotics?
	2. Interaction between plant and environment. See chapter 3.1.2.	a. Is the environment, i.e. the ecological conditions in the cultivation area, thoroughly characterised and explained?
		b. Do the HR plant's genome, gene expression or properties change when the plant is cultivated in different places?
		c. Might the metabolism, chemical composition and/or nutritional value of the HR plant change because of the ecological conditions in the cultivation area?
		d. Might the effects of the HR plant on the environment or its interaction with the environment vary, depending on conditions in the cultivation area or the surrounding area?
	3. Gene flow. See chapter 3.1.3.	a. Is there a risk of vertical gene transfer to non-genetically modified plants of the same or related species?
		b. Is there a risk of horizontal gene transfer to other species?
	4. Preservation of biological diversity. See chapter 3.1.4.	a. Might cultivation of the HR plant have health effects (toxic, immunological, including allergic, or anti-nutrient effects) that are acute, chronic or long-term, and/or lead to a change in the viability, fertility and development rate of non-target organisms, i.e. wild populations of • mammals? • birds? • amphibians/reptiles? • insects (herbivores, predators, pollinators and decomposers) • red-listed species? • prioritised species?
		b. Have the conclusions in 4a been drawn on the basis of exposure to • plant material from the HR plant? • the protein expressed by the inserted gene, after extraction from tissue from the HR plant? • the protein expressed by the inserted gene in the organism it is obtained from?
	5. Comparison with control plants. See chapter 3.1.5.	a. Has the HR plant been compared with its closest genetic relative under the same ecosystem conditions?
		b. Have the characterisation and comparative investigations been made with HR resistant plants that • have been sprayed with the herbicide(s) that they are modified to tolerate? • have been exposed to predators or other biotic or abiotic stress factors?

*By HR crops/plants we mean herbicide-resistant genetically modified crops/plants.

Table 1. continued

The herbicide*	6. Characterisation of the herbicide(s). See chapter 3.2.1.	What are the mechanisms by which the herbicide(s) function?	
	7. Effects of altered spraying regime (change in frequency, concentration, quantity, type of herbicide). See chapter 3.2.2.	a. Preservation of biological diversity	i. Will cultivation of the HR plant cause health effects (toxic, immunological, including allergic, or anti-nutrient effects) that are acute, chronic or long-term, and/or lead to a change in the viability, fertility and development rate of non-target organisms, i.e. wild populations of • mammals? • birds? • amphibians/reptiles? • insects (herbivores, predators, pollinators and decomposers) • red-listed species? • prioritised species?
			ii. Might cultivation of the HR crop lead to a change in the biodiversity of weeds and animals (vertebrates and invertebrates)?
			iii. Might cultivation of the HR crop harm microflora and microfauna in the soil?
			iv. Might the herbicide(s) or degradation product(s) thereof affect the growth cycle or division/proliferation of eukaryotic cells, and in such case, how?
			v. Might the herbicide(s) or degradation product(s) thereof have a hormone-mimicking or hormone-inhibiting effect?
			vi. How long and in what concentrations do(es) the herbicide(s) and degradation products remain in plant tissue and different soil types?
		b. Does cultivation of the HR crop result in a change in the timing of herbicide application?	
		c. Does cultivation of the HR crop increase the risk of herbicide drift, and thereby also the risk that non-genetically modified crops in surrounding areas may be unintentionally affected?	
		d. Does cultivation of the HR crop lead to increased/decreased use of herbicide?	
		e. Does cultivation of the HR crop lead to the use of herbicides with more/less adverse effects than previously?	
		f. Might unexpected combinatory effects such as additive or synergistic effects occur when more than one herbicide is used in the same area?	
	8. Resistance of other plants to the herbicide. See chapter 3.2.3.	a. What are the resistance problems associated with the herbicide in the cultivation area?	
		b. What strategies are used to prevent the development of resistance in plants other than the HR crop (example: integrated plant protection) ?	

* By herbicide we mean both the active ingredient and additives, including emulsifiers, stabilisers etc.

Table 1. continued

9. Soil. See chapter 3.3.	a. Does cultivation of the HR plant lead to more/less soil erosion?
	b. Does cultivation of the HR plant lead to a higher/lower soil pH?
	c. Does cultivation of the HR plant lead to a change in the nutrient composition of the soil?
10. Water. See chapter 3.4.	a. Might cultivation of the HR crop change the spraying regime so that water sources and groundwater become polluted by “new” proteins and residues of herbicide or degradation products thereof?
	b. Might the cultivation of the HR crop reduce water evaporation as a result of less tilling?
11. Energy. See chapter 3.5.	Is there an increase or decrease in the energy consumed in connection with cultivation of the HR plant, measured by means of life cycle analysis of the full production and harvesting cycle?
12. Climate. See chapter 3.6.	Do the greenhouse gas emissions associated with the cultivation of the HR plant, as measured by life cycle analysis of the full production and harvesting cycle, increase or decrease?

Table 2. Sustainable development economy and society: questions for applicants

The questions are grouped under main topics and in some cases sub-topics. For each topic or question, there is a reference to a chapter explaining in more detail the point of the question and why it is relevant.

1. The right to sufficient, safe and healthy food. See chapter 4.1.	1.1. Food safety. See chapter 4.1.1.	a. Does the HR plant contribute to reduced/increased input factors per production unit?
		b. Does the yield per unit area increase/decrease?
		c. What is the purpose of the HR plant – will it be used for food, feed, biofuel or material?
	1.2. Food security. See chapter 4.1.2.	a. Will the contents and quantity of herbicide residues (active ingredients in the herbicide) in food increase/decrease?
		b. Will intake of products from the HR plant have health effects (toxic, immunological, including allergic, or anti-nutrient effects) that are acute, chronic, long-term, and/or lead to a change in metabolism and fertility?
		c. Have the conclusions in 1.2b been drawn on the basis of exposure to • plant material from the HR plant? • the protein expressed by the inserted gene, after extraction from tissue from the HR plant? • the protein expressed by the inserted gene in the organism it is obtained from?
	1.3. Food quality. See chapter 4.1.3.	a. Does the HR plant yield better/poorer nutrition in terms of composition, quantity and energy content?
		b. Does the HR plant have properties that make the crop last better / more poorly during storage?
		c. Does cultivation of the HR plant yield greater / less benefits for the consumer?
2. Animal health and welfare. See chapter 4.2.	2.1. Feed quality. See chapter 4.2.	Do the products of the HR plant improve / detract from feed quality?
3. Living conditions and profitability for the farmers who cultivate HR plants, in the short term (less than 5 years) and in the long term (more than 20 years). See chapter 4.3.	3.1. Health and safety See chapter. 4.3.1.	a. Will any changes in the use of herbicide affect the health of the farmers / farm workers positively / negatively?
		b. Will farmers / farm workers be given HES training and access to protective equipment and the information they need in order to use the herbicide(s) that is/are to be used with the HR plant?
	3.2. Contracts and framework conditions. See chapter 4.3.2.	Are there restrictions on access to seed, the right to terminate contracts, or on information about seeds, spraying schedules and prevention of resistant weeds?
	3.3. Developments in costs and incomes for farmers in the short term (less than 5 years) and in the long term (more than 20 years). See chapter 4.3.3.	a. Will farmers' costs for input factors increase / decrease?
		b. Will the HR plants reduce the need, in the short and/or long term, for other input factors such as production plan, spraying programme, work input and machinery and equipment?
		c. Will any resistance problems increase in the future, and in the event, reduce profitability in the long term?
	3.4. Agronomic factors. See chapter 4.3.4.	What sort of cultivation conditions, soil types and technological standards has the HR plant variety been developed for?
	3.5. The right to seed. See chapter 4.3.5.	Does the applicant restrict the farmers' possibilities of saving, exchanging or selling seed from their own harvest?

Table 2. continued

4. Living conditions and profitability in the production area, in the short term (less than 5 years) and the long term (more than 20 years). See chapter 4.4.	4.1. Health and safety. See chapter 4.4.1.	Will any change in the use of the herbicide affect the health of the community positively or negatively?
	4.2. The democratic rights and profitability of other farmers. See chapter 4.4.2.	a. Are there rules for co-existence, and are they complied with, such that it is possible to choose to cultivate non-genetically modified, for example organic, crops instead of HR crops?
		b. Is there a system for preventing the spread of HR crops to other, non-genetically modified crops?
		c. Is there a compensation system if other farmers are affected by unintentional dispersal of genes, pollen or seed from the HR crop?
		d. Is there a system for keeping GMO and non-GMO crops separate in the production and transport line and, in the event, who pays for this system?
		e. Will cultivation of the HR crop lead to more or fewer problems with weeds for other farmers?
	4.3. Employ-ment. See chapter 4.4.3.	a. Will cultivation of the HR crop create more or less employment locally and regionally?
		b. Will the cultivation of the HR crop create more or less employment for women?
	4.4. Ownership rights. See chapter 4.4.4.	a. Will the cultivation of the HR crop lead to changes in the ownership of land and/or water in the area?
		b. Will the cultivation of the HR crop lead to changes in ownership of seed in the area?
	4.5. Monitoring. See chapter 4.4.5.	Will the HR crop lead to a greater or reduced need for monitoring of land, water and the environment around the field?
	4.6. Ecosystem functions. See chapter 4.4.6.	Will the HR crop affect ecosystem functions in a manner that yields a positive or negative economic effect?
5. Rules for use of herbicides. See chapter 4.5.	a. Is/are the herbicide(s) to which the HR plant is resistant prohibited or permitted for restricted use in Norway because it is/they are a hazard to health or the environment?	
	b. Does/do the herbicide(s) to which the HR plant is resistant have the same effects in the cultivation country as in Norway?	
	c. Is/are the herbicide(s) on lists of herbicides that should be prohibited, in international agreements?	
	d. What sort of rules does the production country have for the use of herbicides, and are these rules enforced?	
6. Plant genetic resources for food and agricul-ture. See chapter 4.6.	a. Will the HR crop be cultivated in an area defined as a centre of origin or centre of diversity for the corresponding non-genetically modified crop?	
	b. Are there wild relatives of the HR plant in Norway or the country of cultivation?	
	c. Is the HR crop available for further plant breeding?	
7. Independent risk research. See chapter 4.7.	Is the HR crop available for independent risk research?	
8. Free choice of agricultural sys-tem in the future. See chapter 4.8.	How does cultivation of the HR crop affect the possibility of changing in the future to other agricultural systems, such as organic farming or farming without genetically modified organisms?	

Table 3. Sustainable development: questions for Norwegian authorities

The questions are grouped according to topic. For each topic or question, there is a reference to a chapter explaining in more detail the point of the question and why it is relevant.

1. Freedom of choice for consumers in Norway. See chapter 5.1.	a. Will the HR crop make it easier or more difficult for consumers to buy food/products from corresponding non-genetically modified crops in the future?
	b. Is there a labelling system that will enable consumers to choose whether they want to buy GM food?
2. Ecological, economic and social consequences in Norway of importing or cultivating the HR crop in the short term (less than 5 years) and the long term (over 20 years). See chapter 5.2.	a. Can the HR variety be cultivated under Norwegian agronomic conditions?*
	b. Has a system been developed for counteracting resistant weeds in connection with cultivation in Norway?*
	c. Will the HR crop affect ecosystem functions in a manner that yields a positive or negative economic effect?
	d. Will there be increased or reduced economic returns in the value chain in Norway?
	e. Will there be more or fewer jobs in Norwegian food production?
	f. Will the import and/or cultivation of the HR crop affect the goals of food policy?
	g. Is the decision regarding import and/or cultivation of the HR crop consistent with public opinion on GMOs?
3. Plant genetic resources for food and agriculture. See chapter 5.3.	a. Do the farmers in the cultivation area have access to a wide selection of seed?
	b. What measures have been implemented to reduce the adverse effects of monocultures in the cultivation area?
	c. Is the HR crop available for further plant breeding?
	d. Are there rules for co-existence in the cultivation area, and are they complied with, such that it is possible to choose to cultivate non-genetically modified, for example organic, crops instead of HR crops?
	e. Is there a system for keeping GMO and non-GMO crops separate in the production and transport line in the cultivation country and in Norway and, in the event, who pays for this system?
4. Independent risk research. See chapter 5.4.	Is the HR crop available for independent risk research?
5. Consequences of approving many GMOs. See chapter 5.5.	Will approval of this HR crop, together with other approved GMOs, have consequences that in combination will not result in sustainable development?
6. Norway's North-South policy and work for biological diversity. See chapter 5.6.	Will our decision contribute to fulfilling Norway's North-South policy goals and biological diversity policy goals?
7. Norway's international role. See chapter 5.6.	What sort of example will we be setting internationally with this decision?
8. Giving priority to the most important questions. See chapter 5.7.	a. Can cultivation and breeding of the HR crop and products thereof harm plants, animals or humans?
	b. Can cultivation and breeding of the HR crop or products thereof cause harm that is irreversible?

* Applies only to applications for permission to cultivate in Norway

3 Sustainable development: environment/ecology

When assessing sustainable development in the area of environment/ecology, we have focused on the genetically modified plant itself, the herbicide and the cultivation area. By "environment" we mean the natural environment. Included in the concept of environment are soil, water, energy consumption and climate. Ecology is the interplay between the organisms in the local cultivation area and the biotic (living) and physical environment in this area.

The questions we have formulated for applicants seeking approval of an HR crop are presented in Table 1, page 12. These questions must be answered in order to decide whether and to what extent the HR crop affects a cultivation area compared with non-genetically modified crops. After those evaluating the application have defined the differences between the genetically modified and non-genetically modified crop, they must judge whether any differences will cause adverse effects, and then the risk of such effects occurring.

FACT BOX

Different views on the value of ecosystems

The idea of ecosystem services is based on market mechanisms and economic cost-benefit analyses, and the assumption that the value of the services that ecosystems deliver to humans should be quantifiable in terms of money. Ends and means are presented in *The Economics of Ecosystems and Biodiversity* (the TEEB report)[8]. In parallel with this, an ecological economy approach based on ecosystem management was developed which attempts to combine economic, biological, ethical and ecological considerations in a sustainable manner. The background to this approach is presented in *International Assessment of Agricultural Knowledge, Science and Technology for Development* (the IAASTD report)[9].

Plants that have been genetically modified to tolerate particular herbicides have been created for a particular cultivation practice, where these herbicides are to be used to protect crops against weeds. Unless they use these herbicides, the farmers do not reap any benefit from cultivating the HR crop. Thus both the positive and the negative effects of the change in use of herbicides must be assessed, in addition to the effects of the plant in itself. The questions therefore differentiate between the direct effects of the genetically modified plant (see chapter 3.1.) and the indirect effects, i.e. the impacts on organisms and the environment of, among other things, the change in the use of herbicides (see chapter 3.2). Soil, water, energy consumption and climate may also be indirectly affected by changes in the cultivation method (see chapters 3.3–3.6).

The questions for applicants have been grouped under a total of twelve main topics divided into the three blocks genetically modified plant, herbicide and other topics. These main topics are:

The genetically modified plant:

1. characterisation of the HR crop
2. interaction between plant and environment
3. gene flow
4. preservation of biological diversity
5. comparison with control plants

The herbicide:

6. characterisation of the herbicide(s)
7. effects of altered spraying regime
8. resistance of other plants to the herbicide

Other topics:

9. soil
10. water
11. energy
12. climate

There is a discussion in progress internationally on whether sustainable use of genetically modified organisms should be based on the concept of ecosystem services or ecosystem management; see fact box. The same issues must be assessed in connection with ecological sustainability, irrespective of one's preferred view of the value of ecosystems.

3.1 The genetically modified plant:

To enable us to assess the effects that the genetically modified plant itself has on its surroundings, the HR crop must be thoroughly characterised; we must know the distinctive features of the HR crop. The interplay between plant and environment, gene flow, i.e. the transfer of genes from one organism to another, and the effect on preservation of biological diversity must also be mapped. It must also be clear what sort of control plants we should compare the HR crop with, and how the comparisons should be made.

3.1.1 Characterisation of the HR crop

3.1.1.1 Phenotype and genotype

In order for us to be able to draw conclusions about the HR crop, it must be thoroughly characterised, both phenotypically and genotypically. "Phenotype" has to do with properties and content, while "genotype" has to do with changes in the original DNA sequence of both the inserted gene and the recipient genome. Small RNA molecules that regulate how gene expression is switched off or on and fine-tuned must also be characterised. In some cases, these RNA molecules can be inherited.

3.1.1.1.1 Lack of knowledge about new proteins

The protein EPSPS is an enzyme that occurs naturally in plants. It is necessary for producing certain amino acids that plants need in order to live. Glyphosate binds to EPSPS so that these amino acids are no longer produced, and the plant dies. In Roundup Ready plants, a gene for the protein EPSPS from a bacterium, *Agrobacterium tumefaciens* strain CP4, is inserted, so that they produce this bacterial version of the EPSPS protein (named CP4 EPSPS). The bacterial EPSPS binds glyphosate in a manner that does not prevent the production of amino acids. As a result the plants are resistant to glyphosate.

Very little is known about the properties and effects of the CP4 EPSPS proteins produced by the genetically modified plant, as little research has been done on them. There is a particular lack of independent research.

Scientists in a maize field. Photo: Ken Hammond / USDA

The sequence of amino acids in the CP4 EPSPS version created by the genetically modified plants is somewhat different from the original bacterial version. The DNA sequence of the CP4 EPSPS gene has also been slightly altered to make the protein more efficiently produced in the plant. It is also unclear whether the newly created CP4 EPSPS proteins have been altered in other ways. This may for instance happen by post-translational modification, i.e.

changes that take place after the amino acids of which the protein is made up have been linked together. For example, sugar groups may become linked onto the protein. Such modifications may confer unintended properties and effects on the protein in addition to the intended herbicide resistance. It is also conceivable that the new CP4 EPSPS protein may be able to form complexes with one or more of the other proteins in the plant. Such formation of complexes may both counteract existing biological effects and create new ones.

Despite the knowledge gaps, studies performed on CP4 EPSPS proteins isolated directly from bacteria have been used to draw conclusions about the safety of CP4 EPSPS proteins made in the Roundup Ready plants on the market today (see chapter 3.1.4.2). The same uncertainty and lack of knowledge also applies to the transgenic proteins (the proteins that the inserted genes express) that confer resistance to glufosinate, 2,4-D and dicamba. See also fact box p. xx.

3.1.1.2 Stability
Genetic modifications in a plant are not always stable over time or inherited by the next generation. We must therefore investigate whether the genome (DNA), the gene expression (production of RNA and proteins) and properties are stable over extended periods of time and over several generations.

3.1.1.3 "Substantially equivalent to"
The HR crop can be regarded as "substantially equivalent to" the non-genetically modified plant if it contains the same substances in the same quantities with the exception of the new proteins and the properties that can be expected as a result of the genetic modification. It is necessary, nonetheless, to be aware that a conclusion of "substantial equivalence" has often been made on the basis of imprecise methods. For example, the total protein content has been compared to determine whether one genetically modified and one non-genetically modified plant are "substantially equivalent". But plants express many thousand proteins all the time, and the production of important individual proteins may be strongly adjusted upwards or downwards without significant change in the total protein content.

3.1.1.4 Resistance to more than one herbicide
In recent years, an increasing number of so-called stacked lines have come onto the market. This means that one HR crop that is resistant, for example to glyphosate, is crossed with another HR crop that has been genetically modified to tolerate one or more other herbicides, such as glufosinate, 2,4-D or dicamba. The HR crop may also be crossed with a Bt crop (insect-resistant genetically modified plant) that produces one or more different Cry proteins that make the plant resistant to certain pest insects. It is unclear whether a number of new proteins, as they occur in stacked lines, may act in an unexpected way in combination compared with individually. Such unintended effects may be both cumulative (the combined effect is equal to the sum of the different partial effects) and synergistic (the combined effect is greater than the sum of the partial effects).

Using cultivated plants that are resistant to more than one herbicide increases the risk that the cultivated plants themselves may emerge as multi-resistant weeds among other crops cultivated in the same fields as part of a crop rotation programme. Crop rotation involves switching between different types of crops on the same piece of land from one year to the next according to a certain plan. For instance, HR soybean may grow as a weed in HR maize fields if maize and soybean are grown alternately in the same fields. A multi-resistant weed is resistant to several herbicides, and can thus be difficult to control with the herbicides that are available. The genes that make the HR plant resistant to more than one herbicide may also become crossed into wild, related species. However, that a multi-resistant cultivated plant may itself appear as a weed among other planted crops seems more likely and is a greater potential threat.

3.1.1.5 Antibiotic resistance genes
Some HR plants contain a gene for resistance to an antibiotic. That gene is inserted along with the gene that makes them resistant to a herbicide. The rationale is to use the antibiotic for selecting the plant cells that have become genetically modified during the development process in the

laboratory. When the plant cells receive nutrients containing the antibiotic, the un-modified plant cells will die, while the genetically modified plant cells will survive. The new HR plants are then cultivated from the cells that survived. Today the plants that have been genetically modified can be selected in other ways than by using antibiotic resistance genes.

We cannot rule out the possibility that antibiotic resistance genes may be transferred from plants to bacteria in the soil and then further to bacteria that cause disease (pathogenic bacteria), thereby enabling the pathogenic bacteria to develop resistance to the corresponding antibiotics. This may mean that diseases can no longer be treated with these antibiotics, and the consequences may be considerable. Antibiotic resistance genes in genetically modified plants therefore make a negative contribution to sustainable development. See also chapter 3.1.3.2.

3.1.2 Interaction between plant and environment

3.1.2.1 Environment and ecology in the cultivation area

The questions we ask about ecological sustainability are intended to increase our knowledge of how the release of HR plants may change the environment in the release area and in the surroundings. By environment we mean, among other things, the composition and state of health of organisms and their physical and biological habitat. It is now generally accepted that changes in environmental conditions may affect plants and the chemical reactions in plants, whether they are genetically modified or not.[10]

Conducting studies of interactions in the ecosystem and the environment is very complicated. Many of the microorganisms in the soil and in aquatic habitats have still not been isolated and characterised. The composition of the microorganism populations in the soil, and the interaction among them, may vary substantially from place to place due to environmental factors. There is inadequate knowledge about these environmental factors as yet. A survey from the UK concludes that each agriculture field has a unique combination of weeds and invertebrates.[11] Our knowledge gap is particularly large when it comes to the interplay among the networks of varying soils, plants, microorganisms and animals, and how these networks will be affected by climate change and loss of biodiversity. This applies both to loss of biodiversity that is already under way, and to losses that may occur in the future.

3.1.2.2 Changes in genome, gene expression and properties under different environmental conditions

When a plant grows in different locations (biotopes), different growth conditions may cause different genes to be expressed, and genes that are constitutively active may be expressed at different levels. Studies of insect-resistant genetically modified plants, Bt crops, show that both Bt crops and non-genetically modified parent lines of maize express different proteins and different relative amounts of these proteins at different cultivation sites.[12,13] Consequently, in areas with environmental conditions that cause plants to have low expression of the Bt gene, there is a risk of insects developing resistance to the Bt toxin. In such cases, prospective cultivators should be advised that the area is not appropriate for the cultivation of this Bt plant. Similar studies should be required for HR crops.

3.1.2.3 Changes in metabolism, composition and nutritional content under different environmental conditions

Certain factors in the cultivation area may affect the metabolism, chemical composition (the composition of trace elements, vitamins, carbohydrates, fats and proteins) and/or the nutritional content of the HR crop. The effect may stem from the fauna, adjacent ecosystems and soil and organisms in the soil, in addition to meteorological and climatic conditions. Such effects must also be mapped thoroughly.

3.1.2.4 Changed influence on the surroundings due to environmental factors

As mentioned, different conditions in an ecosystem may affect the gene expression and functions of the cultivated plants in different ways. But plants interact with their surroundings, and changes in a plant may therefore also influ-

FACT BOX

Gene flow

In gene flow, genetic material is transferred from one organism to another. Transfer from parent to offspring via sexual or asexual reproduction is called vertical gene flow or vertical gene transfer. This takes place between plants of the same or related species. In horizontal gene flow or gene transfer, genes are transferred in other ways. Such gene flow can take place from one species to another, for example from HR plants to bacteria, or between bacteria.

ence the environment around it. It should therefore be investigated whether the HR crop, as opposed to the non-genetically modified plant, has undergone a change in nutritional content, whether it contains more or less hormone mimics or hormone inhibitors, or molecules that may trigger the immune systems of animals or be noxious to particular species. Such changes may be small, but nonetheless have a strong impact on the environment over time.[14,15,16,17]

Molecular profiling methods, i.e. measuring the activity (expression) of thousands of genes at a time, may reveal any important changes brought about by the environment, in addition to changes attributable to the genetic modification.[18] These are issues about which we have inadequate knowledge. Studies comparing HR crops and the non-genetically modified parent lines under selected ecosystem conditions may increase our knowledge. This may make it easier to carry out evidence-based risk assessments of the interplay between plants and environment as well as the effect that plants have on the environment.

3.1.3 Gene flow

3.1.3.1 Vertical gene transfer

Vertical gene transfer (see fact box) from an HR crop can take place through the spreading of pollen to non-genetically modified plants of the same or related species. One such example is crossing between *Brassicaceae* plants, for example oilseed rape and turnip. Genes from an HR crop may be transferred to both cultivated plants and wild relatives. The distance the pollen is dispersed determines the extent to which areas with non-genetically modified plants will be affected. The dispersal distance depends on factors such as wind direction and strength and the activity range of the insects that pollinate the plants. Oilseed rape, maize and rice are examples of plants that can spread over long distances.

3.1.3.2 Horizontal gene transfer

Like the better understood vertical gene transfer from parents to offspring, horizontal gene transfer across species (see fact box) is now regarded as important for evolution. An example of horizontal gene transfer attributable to humans is the antibiotic resistant, pathogenic bacteria that are now a health hazard for both humans and animals in many parts of the world. Overuse of antibiotics has led to selection of resistance genes; in other words, only bacteria with the gene for resistance to the antibiotic in current use survive. That resistance gene is then transferred horizontally within and between bacterial species. Published studies suggest that the laboratory methods that are available today will not, for instance, reveal transfer of the EPSPS gene from plants to organisms in the soil until this has taken place on a large scale.[19] See also chapter 3.1.1.5.

3.1.4 Preservation of biological diversity

All organisms are interconnected in food webs in which various food chains are woven together. Thus a change in one plant may have repercussions for other organisms in the food web. A whole ecosystem may be changed if the living conditions of key species improve or deteriorate.[20] The aim of cultivating HR crops and spraying with a particular herbicide is to get rid of weeds, which are accordingly called *target organisms*. But there is a risk of also affecting both the development and the behaviour of other organisms, and these are called *non-target organisms*. Non-target organisms may be affected by both the herbicide

FACT BOX

Red-listed species

Red-listed species are species classified according to one of the following categories of the *International Union for Conservation of Nature* (IUCN): extinct (EX), extinct in the wild (EW), regionally extinct (RE), critically endangered (CR), endangered (EN), vulnerable (VU), near-threatened (NT) or data deficient (DD).

Prioritised species are designated in accordance with section 23 of the Nature Diversity Act. When the authorities decide whether a species should be regarded as prioritised, they attach weight to whether developments in the stock of one species indicate that the species is not viable, whether the species has an essential part of its natural range or unique genetic traits in Norway, or whether the species is on lists in international conventions.

(see chapter 3.2.2.1.1) and by new proteins produced by the HR plant.

3.1.4.1 Effects on the health of non-target organisms

Investigations should be initiated in order to study how the HR plants, the new, transgenic proteins they produce, and the herbicide (see also chapter 3.2.2.1.1) affect wild mammals, birds, amphibians, reptiles, fish, insects and other arthropods, both in the cultivation area and in neighbouring areas. A study of insects must include examining how herbivores, predators, pollinators and decomposers (insects that live off dead material) are affected. In these studies, special attention should be devoted to red-listed species and prioritised species (see fact box).

In combination with up- or down-regulation of the plant's own genes (changes in gene expression pattern), the content of novel proteins in the HR plant such as CP4 EPSPS may alter the chemical composition of the plant. Whether the changes may apply to few or many proteins is unpredictable. The affected proteins may be particularly important or may have no effect on the health of either the HR plant or non-target organisms. It should be investigated whether non-target organisms are exposed to acute or chronic toxicity, immune system reactions, such as allergies, or effects due to anti-nutrient substances (substances that inhibit the uptake or effect of important nutrients). In addition, a study should be made of whether the herbicide resistance protein affects fertility, the rate of development or the viability of non-target organisms.

Non-target organisms may be directly affected by ingesting or inhaling material from the HR crop, and also indirectly through the food web. A number of vertebrate species may either consume HR crops directly, or they may be exposed by inhaling pollen or finely powdered plant tissue. Insects often find their food by navigating by the odour of the plants. These volatile odours may change when the chemistry of the plant is altered, which in turn may affect the behaviour of insects searching for food.

It is particularly important to study the effects of non-target organisms in locations with relatively close contact between cultivated and uncultivated areas, as is the case in Norway. Non-target organisms may be affected in both terrestrial and aquatic ecosystems. Depending on local environmental conditions, plant debris and exudations from plant roots may be washed out into lakes, rivers and streams and affect the organisms living there. Non-target organisms in marine ecosystems may be affected when the HR plant is used for feed in aquaculture.

See chapter 3.2.2.1.1 for more about how herbicides may affect non-target organisms.

3.1.4.2 Test material

The version of CP4 EPSPS and other transgenic proteins produced by the plants may be different from the original versions produced by bacteria (see chapter 3.1.1.1.1). This makes it important to carry out impact studies of non-target organisms with the proteins as they are produced in the HR crop. Under natural conditions, organisms will also as a rule ingest more of the plant than merely the transgenic protein, and feeding studies should therefore also be conducted with whole plant material or relevant feed from the plant material. Experiments must be carried out on relevant experimental animals and cell cultures.

There are a few short-term, manufacturer-financed studies in which bacterial versions of the HR protein have been used. The evidence base is particularly weak when it comes to the health effects of the transgenic CP4 EPSPS protein compared, for example, with the Cry protein that occurs in insect-resistant genetically modified plants, Bt plants.[21]

In most studies funded by GMO manufacturers, DNA or protein sequences from the transgenic proteins are compared with the sequences of known toxins or allergens. But the sequences are not always the most important factor. In many cases, it is equally the folding of the protein and the formation of complexes with other macromolecules that determine whether a protein is toxic or causes immune reactions. This also applies to other modifications, like the addition of sugar groups. These properties may be quite unique when the protein is expressed in a plant cell instead of a bacterial cell. The changes may provide a basis for new, harmful immune reactions in organisms that consume the HR plant. Whether such reactions can be demonstrated in feeding experiments depends on the type of experimental animal and experimental conditions chosen.[22]

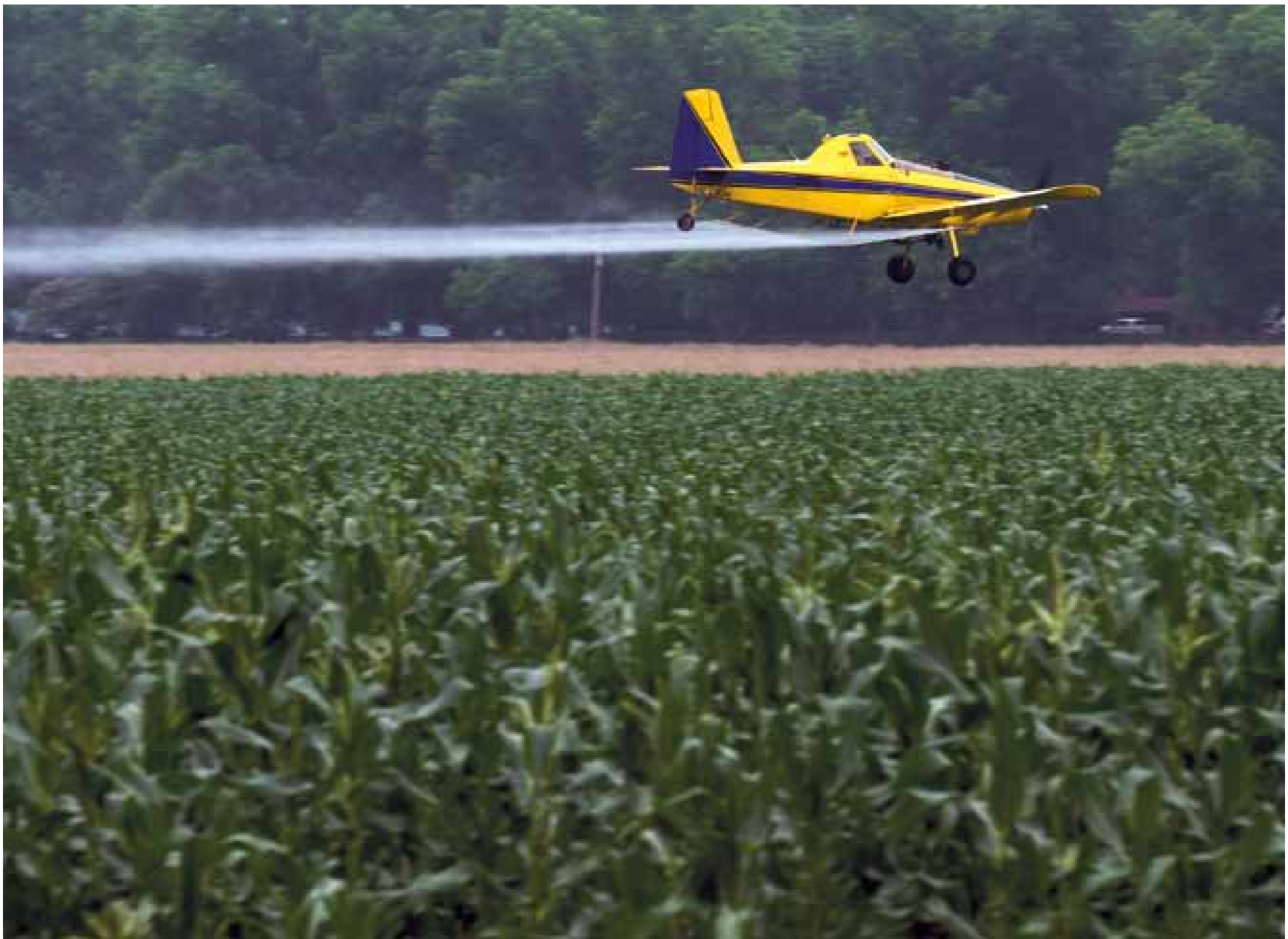
Little research has been published on how CP4 EPSPS, PAT and other transgenic proteins in HR crops affect organisms that either eat these plants or encounter them in some other way in nature (see also chapter 3.1.1.1.1). Recently published studies of the plant version of CP4 EPSPS show that the CP4 EPSPS protein in Roundup Ready soybean is not broken down as easily as has been believed up to now.[23] There is a greater risk of proteins with a high persistence affecting non-target organisms.

3.1.5 Comparisons with control plants

In order to find out how the genetically modified plant affects its surroundings, a comparison must be made with one or more control plants (comparators). Agricultural practice and the use of herbicides and other input factors (see fact box p. 38) must be the same during testing as they would be under large-scale cultivation.

One principle that is laid down in the Norwegian Gene Technology Act, relevant EU directives and international agreements like the Cartagena Protocol, is that genetically modified plants must be assessed case by case and step by step. Experiments must first be conducted in the laboratory, then in small field studies (semi-field studies) and then in large field studies. The first thing to do is to identify the *differences,* i.e. determine whether the plant is identical to the non-genetically modified variety with the exception of the expected change. Next, it must be decided whether the differences observed indicate that the genetically modified plants may cause *harm* to the environment or to the health of people, domestic animals and wild animals. Further studies are required for this purpose. Finally, the *risk* must be assessed.

Risk is defined as the probability of any potentially harmful effect occurring, multiplied by the consequences of the effect occurring (risk = probability x consequence). In order to perform a complete risk assessment, knowledge of three fields is thus required: first, a knowledge of all the undesirable and harmful effects that *might* arise is required; second, we need to know how often and under what circumstances each individual effect may occur; third, we need to know the consequences of each individual effect, and the overall consequences of the effects. It is self-evident that we can never obtain full insight into all these areas. When there is a knowledge gap in the decision-making process, we use criteria for weighing up benefit against possible harm, and consider whether there are grounds for applying the precautionary principle.



Herbicides sprayed from aircraft drift with the wind from fields to neighbouring areas, causing problems. Photo: iStockphoto

3.1.5.1 Closest relative and same environmental conditions

The genetically modified plant must first be examined for differences from its closest genetic (isogenic) relative, ideally the non-genetically modified parent plant. To enable comparison of the two plants, they must be tested under the same ecosystem conditions. In other words, the two plant lines must be sown and harvested in the same place and at the same time. Sample material for comparative laboratory analyses must also be taken at the same time from the same plant tissue and organ. The same applies to collection of target and non-target organisms.

3.1.5.2 Exposure to herbicides and stress factors

All tests on HR plants must be conducted with plants that have been sprayed with the herbicide(s) they have been genetically modified to tolerate. The plants must also have been exposed to predators and other biotic (living) or abiotic (non-living) stress factors that are naturally present in the environment. Abiotic stress factors may be changes in nutrient content, drought and cold.

3.2 The herbicide

3.2.1 Characterisation of herbicide(s)

Chemical pesticides are used in agriculture to combat weeds, among other things. Pesticides specifically for combating weeds are also called herbicides. Before we can assess the consequences of using a herbicide, the underlying mechanisms of action must be determined. The commercial herbicides used in fields contain other, often many other, ingredients in addition to the active herbicide ingredient. For example, the various Roundup products that are for sale contain the active ingredient glyphosate, but in addition they contain various additives, or "inert ingredients" or "adjuvants", in varying concentrations. These additives may have biological effects. When we talk about a herbicide, we therefore mean not only the active ingredient, but also the whole product, with emulsifiers, stabilisers and other additives.

3.2.1.1 Active ingredients

The genetically modified plants that are most widely cultivated, Roundup Ready plants, are resistant to herbicides containing the active ingredient glyphosate. HR crops that are resistant to glufosinate ammonium are also cultivated. Plants that are resistant to dicamba, isoxaflutole and 2,4-D and AOPP herbicides have also been developed, but are not yet in use at commercial level. A box on active ingredients is presented on page 64.

3.2.1.2 Additives

In the rules and regulations of many countries, pesticide ingredients are divided into two groups: active and inert.[24,25] It is the active ingredients that kill the weed, while the inert ingredients, or additives, are not intended to affect the weed. In some contexts, additives are called "other ingredients", "adjuvants" or "coformulants". They are often regarded as trade secrets, and are not required to undergo risk assessment in the same way as the active ingredient. But in both Norway and the new EU regulations, the additives that are used in pesticides are now required to be documented.

Despite the denotation "inert", additives may be chemically or biologically active. Many of the tests required to determine whether a pesticide is safe, are conducted on the active ingredient alone, and not on the fully formulated product. In many countries, the additives are not registered on the product declaration, and they are often described as confidential information.[26] In a review of more than 100 pesticides for agricultural purposes, the pesticides were found to consist more than 50 per cent of additives.[27]

The additives may also augment the overall biological effects of the product, for example by affecting the nervous system, binding to DNA so that it does not function normally (genotoxic effect) or have hormone-mimicking or hormone-inhibiting effects; see chapter 3.2.2.1.5. This has been demonstrated in animal and cell-culture experiments with herbicides where glufosinate, glyphosate or 2,4-D are active ingredients. Additives may also make it easier for the herbicide to penetrate the skin. A number of studies have shown that the entire product may penetrate the skin 3–30 times more easily than the active ingredient alone.[28]

POEA (polyethoxylated tallow amine), which occurs in some Roundup products, is one of the substances that facilitate glyphosate penetration of cell membranes. A number of research reports indicate that it may also be toxic in itself and cause glyphosate to break down more slowly and accumulate in living organisms.[29,30,31,32] Additive effects of this nature may significantly impact both wild and domestic animals and humans.

3.2.1.3 Metabolites

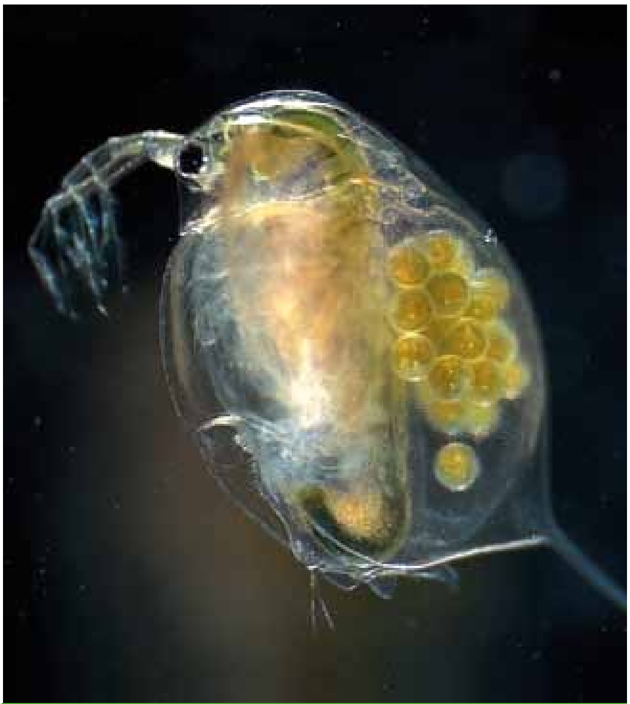
There has been little research on how different herbicides are broken down in plants and animals and in the soil. The same applies to the properties of the degradation products (metabolites), and their biological and chemical activity. For example, studies have shown that AMPA (aminomethyl phosphonic acid), the most common metabolite of glyphosate, is both potentially toxic and capable of affecting the hormone balance.[33]

3.2.2 Effects of a change in herbicide regime

Cultivation of HR crops leads to a change in the use of herbicides and affects the agronomic methods used. The aim of using HR crops should be for farmers to be able to control weeds better and spray less often, and thereby use less herbicide. Another goal might be to replace harmful herbicides with herbicides that are regarded as less harmful, such as glyphosate. If an HR crop is to contribute to sustainable development, any benefits exhibited during the first few years must also persist over time.

Among other things, it should be investigated whether changes in herbicide use may impact biological diversity in new and unintended ways. In addition to the weeds they were intended to kill, the herbicides may affect other, non-target organisms. The biodiversity of weeds and animals may be changed, as may the microflora and microfauna in the soil. Herbicides may cause changes in the cell cycle and act as hormone-mimickers or hormone-inhibitors.

The effects of changes in the use of herbicides depend among other things on the persistence of the herbicide and its metabolites, as well as the quantity and type of herbicide, whether the time when spraying takes place changes, whether the risk of drift increases, and whether several herbicides used together yield unexpected effects.



Water fleas (*Daphnia magna*) are examples of freshwater organisms that may be harmed by herbicides such as glyphosate and glufosinate. Photo: Hajime Watanabe (Wikimedia Commons)

3.2.2.1 Preservation of biological diversity

3.2.2.1.1 Non-target organisms

The aim of cultivating HR crops and spraying with a particular herbicide is to get rid of weeds, which are accordingly called *target organisms*. But the development and behaviour of organisms that are not intended to be harmed may also be affected. These non-target organisms may be affected by both new proteins produced by the HR crop (see chapter 3.1.4), and by the herbicide.

Wild mammals, birds, amphibians, reptiles, fish, insects and other arthropods, both in the cultivation area and in its vicinity, may be affected. Studies of insects must examine how plant-eaters, predators, pollinators and decomposers (insects that live off dead material) are affected. Red-listed and prioritised species (see fact box p. 23) should receive special attention in such studies.

Health effects may be acute or chronic, and arise early or after a long period of exposure. It must be investigated whether immune system reactions may occur, such as allergies, or effects due to anti-nutrient substances (substances that hinder the uptake or effect of important nutrients). In addition, the effects on the fertility, development rate and viability of non-target organisms must be studied.

Glyphosate is generally toxic to plants. The effect of glyphosate compared with various Roundup combinations on other groups of non-target organisms has not been thoroughly investigated.

Non-target organisms may be affected in both terrestrial and aquatic ecosystems. For example, studies have been published that show that glyphosate, glufosinate and 2,4-D are harmful to freshwater arthropods that may be key species in aquatic food webs, such as water fleas

(*Daphnia magna*) and caddis flies (*Trichoptera*)[34] A key species is one that affects other species in an ecosystem to an extent disproportionate to its prevalence, and contributes substantially to preserving the ecosystem. Water fleas are moreover recognised model organisms that are used to detect toxicity effects that may also affect vertebrates.[35,36,37]

Pesticides may affect non-target organisms by altering their growth cycle and cell division (see chapter 3.2.2.1.4), by acting as hormone mimics or hormone inhibitors (see chapter 3.2.2.1.5) or in other ways.

The mechanisms by which 2,4-D affects non-target organisms have not yet been fully determined. 2,4-D inhibits several enzymes that are important to cells' reactions to stress. When these enzymes do not function, the cell surface is weakened, with the result that substances other than the usual ones can be transported into and out of the cells. Some research results indicate that 2,4-D can affect DNA and cause chronic metabolic disturbances.[38] In addition to in agriculture, 2,4-D has been used in water reservoirs to control algal growth.

Among other things, dicamba inhibits the enzyme acetylcholinesterase, which is found in the nervous system of most animals. Dicamba shares this characteristic with several groups of insecticides, such as organophosphates and carbamates.[39] Dicamba appears to activate a series of genes in *Arabidopsis thaliana* which are normally activated when the plant is subjected to stress. Genes that play a part in the cells' signalling systems are also activated.[40]

See also chapter 3.2.1 on characterisation of herbicides and chapter 3.1.4 for more on non-target organisms.

3.2.2.1.2 Biodiversity of weeds and animals

A number of the herbicides that it is relevant to use in connection with HR crops, such as glyphosate, are generally toxic to plants. When the herbicide regime changes, particular attention should be paid to whether rare or important plants are adversely affected. Weeds are also a part of the biological diversity surrounding the field, and if all the weeds are killed, this reduces the biological diversity in the food chains. As a result, spraying of vegetation around the edges of fields is prohibited in Norway.

The biggest survey carried out to date of how herbicide-resistant plants affect biodiversity is the British *Farm Scale Evaluation* project, which ran for three years.[41] The main conclusion was that the biodiversity of certain plants, vertebrates and invertebrates was higher in and around non-genetically modified oilseed rape and sugar beet fields than around similar GMO fields. The reason was that the non-GMO fields had more weeds, which was important for the fauna. With maize, the results were the reverse, because non-genetically modified maize fields were sprayed with the highly toxic, now prohibited herbicide atrazine, which killed all weeds. The genetically modified maize was sprayed with glufosinate ammonium.

3.2.2.1.3 Microflora and microfauna in the soil

The root systems of plants are dependent on a complex interplay between bacteria, fungi and minerals in the soil. The balance in this ecosystem, the rhizosphere, determines how well plants are protected against disease, and helps to make photosynthesis efficient. When the herbicides glyphosate and 2,4-D are sprayed on plants, the herbicide penetrates the surface tissue and migrates down to the roots, from which it is secreted into the soil.[42,43] It appears that this may have a negative impact on the rhizosphere, which in turn may affect the health and photosynthesis of plants and make them more susceptible to parasites and pathogenic microorganisms.[44,45] It may also make the plants less appropriate as food and feed for wild and domestic animals as well as humans. Some studies indicate that glyphosate may harm earthworms and various kinds of insects in the soil.[46] Helander et al. (2012) consider whether herbicides may have more negative effects in the Nordic countries than in more southerly, warmer climate zones, because they degrade more slowly.

It is difficult to draw general conclusions from published studies because ecosystems and microorganism communities in the soil differ from place to place, with the result that herbicides may have different effects in different places.

An oilseed rape field. Photo: Yay Images

3.2.2.1.4 Changes in growth cycles and cell division

The cell cycle or cell division cycle is the sequence of coordinated events and processes leading to growth and division of a cell. According to a number of studies, many herbicides affect the cell cycle and state of health of cells in addition to their physical integrity, i.e. control of what goes in and out through the cell surface. This applies to glyphosate, glufosinate, 2-4-D and dicamba alike. A number of the studies were published in the late 1990s, but they aroused little response. In 2002 came the first study that showed that Roundup affected the initial cell divisions in sea urchins.[47] The work has subsequently been confirmed in studies of mammalian cells. Up to the present, these studies have not affected the status of glyphosate in either Norway or other countries.

3.2.2.1.5 Endocrinal effects (hormone mimicry and inhibition)

Chemicals that act in a manner that resembles and/or augments natural hormone effects in animals, or that inhibit such effects, are called hormone mimics or inhibitors, or *Endocrine Disrupting Chemicals* (EDC). It has long been known that a number of herbicides can act as hormone mimics or inhibitors in some types of animals and cells.[48] This also applies to glyphosate, 2,4-D and dicamba. A number of studies of Roundup products indicate that ingredients other than the active substance(s) contribute to and augment the hormone-mimicking and hormone-inhibiting effects of glyphosate, or that the entire effect is due to one or more ingredients other than the active substance(s).

A soybean plantation. Bangalore, India. Photo: Scanpix

3.2.2.1.6 Persistence and residual concentrations of herbicide

The consequences of changing the herbicide regime depend on how long, and in what concentrations, the herbicides and their metabolites remain in the plant material and in the different soil types. This may determine how the herbicide acts on the environment, and whether there will be more or less herbicide residues in food and feed produced from HR crops.[49] A number of scientists criticised EFSA for recommending that Roundup Ready soybean be approved for cultivation in the EU without including residual concentrations of glyphosate and its metabolites in the risk assessment. They were also of the opinion that EFSA should have proposed monitoring for possible adverse effects on health due to herbicide residues in plant material because the quantities of herbicide residues might increase if the cultivation method were to change.

3.2.2.2 Time of spraying

If a herbicide that is toxic to all types of plants is used, spraying must take place after harvesting or before sowing. With genetically modified crops that tolerate herbicides, it is possible to spray throughout the growing season without harming the harvest. This makes it possible to use more herbicide than before if there are problems with resistant weeds, and spraying can also take place close to harvest time. This in turn increases the risk of harm to the environment and of herbicide residues in food and feed.

3.2.2.3 Drift of herbicides with the wind
Herbicide particles may be carried by the wind to areas where there was no intention of spraying. This is known as herbicide drift. The risk of this happening increases when it is windy, when the air is dry, when the air and soil temperature rises, or when pressure nozzles that create fine drops are used. Drift also occurs more easily when spraying takes place from an aircraft. Herbicides may also evaporate from the field and move through the air in gaseous form. Dicamba and 2,4-D are among the herbicides that most easily drift and evaporate and can thereby harm both crops in neighbouring fields and non-target organisms.

3.2.2.4 Quantity and type of herbicide
When farmers start using an HR crop, they should in theory be able to spray less and in some cases replace more harmful herbicides with less harmful ones. It is not necessarily the actual volume of the herbicide, but rather the quantity and toxicity of the active ingredients that determine the impact of one herbicide compared with another.

Whether the use of herbicides really declines, particularly in the long term, is a matter of contention. A report from the consulting company PG Economics, based on figures from the GMO industry and market surveys, shows that the global use of herbicides from 1996 to 2011 decreased by 474 thousand tonnes of active ingredients as a result of the use of genetically modified plants.[50] However, according to a report based on statistics from the US Department of Agriculture (USDA), the introduction of glyphosate-resistant plants caused the total use of herbicides in the USA to fall from 1996 to 2001, but it then rose again, so that in 2006 the total use of herbicides was again at the level in 1996, and it continued to rise in subsequent years.[51] From 1996 to 2010, the use of herbicides in the USA had risen by a total of 239 thousand tonnes due to the cultivation of HR crops. This was calculated by comparing herbicide use per hectar for HR crops and non-HR crops. The cultivation of genetically modified insect-resistant plants resulted in a reduction of 56 thousand tonnes in the use of insecticide during the same period. Overall use of herbicides nonetheless rose by 183 thousand tonnes, which is equivalent to a 7 per cent increase. Two other reports, which also used data from the USDA and the US Environmental Protection Agency (EPA), draw similar conclusions.[52,53]

Glyphosate-resistant weeds have become a steadily increasing problem for agriculture (see chapter 3.2.3). In South America, the use of paraquat, which was phased out in the 1990s, is increasing again because weeds have become resistant to glyphosate.[54] Paraquat is prohibited in Europe because of the risk of adverse effects on health and the environment. In the USA, the use of 2,4-D appears to have risen in the last ten years, after falling in the previous ten.[55] Chemicals companies are now developing new herbicide-resistant plants that tolerate 2,4-D and other herbicides that are more toxic than glyphosate.

3.2.2.5 Combination effects (additive and synergistic effects)
Combination effects occur when various substances act in a different way together than they do individually. With additive effects, the combined effect is equivalent to the sum of the various individual effects. We talk of synergistic effects when the combined effect is greater than the sum of the individual effects. Additive and synergistic effects are one of the risk areas upon which least research has been carried out, not only in connection with HR plants, but with respect to herbicide use generally.

3.2.3 Herbicide-resistance

3.2.3.1 Resistance
Weeds may develop resistance to herbicides. These weeds will survive more easily when the weed population is exposed to herbicides, and after a while they may constitute the bulk of the weed population. The resistant weeds may also spread by means of pollen or seeds to neighbouring fields and uncultivated areas in the neighbourhood. Because farmers can spray throughout the growing season without harm to the HR crops, they can use more herbicide than before. When HR crops are cultivated as monocultures over large areas, there is a strong risk of weeds developing

resistance. The result may be that herbicides lose their effect, and farmers have to spray with other, often more toxic herbicides. This may place constraints on the use of HR plants.

According to the *American Chemical Society,* farmers, chemists, plant geneticists and agronomists are engaged in an "arms race" against weeds, particularly weeds that have developed resistance to glyphosate.[56] A new generation of herbicide-resistant cultivated plants is now on its way. Monsanto is planning to sell dicamba- and glyphosate-resistant soybean (Roundup 2 Xtend) from 2014, while Dow Agro-Sciences has developed genetically modified maize, soybean and cotton that are resistant to 2,4-D.

Dow is marketing the 2,4-D-resistant plants as a solution to the problem of weeds becoming resistant to glyphosate. Globally, however, 26 varieties of weeds from 16 families have already been found to be resistant to herbicides with the same mechanisms of action as 2,4-D. Of these 26 species, 17 are resistant only to 2,4-D. By way of comparison, 24 species have now been found to be resistant to glyphosate.[57]

The strategy of genetically modifying plants to make them resistant to new types of herbicide may result in becoming too dependent on chemical means of eliminating weeds.[58] Many are of the view that the global dissemination of herbicide-resistant weed species calls for a radical new approach to protecting our crops against weeds. Given that resistant weeds are a direct result of the overuse of herbicides, inserting new resistance genes into cultivated plants cannot solve the problem. Many scientists therefore argue that integrated plant protection strategies are a better and more sustainable alternative.[59]

3.2.3.2 Strategies for preventing resistance

When herbicides are used in agriculture, it is important to preclude the possibility of weeds becoming resistant. This is particularly relevant when cultivating HR crops because they have been created for use with a certain type of herbicide. Integrated pest management, IPM (also known as integrated plant protection (IPP) or integrated weed management (IWM)), is an important strategy for achieving this. Both Norway and the EU are focusing on integrated plant protection. This is to be the norm for pest control. Integrated pest management means combining various chemical, biological and mechanical means of combating weeds and pests, with the aim of reducing the use of chemical herbicides as much as possible. Decisions as to which measures to implement must be based on the environment in which the plant grows.

Examples of strategies that have been used to prevent weeds developing resistance in connection with the cultivation of HR crops are:

- rotating HR crops and non-genetically modified plant lines, alternating them from year to year
- avoiding monocultures by also cultivating crops for which herbicides with different mechanisms of action can be used
- taking steps to eliminate weeds using mechanical weed control

Establishing refuges, i.e. small areas that are not sprayed, will help to maintain biodiversity but will not be a strategy against resistant weeds.

HR crops may also be useful in anti-resistance strategies. The resistance to herbicides that is increasing most at present, both in Norway and in other countries, is tolerance to the important sulphonylurea group. This group of herbicides has been very important for cereals for the past 30 years. A glyphosate-resistant crop that could be alternated with cereals would thus be useful.

3.3 Soil

Whether or not cultivation of HR crops leads to more or less soil erosion depends on how the field is cultivated. When farmers use HR crops, they do not need to till in order to keep weeds away; they can spray instead. Less working of the soil through tilling may prevent erosion and the reduction of organic material in the soil layer. This will strongly influence the quality and production potential of the soil. If, on the other hand, farmers have problems after a while with resistant weeds and have to spray more, remove the weeds with machinery or start tilling again, the benefit of less working of the soil will be reduced.[60]

There are few studies available that address the question of whether the cultivation of HR crops results in a higher or lower soil pH. A study based on four years of cultivating different Bt maize varieties, revealed no difference in pH levels between soil where Bt varieties had been grown and that in which unmodified varieties had been grown.[61] It is difficult, nonetheless, to say anything definite about whether these results can be applied to HR crops. The pH of the soil determines, among other things, which nutrients are present and how well the plants absorb these nutrients.

In production systems where HR plants are cultivated and glyphosate is used to eliminate weeds, the quantity of nutrients in the soil has decreased over time.[62] Part of the explanation may be that glyphosate binds to certain minerals in the soil, such as calcium and magnesium, but long-term monoculture in itself has been known to result in a deficit of certain minerals (deficiency diseases).

Another relevant question is whether cultivation of HR crops may damage microflora and microfauna in the soil; see chapter 3.2.2.1.3.

3.4 Water

If the cultivation of HR crops means less tilling, this in turn means that the soil will hold water better, and that less water will evaporate from the field. According to a literature study from Wageningen University in the Netherlands, the cultivation of HR soybean and maize has probably contributed to soil conservation strategies becoming more widespread in North and South America, partly because of less tilling. These cultivation strategies have also increased in scope in connection with cultivation of plants that are not herbicide-resistant, but with higher herbicide consumption than when tilling was used for cultivation.[63]

If cultivation of HR crops leads to less use of herbicides, there will be less contamination of ground water and other water sources such as rivers, streams and lakes. Should the opposite be the case, residues of herbicide and herbicide metabolites may contaminate the water sources along with "new" proteins from the HR crops.

Another aspect of the herbicide regime for HR crops is the type of herbicide that is used. If farmers switch to a new, less toxic herbicide, it will have a positive effect on water quality. Glyphosate, which is the herbicide most commonly used with HR crops, is less toxic than many other kinds of herbicide, and is broken down more quickly in the soil. But because the use of glyphosate has increased in connection with the cultivation of HR crops, due to the steady increase in glyphosate-resistant weeds, this positive effect may be neutralised. The literature study from Wageningen University concludes that there is no scientific evidence that the use of Roundup Ready soybean has contributed to better groundwater quality.[64]

3.5 Energy

Two of the most important input factors (see fact box p. 38) that may influence the amount of energy consumed in the cultivation of HR crops are fuel for the agricultural machinery and the energy involved in producing these herbicides. The fact that farmers do not need to till, and can drive over the fields to spray fewer times during the growing season, will reduce fuel consumption in connection with the cultivation of the plants. In theory, therefore, it is possible to save energy by cultivating HR plants, but this is dependent on the advantage of less tilling and less spraying persisting over time. The effect is difficult to quantify on the basis of the material we have had available.

The issue of the energy used by herbicides has two aspects: First, there is the question of how much energy is involved in producing the herbicide; second, how much herbicide is used per hectare. Glyphosate requires more energy to produce than many other herbicides. In order for glyphosate to yield a positive energy gain, either the quantity used per hectare must be lower than for other herbicides, or the reduction in fuel consumption by the agricultural machinery must make up for the extra energy used in glyphosate production. As there is much to indicate that the use of herbicides has increased since the introduction of HR crops (see chapter 3.2.2.4), it seems doubtful whether the cultivation of these crops has reduced the energy used in the production and use of herbicides.

3.6 Climate

The question of whether greenhouse gas emissions increase or decrease in connection with the cultivation of HR crops is partly related to energy consumption, since energy consumption contributes to greenhouse gas emissions (see chapter 3.5). To this must be added the possible effects that less tilling may have on greenhouse gas emissions.

It has commonly been assumed that tilling releases CO2 that is stored in the soil, thereby increasing greenhouse gas emissions. According to the industry-financed ISAAA report, global CO_2 savings due to reduced use of fuels, less herbicide and less tilling in connection with the use of HR crops in 2010 amounted to 19 billion kilos of CO_2, of which 17.6 billion kilos is due to less tilling.[65]

The Wageningen University report also stresses that soil preservation measures may have a significant effect on the release of greenhouse gases, but points out that this is contested in the scientific literature.[66] The general perception has been that less working of the soil, for example owing to less tilling, means that less carbon is stored in the uppermost soil layer when the soil is not turned. Recent studies, however, indicate that a change in working of the soil does not result in more organic material in the soil all in all, but influences where in the soil layer the organic material is located.[67] This means that less tilling does not result in more binding of carbon in the soil. In the light of this knowledge, there are no grounds for maintaining that less tilling owing to cultivation of HR crops will either decrease or increase greenhouse gas emissions. It will, however, lead to more organic material in the uppermost soil layer, which in itself is important because it changes the physical properties of the soil, making it a better conductor and retainer of water and nutrients.

4 Sustainable development: economy and society

Many questions pertaining to sustainable development and HR crops can be grouped under both economy and society. We have therefore chosen to combine the two areas and grouped questions to the applicants under eight main topics with sub-topics. These topics represent values that we want to safeguard and develop in a sustainable manner. The questions to the applicants are presented in table 2 (page xx). The main topics are:

1. The right to sufficient, safe and healthy food
2. Animal health and welfare
3. Living conditions and profitability of farmers who cultivate herbicide-resistant crops in the short term (less than 5 years) and in the long term (more than 20 years)
4. Living conditions and profitability in the production area in the short term (less than 5 years) and in the long term (more than 20 years)
5. Rules for the use of herbicides
6. Plant genetic resources for food and agriculture
7. Independent risk research
8. Free choice of agricultural system in the future

In the individual application, it will be most correct in the areas of economy and society to compare the HR crop with the plant it is to replace, or with the cultivation system that is common in the area where the plant is to be cultivated.

Whether the combined effect of several HR crops will be a contribution to sustainable development if they are approved for cultivation or import, is a question the Norwegian authorities should be responsible for answering. The same applies to the question of whether an approval is consistent with the goals of Norwegian food policy.

FACT BOX

The right to food: The right to food is laid down as a fundamental right in the UN Universal Declaration of Human Rights. The UN Committee on Economic, Social and Cultural Rights defines the right to food as realised when "every man, woman and child, alone or in community with others, has physical and economic access at all times to adequate food or means for its procurement."[68] The right to food includes food security, food safety and food quality (see below), and these concepts overlap to some extent.

Food security: The Food and Agriculture Organization of the United Nations (FAO) defines food security as follows: "Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life".[69]

Food safety: By food safety we mean that food must be free of infectious agents or toxins that constitute a risk to health, such as pathogenic bacteria and other microorganisms, biological and chemical contaminants and additives.[70]

Food quality: Food quality is defined as the ability of food to satisfy consumers' needs, desires and requirements. Food must provide sufficient energy and contain sufficient nutrients, and at the same time be safe. Food must also meet requirements as to taste, aroma, consistency and shelf-life, and some also place emphasis on labelling requirements and an environment-friendly and ethically responsible mode of production.[71]

4.1 The right to sufficient, safe and healthy food: food security, food safety and food quality

The right to food was first recognised as a fundamental human right in the Universal Declaration of Human Rights in 1948, and was later laid down in the UN International Covenant on Economic, Social and Cultural Rights, which is binding on those states that have ratified it.[72] If we are to achieve sustainable development, the right to food is one of the fundamental human needs that must be met. The right to food encompasses food security, food safety and food quality; i.e. sufficient safe food of good quality (see fact box). If products made from an HR crop contribute to greater food security, safety and quality, the HR crop can be regarded as contributing to sustainable development.

Ensuring that all people have access to sufficient, safe and nutritious food contributes to sustainable development.
From the Philippines. Photo: © Hartmut Schwarzbach / Argus / Samfoto PHL

4.1.1 Food security

Food security is, among other things, about access to sufficient food. Changes in yields and input factors (see fact box p. 38) play a part in determining whether more or less food will be produced when a farmer switches to HR crops. Whether the HR crops are to be used for food, feed, fuel or materials, is also relevant.

4.1.1.1 Changes in yields and input factors

If the yield per unit area increases when the farmer switches to HR crops, this counts positively in principle, because there will be more food. It is too limiting, nonetheless, to consider only whether HR crops give higher yields, since an increase in yield may also depend on the farmer using more input factors. By input factors we mean more labour, capital, herbicides, fertiliser, fuel etc. (see chapter 4.3.3.1). In order to determine the size of the yields relative to the resources required to produce them, one should rather investigate whether the input factors per production unit change when HR crops are cultivated. If the input factors per production unit change, it may affect the size of the crop the farmer wants to produce, and how much she/he does produce in the end. If HR crops result in reduced use per produced unit of input factors which are important and in short supply in food production, for example phosphorus, this may also contribute to an increase in food security. See also section 4.3.3 on changes in farmers' costs and income.

4.1.1.2 Food, feed, fuel or material

Whether, and to what extent, HR crops contribute to altering food security depends on whether the plant is to be used for food, feed, fuel, material or clothing. Some HR crops, such as HR soybean, are used mainly for food and feed, while others are used primarily in manufacturing. For example, cotton fibre is used to produce clothing, other parts of the plant go to feed, while oil from the seed is also used for food and feed. Oil is produced from HR oilseed rape for use in food and feed production and biofuels, while the residue from pressing the oil is used for animal feed. HR sugar beet is used in sugar production.

HR crops contribute most to food security if they are used for food, because more energy is recovered when plants are used directly for food than when they are used for animal feed. The UN Environmental Programme (UNEP) has advised that in order to augment access to food, subsidisation of first-generation biofuels that compete with food production should be reduced and less cereals should be used in feed.[73] It therefore counts positively in the sustainability assessment if HR crops are grown for use as food. HR crops that are not used for food compete for space with food production in some cases, but since conflicts about use of space are not confined to genetically modified plants alone, the fact that HR crops are not to be used for food should not count either positively or negatively. An HR crop that is intended to be used in other ways than for food may also contribute positively to sustainability in other ways.

An HR crop may be assessed differently if it is to be cultivated in countries where the corresponding non-genetically modified crop is the principal food plant. This applies, for example, to maize, which is a very important food plant in Central America, East Africa and southern Africa. Communities that eat a large amount of maize will be most affected if the maize has adverse effects on health. It may also be important to prevent HR maize crossing with local varieties; this is particularly important in countries that are a centre of origin for maize (see chapter 4.6.1).

4.1.2 Food safety

Food safety means that food must not contain substances that make it a health hazard. Because HR plants are developed for use with a particular herbicide, herbicide residues and herbicide metabolites have a bearing on food safety. Also of relevance is whether the genetic modification itself has caused changes in the plant that may adversely affect health.

4.1.2.1 Herbicide residues in food and feed

Herbicide residues in food and feed may be a health hazard in overly large quantities. For this reason, Norway has introduced threshold values for how much and how close to harvest time spraying is allowed, and how much herbicide residue is permitted in food and feed. Both Norway and the EU aim to reduce the effects of herbicides in agriculture.

At present there are reports claiming that the use of herbicides has increased, as well as reports stating that use has decreased since the introduction of HR crops (see chapter3.2.2.4). Thus it is not given that HR plants will lead to a long-term reduction in the use of herbicides, and that these plants will cause farmers to switch to more environment-friendly herbicides. If the use of herbicides increases in the long term and spraying times change, the risk of finding harmful herbicide residues in food and feed will also increase.[74] In such case, HR crops will contribute negatively to sustainable development.

Possible adverse effects on health may result from both the herbicide itself (the active ingredient and additives) and its metabolites. Little is known at present about the biological effects of herbicide metabolites. We also lack knowledge of the "cocktail effect", i.e. what happens when many chemical substances from herbicides or metabolites act simultaneously. If an HR crop is resistant to more than one herbicide, a specific study should be carried out to identify whether there are any health risks associated with the combined effects of the herbicide residues. See also chapters 3.1.1.4 and 3.2.1.

4.1.2.2 Adverse effects on health of the genetically modified plants

In theory, eating food derived from HR crops may affect the health both through herbicide residues (see chapter 4.1.2.1) and through changes in the plant as a result of the genetic modification. Effects may include acute or chronic toxicity, immune system reactions, such as allergies, or effects due to anti-nutrients (substances that prevent the uptake or effect of important nutrients). Changes in metabolism and fertility must also be studied.

To the best of our knowledge, no studies have been published to date of potential effects on human health of ingesting food or inhaling pollen and seed residues from HR crops. As mentioned in chapter 3.1.4, there are few published studies on experimental animals and cultured cells of possible toxic and immunological effects of whole plant material or the purified, new, transgenic protein CP4 EPSPS as it is made in the plant.

The results of the first long-term feeding study with a herbicide-resistant crop, the Roundup Ready maize NK603, were published in 2012.[75] This was the first feeding study that lasted for two years, i.e. a whole lifetime for the rats. The researchers reported higher incidents of tumours and kidney and liver damage among the rats fed GM maize and/or Roundup compared with those that were given the unmodified maize variant. On the whole, these effects developed subsequent to the conclusion of earlier feeding experiments. However, the study had deficiencies and was controversial. As this was the first study of its kind and researchers disagree as to how the results should be interpreted, it is reasonable to require that the study be followed up by more lifetime feeding experiments on rats.

4.1.2.3 Experimental material

Investigations of how an HR crop and the herbicide affect the health of humans and domestic animals should be carried out on the proteins in the form in which they occur in the HR crop, and using whole plant material or relevant feed from the plant material. Read more about this in chapter 3.1.4.2.

FACT BOX

Input factors

In economic theory, input factors are defined as resources used in a production process. In agriculture, these comprise labour, natural resources such as land and water, and/or real capital, i.e. concrete, physical objects such as machinery, tools, seed, fertiliser, herbicides and irrigation technology.

4.1.3 Food quality

Food quality is about consumers' needs, wishes, requirements and expectations regarding food. Factors of relevance here are storage properties, how appropriate the food is for different types of processing, what nutrients the food contains, and nutrient and energy quantities. Other qualities include consistency, colour, aroma, taste and appearance.

4.1.3.1 Nutrients and energy

HR crops are not, in principle, intended to change the nutrient or energy content of the plants, but to be resistant to herbicides. Because we cannot control where in the DNA the new genes end up, the genetic modification in itself may lead to unexpected changes in the HR plant. For example, the nutrient content may change. This must be investigated before the plant can be approved.

4.1.3.2 Storage properties

The amount of food that is thrown away or lost during production is a great challenge to sustainable food production worldwide. FAO and the Swedish Institute for Food and Biotechnology calculated in 2011 that a third of all food produced for human consumption, i.e. 1.3 billion tonnes, is lost during production or discarded.[76] Production wastage takes the form both of loss of crops during cultivation and of waste after the plant or plant product has entered the logistics chain. Properties that preserve a crop better during storage may result in less wastage, and enhance both food quality and food security.

Chicken production at Høylandet in Nord-Trøndelag County, Norway. Photo: Annemor Larsen / VG

To the best of our knowledge, no studies have been published to date on storage effects. Thus, there is no information on whether the HR crops keep better during storage than other crops or not as well. A general challenge posed by monocultures and reduced working of the soil (less tilling) is that there may be more fusarium fungus in the plants, which results in more wastage. This may also be of relevance to the cultivation of HR crops.

In developing countries, loss of crops during cultivation is a greater problem than wastage further down the production chain. If crop loss can be prevented, the result could be more and cheaper food, which is particularly important in poverty-stricken areas.

4.1.3.3 Benefits to the consumer

HR crops are genetically modified to tolerate herbicide. This is a property that on the whole benefits only the farmer. Consumers do not benefit directly from HR crops, as opposed to plants that have been genetically modified to contain vitamins or extra/other nutrients. On the other hand, cultivation of HR crops may result in a need for lesser quantities of input factors, and thereby lead indirectly to cheaper food, feed and biofuels. However, it is not certain that the quantities of input factors really will be reduced, particularly in the long term. Because of this and other factors such as contracts / framework conditions and other issues related to costs and income (see chapter 4.3), it is difficult to determine whether products really will be cheaper.

4.2 Animal health and welfare

Good animal health and welfare are important preconditions for sustainable development. At present, most of the HR maize and HR soybean produced in the world goes to animal feed. The question of whether feed quality will be superior or inferior is of relevance for determining whether HR crops make a difference to the health and welfare of domestic animals.

By good feed quality we mean that the feed must produce enough energy and contain enough nutrients, and at the same time be safe to eat. All domestic animals have an intrinsic value, and should therefore have enough food to survive, and enough safe food to thrive and not become sick. Feed quality is also important because the resulting products are of higher quality: for example, meat that tastes good and is nourishing. Moreover, humans must not be made ill by the products, in either the short or the long term. Farmers and fish farmers also want to use feed that results in healthy animals, because it pays to have good welfare.

The questions we discuss in chapter 4.1.2 about food safety, herbicide residues, adverse health effects and experimental material should also be asked about animal feed. It should be investigated whether the feed may have adverse effects on health such as acute or chronic toxicity, immune system reactions, such as allergies, or effects due to antinutrients (substances that prevent the uptake or effect of important nutrients). It should also be investigated whether fertility and metabolism are affected. See also chapters 3.1.4.1 and 3.1.4.2 on non-target organisms and chapter 4.1.3.1 on nutrients and energy.

4.3 Living conditions and profitability for farmers who cultivate HR crops in the short term (less than 5 years) and in the long term (more than 20 years)

Living conditions and profitability are topics with a bearing on sustainable development within the areas economy and society. This applies both to farmers and farm workers who cultivate HR crops, and the general population in the production area. Sustainable development must be assessed in a long-term perspective, and must ensure that the fundamental needs of future generations are also satisfied. However, it is not possible in practice to predict developments in living conditions and profitability ad infinitum. If we regard “long term” as being at least 20 years, we require an assessment that extends over more than one generation, at least.

Aspects of sustainability of relevance to farmers who cultivate HR crops are health and security, contracts and framework conditions, changes in costs and income, agronomic factors and the right to seed.

4.3.1 Health and safety

The cultivation of HR crops may affect the health of farmers and farm workers if herbicide use changes. As HR crops are created for use in combination with certain herbicides, it is important that farmers and farm workers receive training and information on herbicide toxicity. They also require access to the correct protective equipment.

In many developing countries, health, environment and safety (HES) systems are poorly developed. Many users have an inadequate knowledge of herbicides and/or use them incorrectly. Empty herbicide barrels are also used to store food and water. Many do not have access to, or cannot afford, protective equipment.

There is also a difference between changing from agriculture *with* herbicides to agriculture with HR crops, and changing from agriculture *without* herbicides to HR crops. For those who have used herbicides before, HR crops can offer benefits if the farmers / farm workers can use more health- and environment-friendly herbicides and lesser quantities of herbicide. As well as impacting the environment, changes in the use of herbicides have a bearing on the health, safety and profitability of the farmers. The effects of herbicides on health are discussed in chapters 3.2.1, 3.2.2.1.4 and 3.2.2.1.5.

4.3.2 Contracts and framework conditions

A number of companies that sell HR crops require that farmers sign a contract before they are allowed to buy and cultivate HR crops. They may also have to pay a technology charge or for a licence when they buy seed.

Because only a few producers sell genetically modified plants and input factors, they may behave in a monopolistic fashion. Seed companies may sell seed and input factors cheaply during an introductory phase, and then raise prices once a customer relationship has been established. As a result, farmers who cultivate genetically modified crops may have less freedom of choice.[77] For example, it may be difficult to start cultivating non-GMO crops after a few years of HR crops if the farmers are bound by contracts.

Companies should also give farmers the information they need about seed, spraying schedules (how often, how and with which herbicide they should spray) and how they can prevent resistant weeds. In this way, the farmers can obtain the greatest possible return for their input factors, while taking the environment into account.

See also chapter 4.3.5 on farmers' right to seed and chapter 4.7 on independent risk research.

4.3.3 Changes in farmers' costs and income in the short term (less than 5 years) and in the long term (more than 20 years)

The way in which farmers' costs and income change determines their profitability in the short term (less than 5 years) and in the long term (more than 20 years). Profitability, in turn, affects their living conditions. The cultivation of HR crops can affect production costs if greater or smaller quantities of input factors are needed (see fact box p. 38) to cultivate HR crops compared with non-genetically modified crops. Changes may take place in both the short and the long term. Of particular relevance in the long term is whether weeds will become resistant more quickly to the herbicide that is to be used with the HR crop.

4.3.3.1 Input factors

HR crops are intended to reduce production costs by enabling farmers to use less of the input factors herbicide, tilling, fuel and labour, compared with non-genetically modified crops. If less herbicide and tilling are needed to cultivate HR crops, and other costs do not increase, farmers will save both time and money. It will be particularly beneficial if less tilling and other working of the soil are required in cultivation areas where soil erosion is a problem. HR crops may also reduce labour requirements in areas where intensive labour is required for weeding.

Experience gained from the Green Revolution shows that it may be more important for small farmers to reduce the price of input factors such as fertiliser, seed and irrigation, possibly by using less of the input factors, than to increase their harvests (see chapter 4.3.4.1). Whether the use of herbicides and labour is really reduced after the first few years of cultivating HR crops is a matter of contention (see chapter 3.2.2.4).

The price of seed also has a significant effect on production costs. If the seed of the HR crop is more expensive than that of the corresponding non-genetically modified crops, this may affect farmers adversely. If, on the other hand, the HR seeds are more expensive, but result in farmers needing less of the other input factors, farmers may still save money.

Consumer demands, such as special preferences with respect to taste, nutritional content or production method, are also factors that determine whether it is possible to charge the same or higher prices, and thereby maintain or increase production profitability.

4.3.3.2 Resistant weeds

Sustainable development must be assessed over a number of generations. If the first generation that cultivates HR crops benefits from any ensuing advantages, while the next generation has to bear burdens, known or unknown, the HR crop is not contributing to sustainable development. The development of resistant weeds may be one such burden. The costs of input factors may fall from the first day because less herbicide is needed, but may rise again after a number of growth seasons if weeds become resistant to the herbicide. When weeds develop resistance the farmers have to use more herbicide or get rid of the weeds in other ways (see chapter 3.2.2). In order to avoid profitability deteriorating in the long term, risk assessments should be planned or carried out, and steps should be taken to counteract the development of resistant weeds.

4.3.4 Agronomic factors

HR crops may not necessarily be equally favourable for all types of agriculture. Since these crops have been developed for cultivation involving the use of a certain herbicide, they may have different consequences for small-scale than for large-scale agriculture. The fact that many HR crops are hybrids (see chapter 4.3.4.2) also largely determines the type of agriculture they are suited to.

4.3.4.1 Small-scale agriculture

Half of the world's population lives in towns and urban areas. The other half lives in rural areas, and about two thirds of those who live in rural areas are food producers. Most of the world's farmers are small farmers of various kinds and many of them produce food based on local varieties of edible plants and domestic animals that are adapted to the local cultivation conditions. These plant varieties and domestic animal species contribute to maintaining a wide biological diversity in agriculture.[78,79] Small farmers traditionally use agronomic methods that require limited external input factors, such as purchased seeds and herbicides. They produce primarily for local markets and for subsistence. Production for local and national markets is important because if a country becomes too dependent on imports, its food security may be threatened.

Work-time studies of small-scale production show that a large amount of time is spent on weeding, and that in many cultures it is primarily women who do the weeding. Small farmers often lose a large proportion of their crops because of weeds and pests, and may perhaps only be able to harvest between half and three quarters of the potential crop. In principle, it would be desirable to produce a larger net harvest without working substantially more, and it is possible that HR crops may help to make this possible. But small farmers often have little purchasing power, live and farm far from cities, and find little support in the form of agricultural guidelines and research adapted to the cultivation conditions and farming methods they use. Today there is only a limited possibility of changing agronomic methods so that small farmers can benefit from HR crops. Those HR crops that are marketed today for use in the production systems of small farmers are therefore few and have a narrow genetic base. They are often also poorly adapted to the more marginal conditions under which small farmers live and work, particularly in developing countries. Modern seed often gives a poorer yield than the traditional varieties in places like this because small farmers do not have access to the necessary input factors.

When HR crops are poorly adapted to the farming conditions, small farmers may experience crop failure, but at the same time be unable to extract themselves from the debt problems that may arise because they are unable to secure new loans and credit to help them pay off debt to sellers of seed and herbicide. The sellers, for their part, may attach the farmers' harvests, equipment or property. The health, environment and safety (HES) systems in developing countries are often poorly developed. As a result, there are more health problems among those who use herbicides, and a greater risk of the countryside being polluted through both the spraying process itself and storage of the herbicide.

Small-scale producers in industrial countries can more easily deal with the challenges posed by the use of herbicides and possible crop failure. In the current situation, small farmers in developing countries may be particularly vulnerable if national agricultural ministries or private sales organisations try to persuade small farmers to use production systems that require the use of relatively untested input factors, such as HR crops. This may happen if such change is not viewed in the context of a more general strengthening of infrastructure, knowledge systems and financing options.

4.3.4.2 Hybrids

Hybrid crops are crosses between plants with different genetic backgrounds. When the offspring is superior to both parent plants, the phenomenon is called heterosis, hybrid vigour or outbreeding enhancement. Most of the maize varieties used in modern large-scale agriculture are hybrids, whether they are genetically modified or not. Many hybrids of cotton are also cultivated, and some of oilseed rape, but none of soybean. The most common means of producing hybrids that are superior to the parent plants is to produce two pure lines and cross them. If their off-

Picking cotton. Photo: ©Link / Samfoto

spring, which are hybrids, are then crossed with each other, the resulting plants are inferior to their parents. Farmers therefore cannot achieve the same outbreeding enhancement for each harvest by taking seed from their own crop, but must buy new seed each year.

The HR maize varieties cultivated today are hybrids. Many HR crops are hybrids of one HR crop and one insect-resistant crop, or of one HR crop that tolerates glyphosate and one that tolerates glufosinate. Pure lines of HR maize can also be crossed with lines of ordinary maize to produce a hybrid.

Hybrids generally require greater quantities of input factors such as water and herbicide and special knowledge of how the plants should be cultivated in order to obtain the highest possible yield. In some cases, farmers may have to raise loans in order to finance the input factors. The varieties of HR maize available today are therefore not very appropriate for small farmers in developing countries.

4.3.5 The right to seed

Over a period of ten thousand years, farmers have developed thousands of varieties of our most important cultivated plants, which form the basis for all food production. Local varieties are adapted to local conditions, and farmers preserve the genetic diversity by developing and maintaining these varieties and the knowledge of how they should be cultivated. It is a dilemma that this know-how may be lost if the cultivators switch to buying seed every year.

Oilseed rape plants that have spread. France. Photo: Scanstockphoto

To permit further development, and the production of new varieties, farmers and plant breeders are dependent on access to a rich diversity of genetic variation (see also chapters 4.6 and 5.3.1). The FAO Plant Treaty, which Norway has ratified, stipulates how we must preserve plant diversity for the future through conservation and sustainable use.[80] The Treaty states how farmers contributed to developing the plant diversity we have today, and that countries have responsibility for farmers' rights. Farmers should have the right to participate in making decisions, to share in the benefits arising from the utilisation of plant genetic resources, and to save, exchange and sell seed from their own harvest.[81] A number of surveys show that the right to save seed from one's own harvest is regarded as the most important factor for enabling farmers to preserve and further develop plant diversity for the future.[82,83,84,85,86]

Using seed from one's own harvest is particularly important for small farmers in developing countries (see chapter 4.3.4.1), but in Norway, too, about one in five farmers uses seed from their own harvest. In Norway, plant breeding law gives farmers the right to use seed from their own harvest and exchange seed from protected varieties amongst themselves, but they do not have the right to sell seed from protected varieties. The authorities have concluded that this solution provides the best balance between the rights of the farmers and the rights of the plant breeders to compensation and benefits from the plant breeding.

However, if the genetically modified plant is a hybrid (see chapter 4.3.4.2), saving seed is not an option for farmers.

4.4 Living conditions and profitability in the production area in the short term (less than 5 years) and long term (over 20 years)

In order for an HR plant to contribute to sustainable development, it should have positive effects on the living conditions and profitability not only of the farmers who grow the HR crop, but also of other persons living in the production area, both in the short term (less than 5 years) and in the long term (over 20 years). Relevant issues in this context are health and safety, the democratic rights and profitability of farmers that do not grow HR crops, employment, ownership rights, GMO monitoring and the economic consequences of changes in ecosystem functions.

4.4.1 Health and safety

The herbicides to which farmers and farmworkers (see chapter 4.3.1) and other members of the population are exposed may give rise to health and safety issues. Changes in the spraying regime, such as changes in the type and quantity of herbicide that is used, the persistence of the herbicide and its metabolites and the time of spraying are all relevant factors (see chapter 3.2.2). The spraying methods that are used also have a strong bearing on the way the population's health is affected. Spraying from an aircraft is particularly controversial because it often leads to the herbicide being carried by the wind from the field to neighbouring areas (herbicide drift) (see chapter 3.2.2.3). Aerial spraying is used in industrial agriculture on a general basis, and available data give little reason to believe that the cultivation of HR crops per se makes aerial spraying more or less necessary than in other industrial agriculture.[87] A more relevant question is whether the quantity and type of herbicide that are used change. The effects of herbicides on health are discussed in chapters 3.2.1, 3.2.2.1.4 and 3.2.2.1.5.

4.4.2 The democratic rights and profitability of other farmers

When a farmer decides to cultivate HR crops, this choice may also affect other farmers in the area. The harvests of neighbouring farmers may be contaminated by the dispersal of pollen or seeds. But farmers may also be affected by genetic contamination because they share agricultural machinery, or because HR crops or HR seeds are transported through their areas. The actual use of a herbicide may also affect the neighbours. If neighbours do not cultivate HR crops, their harvests will be negatively affected by unintended herbicide spraying or by wind drift. Weeds may also become a greater problem for neighbours, either because HR plants spread like weeds to their fields, or because other resistant weeds spread.

If the crops of farmers who cultivate non-genetically-modified crops are contaminated by HR plants, they can no longer sell their harvests as conventional or organic, which means that they are deprived of the freedom to choose their method of cultivation. There have been cases in the USA where farmers whose fields have been contaminated by HR crops have been sued by the seed manufacturer because the HR crop was patented.[88,89] Furthermore, producers of non-GMO soybean in Brazil have had to pay royalties to GMO companies because their products have been contaminated by genetically modified soybean in the course of the production process.[90] Farmers who cultivate HR plants may also be affected by contamination since HR crops that are resistant to various herbicides can contaminate one another, resulting in multi-resistant HR plants. In such cases, however, the farmer can still sell his/her crop as before because the plants have been genetically modified in any event.

There must be rules for co-existence, compensation and risk management procedures that prevent the dispersal of HR plants, pollen and seed to areas with non-GMO crops, making it possible to choose to cultivate non-GMO crops instead of HR crops. If the HR crop is to contribute to sustainable development, these rules must be followed. There should also be a system for keeping GMOs and non-GMOs separate, not just in the field, but also in the rest of the production line. If HR crops are imported to Norway, they must continue to be segregated throughout the storage, transportation and processing line.

It must also be determined who is responsible for covering any losses that may be sustained by other farmers if HR crops should spread. For instance, liability may lie with the seed companies that sell the GM plants, or with the farmers who grow them. If farmers who do not grow HR crops are forced to bear the costs of having two production lines, this may be considered a negative effect. The regulatory framework must ensure that those who cultivate non-GM crops are not required to pay royalties to GMO companies. The aim should be to make the polluter pay. Compensation could be provided in the form of money, and should be commensurate with the damage caused. Farmers who cultivate HR crops could also be required to have buffer zones and plant their GM crops at specific distances from non-GM crops.

4.4.3 Employment

The employment situation may change if one or more farmers start to grow HR crops, for example because cultivating HR crops can save labour. Whether these changes are to be considered positive or negative is a question of choice of food production policy. The fact that fewer people work in the agricultural sector is not necessarily negative, provided they can find other employment. Even if fewer jobs are available on a farm where HR crops are cultivated, more jobs may be created further down the supply chain, in functions such as logistics or the processing and sale of products. Changes in employment patterns might enable a country to strengthen its economic position in international trade and bolster its national economy, thereby achieving greater prosperity. In a number of countries, however, some parts of the population and politicians wish to maintain employment in rural areas, and preserve agriculture as a bearer of culture. In this perspective, the loss of jobs in rural areas could be negative for the achievement of the goal of vibrant rural communities.

In small-scale agriculture in developing countries, a great deal of working time is spent removing weeds (see chapter 4.3.4.1). This job is traditionally done by women. If the cultivation of HR crops causes less need for weeding, these women may become unemployed. However, this might also give them more time for other activities such as raising more animals, processing raw materials and the like, which would be a positive effect.

4.4.4 Ownership rights

Cultivation of HR crops can lead to a change in ownership rights to the land, water or seed in the cultivation area. If the quantity of input factors required by farmers increases or decreases, this, combined with the price of the input factors, may affect ownership rights. Such changes are highly dependent on which crops the HR crop replaces, and what type of farming was previously being done in the area. For instance, hybrid crops generally require more water, fertilizer and herbicide to produce good harvests, regardless of whether or not they are HR crops (see chapter 4.3.4.2). Whether these changes should be considered positive or negative is again a question of choice of food production policy.

Water is a scarce agricultural resource in many areas. If cultivation methods are changed, such as by converting to hybrid crops that require more watering, this could result in more competition for the right to use water resources.

The cultivation of HR crops may also lead to changes in ownership of the seed used in the area. This may happen if, for instance, farmers switch from using seed from their own harvests to buying seed for HR crops to which a company has the proprietary rights. The seed manufacturer may limit farmers' rights to save, exchange or sell seed from their own harvest (see chapter 4.3.5), and decide whether seed may be used for further plant breeding (see chapter 4.6.3). In the long term, the right of ownership to seed can go a long way towards determining which varieties will be available in the area (see chapter 5.3.1).

4.4.5 Monitoring

In the EU and elsewhere, a plan is required for monitoring of the production of genetically modified plants and the effects of such production on soil, water and the environment in the cultivation area and its surroundings. The logistics for individual farmers, and for other actors in the production chain, may become more complicated by the introduction of GMOs. Neither the plants nor the seed must contaminate their surroundings, such as non-genetically modified crops in the vicinity. Nor must genetically modified products be mixed with other products. More bureaucracy may be required to ensure that the HR crops are not harmful to health or the environment. Applications, licences and monitoring all entail greater expense.

4.4.6 Economic consequences of changes in ecosystem functions

Ecosystem functions are the interplay between the structure of and processes in the ecosystem.[91,92] The ecosystem's structure consists of its various biological and physical components, of which biological diversity is an important part. The processes in an ecosystem consist of the transfer of matter from one part of the system to another, such as the transport of water or sediment, chemical reactions, photosynthesis or grazing. The ecosystem functions enable the ecosystem to provide ecosystem services, i.e. services that are useful for humans (see the fact box on page 18). Any change in ecosystem functions could have positive or negative economic consequences.

Less varied ecosystems, like those found in monocultures, may be more vulnerable and, for instance, be more affected by changing weather and climate conditions or more susceptible to disease. This may in turn have negative economic consequences. Such problems apply to monocultures in general, whether or not the crops are genetically modified. The question is whether HR crops have different positive or negative effects on the ecosystem than non GM crops (see chapter 3). Different potential effects caused by the cultivation of HR crops may be due to changes in the herbicide regime.

The undesirable spread of genetic material from HR crops to wild relatives of cultivated plants or to weeds may also affect ecosystem functions. This problem is particularly relevant in centres of origin and centres of diversity (see chapter 4.6.1). Such areas have a genetic diversity that is of benefit to the entire world and that is essential if we are to be able to develop new plant varieties in the future. The loss of these resources and our knowledge of them will have economic consequences in the long-term.

Another example of changes in the ecosystem that could have economic repercussions is changes that make an area more or less attractive for tourism, as this will in turn affect industries that make a living from tourism.

4.5 Rules for use of herbicides

Herbicides used in agriculture may be harmful to health and the environment if used in excessive quantities. If it has been documented that the herbicides to which HR crops have been made resistant can have adverse effects on health and the environment, these HR crops do not contribute to sustainable development. On the other hand, if an HR crop leads to a reduction in the use of herbicides that are harmful to health and the environment, it does promote sustainability.

Many chemicals used in agriculture and elsewhere have subsequently proved to be highly harmful to both the environment and health. There are now three UN global treaties on dangerous chemicals: the Stockholm Convention, the Basel Convention and the Rotterdam Convention. Norway is party to all of them.

The Stockholm Convention on Persistent Organic Pollutants, adopted in 2001, which has 179 parties, is a treaty aimed at phasing out the most dangerous substances. Several of them, including endosulfan and lindane, have been used as pesticides.[93,94] The Basel Convention deals with the control of transboundary movements of hazardous wastes and their disposal. The convention contains a list of pesticides that are so harmful to health and the environment that they should be prohibited in every country. To date, no HR crops have been produced that are resistant to any of these pesticides. The Rotterdam Convention concerns prior informed consent procedures for certain hazardous chemicals and pesticides in international trade.

It can take a long time both to obtain scientific evidence that a pesticide leads to adverse effects on health and the environment, and then to win political acceptance for phasing out the pesticide. As a case in point, atrazine, a herbicide that inhibits photosynthesis, has been banned in Norway since 1990 due to its disruptive effects on the hormone system. Other adverse characteristics are related to its persistence and mobility, i.e. the substance remains

Rice farmers in Sekinchan, Malaysia. Genetically modified, herbicide-resistant rice has been developed, but is not yet in use. Photo: iStockphoto

present in the environment for a long time and becomes widely dispersed. In 2004, the use of atrazine was prohibited in the EU, whereas it is still in use in the USA and other countries.

Several of the herbicides to which genetically modified plants have been made resistant are banned for all types of use in Norway. This applies to both glufosinate-ammonium and 2,4-D. Nonetheless, a herbicide that is banned for a certain use in Norway, is not automatically considered to be harmful for all types of use in another country. For example, many herbicides have been rejected in Norway because they break down too slowly in our cold climate. Owing to different climatic, living and sanitation conditions, larger amounts and a wider variety of insecticides and herbicides are needed in many developing countries than in the western part of the world. But if the herbicide to which an HR crop is resistant has the same effects in the country of cultivation as in Norway, and it has been banned in Norway because it is a health and environmental hazard, the HR crop can be said to make a negative contribution in terms of sustainable development.

Like the concept of sustainable development, adverse health and environmental effects caused by pesticides cannot be seen in a purely national perspective. The transport of toxins over long distances is well documented, and was one of the determinant factors for the ban on endosulfan in the Stockholm Convention in 2011.

By introducing national prohibitions against pesticides that have been shown to be hazardous to health and the environment, such as glufosinate, the Norwegian authorities have adopted the stance that food production should occur without the use of these pesticides, and that the use of these substances should be stopped. If, at the same time, our rules and regulations ensure that feed or food consumed in Norway is not based on GMOs that lead to the increased use of these pesticides, this will promote a consistent policy.

Norwegians have a great deal of trust in their government authorities. Their confidence that both pesticides and GMOs are adequately regulated may be jeopardised if the authorities introduce a practice that is perceived as a double standard. This could happen if they approve the import of HR crops that tolerate pesticides which Norwegian food manufacturers are not permitted to use for environmental and health reasons.

HR crops that are resistant to herbicides that are banned in Norway because they constitute a health and environmental hazard, may also increase the risk of adverse health effects caused by pesticide residues in food and feed (see chapter 4.1.2.1).

4.6 Plant genetic resources for food and agriculture

The variety of genetic material in plants provides the basis for all plant breeding and determines whether we can adapt our food production to climate and environmental changes such as drought and frost, and to plant diseases and pests. There may also be changes in demand, with calls for healthier, more nutritional food. Preserving the genetic diversity of cultivated plants and their wild relatives is therefore essential to safeguarding food security and biological diversity in the future, and is an extremely important contribution to sustainable development.

Relevant issues in this connection are centres of origin and centres of diversity, wild relatives of HR plants, possibilities of further plant breeding (see chapters 4.6.1 to 4.6.3) and the right to seed (see chapter 4.3.5). These are questions that should be answered by applicants.

Responsibility for answering questions concerning the selection of seed available, monocultures, co-existence rules (rules for how GMOs and non-GMOs can be cultivated in the same area) and systems for separating GMOs and non-GMOs in the production line should lie with the Norwegian authorities (see chapter 5.3). The authorities should also answer the question of whether the HR plant is available for further plant breeding.

4.6.1 Centres of origin and centres of crop diversity

The centre of origin of a plant species is the geographical area in which this species, whether wild or cultivated, first developed its distinctive characteristics.[95] For example, Mexico and Guatemala are centres of origin for maize, China for soybean and Peru for the potato.

A centre of crop diversity for a cultivated plant is a geographical area where this plant species is cultivated and has a high level of genetic diversity. The centre of origin is usually also richest in genetic diversity, but the centres of crop diversity are not necessarily found exclusively in the centres of origin. Centres of origin and centres of crop diversity have many different traditional varieties of the cultivated plants that are specially adapted to the environment in which they grow. The centres of origin usually have the greatest diversity of wild relatives of cultivated plants. The genetic variation found in these areas is a benefit for the entire world that it is important to protect and develop so as to ensure enough food for future generations and thereby contribute to sustainable development. If HR crops cross with the traditional varieties, undesirable genes from the HR crops may change the varieties' characteristics.

4.6.2 Wild relatives of cultivated plants

Wild relatives of cultivated plants are a part of genetic diversity that may prove to be useful for breeding plants with characteristics that may be needed in the future, for instance to survive in the face of climate change.[96,97] Many wild relatives grow in harsher conditions than cultivated plants and possess properties that render them robust.[98]

Undesirable genes from HR crops may spread to wild relatives through crossing. The probability of such spreading is contingent on the way in which the crops are pollinated, and how easily pollen and seeds are dispersed by the wind. Oilseed rape and rice disperse easily, for example. Wild relatives of oilseed rape are also found in Norway. If the gene for herbicide resistance spreads to other plants and these plants are sprayed with the herbicide to which they are resistant, these plants will have a competitive advantage. Whether the spread of undesirable genes will increase or reduce the ability of the wild relatives to survive in nature must also be considered.

4.6.3 Possibility of further plant breeding

The production of food is based on the constant development of new plant varieties. Both farmers and plant breeders need access to a range of different genetic resources in order to be able to breed new varieties. When the further breeding of plants is prohibited, this access is prevented, with the possible result that fewer new varieties may be bred. The possibility of further breeding is also linked to farmers' right to keep the seeds from their own crops and exchange them with other farmers (see chapter 4.3.5).

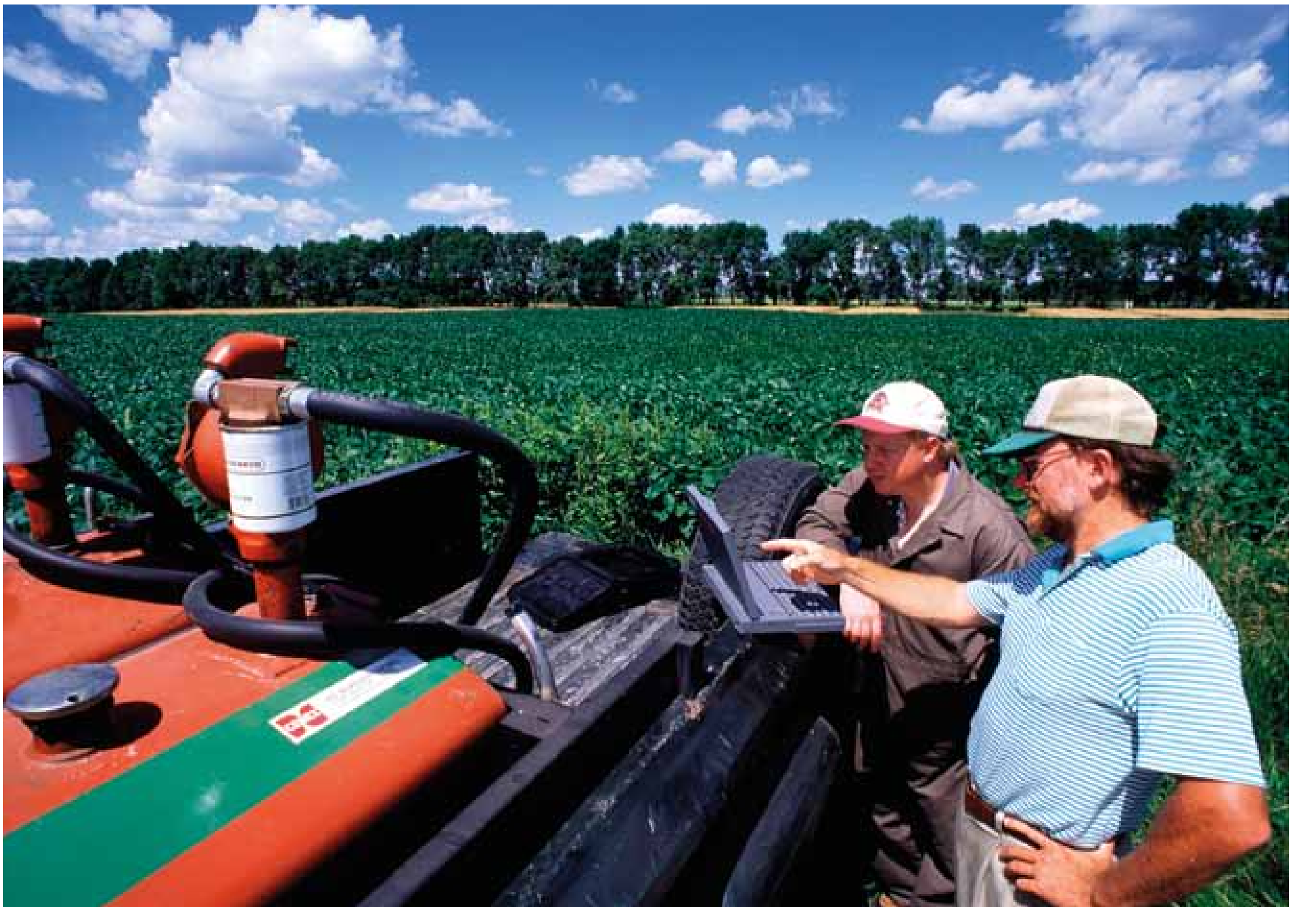
Patents protect those who bear the costs of developing an innovation, and can therefore help to ensure that more products are developed and placed on the market. In the seed sector, however, patent law, and in particular the possibility of patenting genetically modified plant varieties, has instead contributed to a situation in which a few companies control large parts of the global seed trade and there are fewer varieties for sale (see chapter 5.3.1). This is partly due to the fact that a patent on one plant variety makes it illegal in many countries to use the plant material to breed further varieties, and in part to the fact that the administrative costs of patenting lead to increased economies of scale and market concentration in the industry.[99] In other cases, contracts prohibit farmers from both breeding further varieties and saving seed from their own harvests.

Under the current conditions, if Norway, through the European Patent Organisation (EPO), approves a patent on an HR plant, the breeding of further varieties of the plant for commercial use will be prohibited. Nevertheless, the fact that a plant has been patented should not be considered a negative factor when assessing the application. However, if breeding of further varieties of the HR plant is permitted, this should be considered a positive contribution to sustainability. There are also alternatives to patents in the form of plant breeders' rights that assure plant breeders of a profit and compensation while permitting others to use the plants for further breeding.

If the HR crops are hybrids (see chapter 4.3.4.2), the farmers must buy new seed every year in order to obtain a harvest of the same size, which makes it unlikely for them to engage in further plant breeding themselves.

4.7 Independent risk research

To be able to assess risk, scientific studies are required. At present, it is primarily the GMO manufacturers themselves who carry out the experiments to which they refer in their applications. At the same time, there are few relevant peer-reviewed scientific articles on risk assessments of HR crops. Consequently, the bulk of the documentation used by the authorities in their risk assessments is provided by the manufacturers. To ensure good, balanced assessments, it is important that parties other than the seed company be allowed to conduct research on HR crops. This is particularly relevant for research aimed at investigating whether HR crops can have unexpected effects on health and the environment.



Planning measures against the weed Palmer amaranth (*Amaranthus palmeri*) in the soybean field. Photo: Bruce Fritz / USDA

Until now, it has been difficult for scientists at universities and research institutes who wish to conduct research on approved GMOs to obtain access to material from the GMO manufacturers.[100,101] In order to access the material, the researchers must as a rule sign a contract with the GMO company entitling the company to read through articles prior to publication, and possibly to veto their publication. GMOs are often patented, which means that other persons must have a licence from the patent holder to do research on the material. Some patents prevent anyone other than the seed company from conducting research on HR crops. In other cases, contracts prohibit seed buyers from giving seed away for research purposes or researching the seed themselves.

4.8 Free choice of agricultural system in the future

An important question with regard to farmers' freedom of choice is whether a farmer who cultivates genetically modified crops will in future be able to choose other methods of cultivation. Toxic residues of herbicides or seed from volunteer HR plants that survive and re-emerge as weeds in subsequent crops may make this difficult. Oilseed rape seed, for instance, can germinate after several years in the soil.[102] For farmers wishing to switch to organic farming, the possible presence of herbicide residues in the soil may be a problem. It may also be difficult to start cultivating GMO-free crops after several years of HR crops if the farmers are bound by contracts (see chapter 4.3.2.).

5 Questions for the Norwegian authorities

Not all the questions related to the import and cultivation of HR crops should have to be answered by applicants seeking approval of such crops. Some questions are more the responsibility of the authorities in Norway and/or the country of cultivation. The Norwegian authorities must also be the ones to assess the consequences of approving a large number of GMOs. We have therefore compiled a separate list of questions that should be answered by the Norwegian authorities before they decide whether or not to approve a GMO application. These questions should be asked in connection with applications for both the cultivation and import of HR crops to Norway. When the application concerns authorisation of cultivation, the term "country of cultivation" refers to Norway, and when the application concerns import, the term refers to the countries in which the HR crop is to be cultivated. Some of the questions should be posed to both the applicant and the authorities, either because both of them should be responsible for these questions, or because the applicant and the authorities are responsible for different aspects of the issues concerned.

5.1 Freedom of choice for consumers in Norway

To ensure that consumers have freedom of choice, it is important that they be able to choose the food that they prefer. Besides sufficient, safe and healthy food, the right to food as a fundamental human right also encompasses the right of being able to choose culturally acceptable food. Consumers also have a right to be able to make informed choices. If food made from HR crops is approved in Norway, consumers must also be able to choose food that does not contain ingredients from HR crops. Furthermore, they should be able to choose between food from HR crops and equivalent non-GM products. The selection of foods from which consumers are able to choose is a food policy issue for which national authorities, and not individual companies, should assume responsibility.

Labelling raw materials and food products helps to ensure consumers' freedom of choice in Norway. At present, the rule is that all foods containing more than 0.9 per cent material from genetically modified organisms must be labelled accordingly. The end product sold in stores must be labelled, so that the information reaches consumers. For the time being, no food or feed products containing GMOs have been approved for use in Norway.

5.2 Ecological, economic and social consequences in Norway in the short term (less than 5 years) and the long term (over 20 years)

The cultivation of HR crops in Norway and the import of HR crops may both have ecological, economic and social consequences in this country in the short term (less than 5 years) and the long term (over 20 years). The agronomic conditions to which the HR crop is adapted and the measures planned to prevent resistant weeds are only relevant for applications to cultivate HR crops in Norway. Economic consequences of changes in ecosystem functions, economic gains in value chains, consequences for Norwegian food production jobs, Norwegian food policy and the Norwegian people's views on GMOs are relevant in connection with applications both to cultivate and to import HR crops.

5.2.1 Agronomic conditions in Norway

The HR crops that are now on the market are primarily soybean, maize, oilseed rape and cotton. Of these crops, only oilseed rape and feed maize (non-genetically modified) are cultivated commercially in Norway. Soybean and cotton are not cultivated in Norway at all. It is possible that future benefits may arise if farmers who currently use herbicide to eliminate weeds are able to cultivate HR crops of plants such as wheat, rye, oats and potatoes.

Differences in agronomic conditions largely determine which crops are suitable for cultivation in various places (see chapter 4.3.4). If an application is submitted for approval of cultivation of an HR crop in Norway, the Norwegian authorities should first ask themselves whether this crop is adapted to Norwegian agronomic conditions, or whether it is relevant for Norway. If the HR crop is not suitable for cultivation here or is resistant to a herbicide that is prohibited in Norway, it cannot be considered to be of particular societal benefit. In such case there will be less willingness to accept potential disadvantages or risks that the crop may present.

It is important to label genetically modified food in order to give consumers freedom of choice. Photo: Yay Images

A question related to Norwegian agronomic conditions is whether it is possible for genetically modified and non-genetically modified crops to co-exist (see chapters 4.4.2, 5.3.4 and 5.3.5). This is of particular relevance because there is no widespread, large-scale agriculture in Norway except in certain areas of Hedmark, Akershus, Østfold and Vestfold counties. If a farmer wishes to cultivate HR crops, he will therefore find it a challenge to ensure that they are grown at a sufficient distance from neighbouring fields.

The question regarding agronomic conditions only applies to applications for cultivation of HR crops in Norway.

5.2.2 Measures to counter resistant weeds in Norway

Cultivation of HR crops has revealed a risk that weeds may become resistant to the herbicide to which the HR crops are resistant, and which is to be used in conjunction with the HR crops (see chapter 3.2.3). If an HR crop is to be grown in Norway, measures must therefore be implemented to prevent weeds from becoming resistant.

The question concerning measures to avoid development of resistant weeds only applies to applications for cultivation of HR crops in Norway.

5.2.3 Economic consequences of changes in ecosystem functions in Norway

The cultivation of HR crops in Norway may give rise to changes in ecosystem functions that may have positive or negative economic consequences (see chapter 4.4.6). Ecosystem functions are the interplay between structure and processes in an ecosystem, i.e. what takes place in the ecosystem.[103,104] Such changes may, for instance, be a result of changes in the herbicide regime.

Ecosystem functions may also be affected if we import HR crops or products deriving from such crops to Norway. One example of such an effect is the undesirable spread of genetic material from HR crops to wild relatives of cultivated plants or to weeds. The risk of the gene for herbicide resistance spreading to weeds like wild turnip (*Brassica rapa*) is one of the reasons why the Norwegian authorities have not approved the import of HR oilseed rape.

The unwanted spread of genes is a factor that is particularly important to take into account in centres of origin and centres of crop diversity (see chapter 4.6.1). Norway is not a centre of origin nor a centre of diversity for the crops of which herbicide-resistant varieties are cultivated today, so this factor has no relevance in Norway.

Changes in the ecosystem may also make an area more or less attractive for tourism. This will in turn affect the economy of tourism-based industries.

5.2.4 Economic gains in the value chain in Norway

With regard to the import of HR crops, soybean and maize are currently of particular relevance for Norway, for use in feed and other products. Denofa, the main importer of soybeans to Norway, has pointed out that Norway currently pays a high premium to make sure that no GMOs are imported to the country. If Norway continues to pursue a restrictive GMO policy, and it becomes more difficult to obtain GMO-free maize and soybean, this policy may have economic repercussions for the agricultural sector and the aquaculture industry in addition to other social consequences.

5.2.5 Food production jobs in Norway

The import or cultivation of HR crops may change the employment situation in industries associated with food production in Norway. This applies to both overall employment and the breakdown of employment by industry. As in other countries, the question of whether potential changes are to be considered positive or negative is a policy issue. The authorities must assess employment in relation to the goals they have set for social development in Norway (see also chapter 4.4.3.)

5.2.6 Food policy in Norway

The four overall goals for Norwegian agriculture and food policy are food security, maintaining agricultural operations across Norway, increased value creation and sustainable agriculture.[105] The Norwegian authorities should consider whether the cultivation and import of HR crops are compatible with these objectives.

5.2.7 The Norwegian people's views on GMOs

A decision to approve or reject an application for approval of an HR crop should be aligned with the views of the Norwegian people on such crops. There is little demand for genetically modified food and feed in Norway. The fish feed industry would like to have the opportunity to use feed made from certain genetically modified plants if it is impossible to obtain GMO-free feed. Otherwise, 18 organisations, including agricultural interest groups, have joined the Network for GMO-Free Food and Feed, which is a proponent of Norway maintaining its restrictive practice with regard to GMOs.

In questionnaire surveys, over half of the respondents took a negative view of genetically modified food in Norway.[106,107] Labelling genetically modified food and feed will enable consumers to choose for themselves whether they wish to buy food made from HR crops or not. However, labelling will not be sufficient for those who consider that HR crops contribute negatively to sustainable development and therefore wish to prohibit them.

5.3 Plant genetic resources for food and agriculture

Preserving genetic diversity in cultivated plants, the plant genetic resources, is crucial to future food security and thus for sustainable development (see chapter 4.6). Questions that should be answered by the Norwegian authorities under this topic concern the selection of seed available, monocultures, the possibility of further plant breeding, co-existence rules (rules governing ways in which GMOs and non-GMOs can be cultivated side by side) and systems for keeping GMOs separate from non-GMOs in the production line (see chapters 5.3.1 to 5.3.5).

Questions that should be answered by applicants concern centres of origin and centres of crop diversity, wild relatives of the HR crop, possibilities of further plant breeding and the right to seed. These questions are discussed in chapters 4.3.5 and 4.6.

Genetic diversity in maize. From Spain. Photo: Audrun Utskarpen

5.3.1 A wide selection of seed

The genetic diversity in cultivated plants and in their wild relatives is the basis for further plant breeding. Consequently, it is important to maintain this diversity by cultivating as many varieties as possible, an objective that is easier to achieve the greater the number of commercially attractive varieties that are available, and the larger the heterogeneity among them. In many places, local varieties of seed are stored in seed banks, but this is no substitute for continuous use and breeding.

Genetic diversity in cultivated plants is now endangered due to the use of a small number of genetically homogenous varieties. If an HR crop has the effect of reinforcing this trend, it is not a contribution to sustainable development. Sustainability is promoted, on the other hand, when farmers have access to a wide selection of seed and the freedom to choose the seed they prefer, whether hybrids or local varieties, purchased seed or seed from their own or their neighbour's harvest. It is the government authorities, and not applicants seeking approval of a GMO, who must adopt a policy that secures the availability of a wide selection of seed.

In the past few decades, a steadily dwindling number of companies have accounted for a growing proportion of trade in seed. In 2009, for example, four multinational seed companies controlled around 60 per cent of the global trade in vegetable seed.[108] The more one company dominates the market, the more it becomes possible for the company to determine which seeds are to be available on the market and at which price. A study of the seed situation in four EU countries shows that there are now fewer varieties to choose between in countries that grow GMOs.[109]

Two types of legislation in particular have intensified market concentration and weakened the rights of farmers: intellectual property rights (patents and plant breeding rights) and seed laws (laws governing approval of plant varieties and the sale of seed).[110]

Patent protection for living organisms has been strengthened and expanded in the past few decades. Patents often make it illegal or expensive for farmers to save, exchange or sell seed from their own harvests, and may also prevent the commercialisation of new varieties even when breeding is allowed (see also chapters 4.3.5 and 4.6.3). At the same time, it is easier to meet patent criteria and control breaches of the patent for a genetically modified plant than for other plants. Thus, there has been a mutually reinforcing effect between patent practice and gene technology that has promoted market concentration. This trend may be highly determinant for future choices in the field of food and nutrition, not only for farmers but for society as a whole.

In the EU in particular, seed laws have restricted the use of a diversity of plant varieties.[111] Criteria have been set requiring that a variety must be distinct from other varieties, uniform and stable (the DUS criteria). Traditional varieties often do not meet these criteria. They are likely to be more genetically diverse and often not pure varieties. The EU is now in the process of revising its seed laws and regulations.

Not only the production but also the marketing of seed may be subject to a monopoly if there is little competition. If the number of manufacturers and sellers is reduced in the future, farmers will have fewer alternatives and may be compelled to buy HR crops simply because there is no other seed available on the market.[112] Another possible scenario is that the farmer may not be able to afford to buy alternative seed if it becomes more expensive because it is difficult to obtain, or because it must be guaranteed to be GMO-free. A seed company may also refrain from placing their products on the market in countries where their market share is so small that it will not be profitable.

5.3.2 Monocultures

In many cases, monocultures in agriculture pose a threat to biological diversity. This is a general problem in connection with large-scale agriculture and does not apply to HR crops in particular. But if HR crops reinforce a cultivation practice based on monocultures, this effect is detrimental and does not promote sustainable development. Norwegian authorities should therefore find out whether measures have been taken to mitigate the negative consequences of monocultures where the HR crop is to be cultivated.

5.3.3 Possibility of further plant breeding

The question of whether the HR crop is available for further plant breeding (see chapter 4.6.3) should be posed to both applicants and the Norwegian authorities. The applicants control their own crops. But the authorities in the individual countries have the overall responsibility for pursuing a policy that ensures that farmers and breeders alike have access to sufficient varied plant material to be able to develop new varieties in the future.

5.3.4 Rules for co-existence

To ensure that it is possible to choose to continue to cultivate non-genetically modified crops, including organic crops, there must be rules governing the way in which GMOs and non-GMOs can be cultivated in the same area, i.e. co-existence (see chapter 4.4.2). The question is relevant in connection both with cultivation of HR crops in Norway and with applications to import HR crops (in which case it applies to the country of cultivation). If the GMO is to be cultivated in Norway, rules for co-existence must be in place *before* the application is approved. In Norway, there may be special challenges relating to co-existence because we have little large-scale agriculture (see chapter 5.2.1).

5.3.5 System for keeping GMOs separate from non-GMOs

To prevent products from a genetically modified crop polluting GMO-free products, it is also important that a system be established to keep GMOs separate from non-GMOs in production and transport lines (see chapter 4.4.2). When an application is submitted to import an HR crop or products from such a crop, such a system should be in place both in the cultivation area and after the HR crop or a product from the HR crop arrives in Norway.

5.4 Independent risk research

The question of whether the HR crop is available for independent risk research (see chapter 4.7) should be posed to both the applicants and the Norwegian authorities. Producers of HR crops may make them available for research. But it is the responsibility of the authorities to adopt a regulatory framework and a policy that makes it possible to engage in independent risk research.

5.5 The consequences of approving many GMOs

The consequences of approving many GMOs may differ from those of approving just a few. Approval of a single genetically modified plant variety will rarely generate effects such as making it difficult to switch to other agricultural systems in the future, for example organic agriculture or agriculture that does not involve the use of GMOs. Nor will approval of a single genetically modified plant variety lead to monopolisation of the seed sector and a more limited selection of seed. These examples show the weakness of this type of evaluation form: it is easy to adopt a reductionist approach. It may thus be acceptable to say yes to most points and thereby obtain approval for a single genetically modified plant variety, while the sum effect of many individual decisions, i.e. approval of many types of genetically modified plant varieties, may not be consistent with the society to which we aspire.

Another example that shows the importance attached by the authorities to the aggregate effect on nature may be found in section 10 of the Nature Diversity Act. Under this provision, the effect on an ecosystem shall be assessed on the basis of the total burden to which the ecosystem is or will be subjected.

Whether several HR crops in sum contribute to sustainable development, or whether approval of an application is consistent with Norway's agriculture policy objectives, are questions that should be answered by the Norwegian authorities.

5.6 Norway's North-South policy, efforts to promote biodiversity and international role

Norway has a high international profile in areas such as environment, agriculture and regional development policy. Many countries, especially developing countries, see Norway as an example to be followed. It is therefore relevant to ask whether our decision to approve or refrain from approving a GMO helps to achieve the political goals defined in Norway's North-South policy and advances our efforts to promote biodiversity, and what kind of example we set for other countries.

Report No. 15 to the Storting [Norwegian parliament] (2008–2009): Interests, responsibilities, opportunities, a white paper on Norwegian foreign policy, makes the following comment on global environmental efforts: "In the Government's view, it is essential to continue efforts to improve multilateral environmental agreements and make them more stringent, and Norway must continue to play an active role in advocating new and more extensive commitments".[113] Particular mention is made of the UN Convention on Biological Diversity and its Cartagena Protocol, the UN Convention on Climate Change and the treaties relating to chemicals as being of importance for this work. The report also states that "Norway can seek compromise [...] as exemplified by work on rights to the use of genetic resources and patenting of genetic resources under the Cartagena Protocol on Biosafety".[114]

Norway also has other international obligations, such as the EEA Agreement and the treaties under the World Trade Organisation (WTO). It could create a dilemma if Norway adopts national rules that impose different conditions on Norwegian industry than those applicable to industry in other countries, thereby rendering Norwegian industry less competitive should Norway not gain international acceptance for its rules.

5.7 Prioritising the most important issues

The Biotechnology Advisory Board underscores the importance of seeing all sustainability issues in an overall context. However, there may be certain questions that are particularly important. Drawing up a list of priority questions may make it easier to make a decision on an application, while also making it more feasible for an applicant to answer questions and for the authorities to assess whether the HR crop contributes to sustainable development.

To determine which questions and issues should be given priority, emphasis should be placed on whether the cultivation and breeding of the HR crop or products from the HR crop may have serious undesirable effects on human or animal health, plants, the environment and society at large. This applies in both the short and the long term. Undesirable effects are defined here as not just direct, adverse effects on (the health of) certain organisms, but also ecological effects such as changes in habitat or in the relationships between organisms in and around the area of cultivation. Account must also be taken of changes in agricultural systems and changes for consumers.

Adverse effects that are irreversible are particularly serious. Possible examples of such effects are: harm to endangered animal species; cultivation of the HR crop hindering conversion to other agricultural systems in the future; or alternative seed varieties no longer being available.

6 How to decide on an application?

When assessing whether an HR crop contributes to sustainable development, there is little doubt that different groups in society will rank the priority of the various questions differently. It is important to bear in mind that those who incur (the potential) costs will, as a rule, not be those who reap the greatest benefits of the use of HR crops. The answers to many questions will probably also differ from one region to another and from one country to another, because it is also a question of the balance of power in society. In order to assess the usefulness of genetically modified plants in relation to the various types of costs arising from their use, it is therefore reasonable to view all drawbacks and benefits in an overall context, to ensure that nothing is given lower priority at the outset.

A case-by-case assessment is important because a question may be given great weight in one case and less in another. Case-by-case assessments must be supplemented by continuous overall assessment, to ensure that the total effect of individual decisions does not counteract our societal goals. The decision must also be weighed against other instruments for implementing the policy that has been adopted.

The consequences that approval of an HR crop will have for health and the environment must also be considered in the context of sustainable development, in which case the perspective is global and longer term than the perspective in traditional health and environmental risk assessments. The precautionary principle is one of several principles encompassed by the concept of sustainable development. This principle is applicable if it has been documented that there is uncertainty regarding our scientific understanding of adverse health and environmental effects. The Biotechnology Advisory Board has recommended that it should not be applied in order to allow uncertainty concerning negative social impacts to be decisive in assessment of an application.[115] This is because the precautionary principle has been defined very precisely in connection with health and environmental issues, and it is important to prevent the principle from becoming diluted.

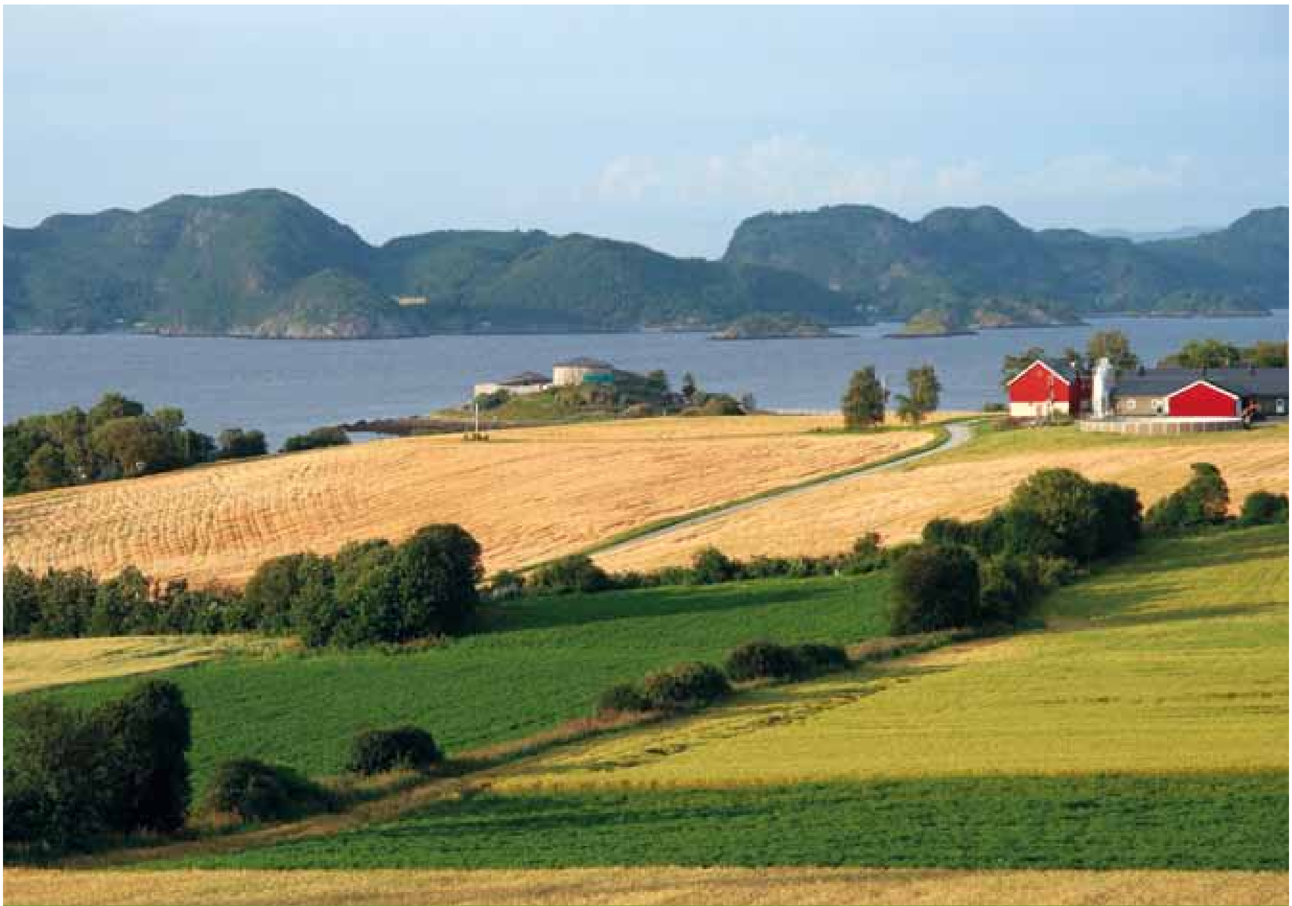
If an HR crop has no special advantages or disadvantages compared with non-genetically modified crops in terms of economic and social parameters, and does not entail any environmental, ecological or health risk, it may be assessed as neutral and not negative. If, on the other hand, the HR crop offers certain benefits in terms of economic and social parameters, this can count as a positive factor, without such benefits being requirements that *must* be met. If we are to accept greater risk or approve an application despite our lack of understanding, the HR crop must have clear benefits that can be said to offset its drawbacks.

Although all the questions must be seen in an overall context, it may be easier to decide an application if some questions are defined as particularly important (see chapter 5.7). If certain questions are to be given priority, weight should be attached to whether the cultivation and breeding of the HR crop or products from the HR crop may be harmful to plants, animals, humans or ecosystems in the short or the long term. Particular importance should be attached to irreversible adverse effects.

The Biotechnology Advisory Board is of the opinion that the following factors are particularly important in determining whether an HR crop may be said to contribute to sustainable development (the factors are not ranked in order of importance):

Environment/ecology:

- whether cultivation or use of the HR crop might be harmful to non-target organisms, especially pollinators (see questions 4 and 7a)
- whether unexpected additive or synergistic effects might occur when more than one herbicide is used in the same area (see question 7f)
- whether cultivation of the HR crop may lead to more resistant weeds, and whether measures have been taken to prevent this effect (see question 8)
- whether the HR crop is easily dispersed in the form of seed or pollen (see question 3)
- whether the HR crop contains a gene for resistance to antibiotics (see questions 1e and 3b)



Norwegian landscape: the Trondheim Fjord. Photo: Scanstockphoto

Economy and society:

- whether the herbicide to which the plant is resistant is prohibited in Norway because it poses a risk to health or the environment, and the herbicide has the same effects in the country of cultivation as in Norway (see questions 5a and 5b)
- whether the herbicide is prohibited or to be phased out under international treaties (see question 5c)
- whether there are long-term effects on the health of farmers (see question 3.1a)
- whether farmers receive training and protective equipment for use of the herbicide (see question 3.1b)
- whether the democratic rights of other farmers are violated, i.e. whether there are rules governing co-existence (how GMOs and non-GMOs may be cultivated in the same area) and compensation for unwanted gene dispersal (see questions 4.2a and 4.2c)
- whether the plant is available for independent risk research (see question 7)
- whether the plant is available for further plant breeding (see question 6c)
- whether farmers will be free to choose cultivation systems (conventional, organic or GMO) in the future (see question 8)

Employment, ownership rights and the economy of the country of cultivation, whether the HR crop is to be grown in Norway or elsewhere, are among the questions that should be given lowest priority.

Some consequences may be so serious that the answer to one single question should constitute grounds for rejecting the application. Cases in which this must be considered are when

- the HR crop contains a gene or genes for resistance to antibiotics (see questions 1e and 3b, environment/ecology)
- the plant is not available for independent risk research (see question 7, economy and society, and question 4, questions for the Norwegian authorities)
- the herbicide to which the plant is resistant is prohibited in Norway because it poses a risk to health and the environment, and the herbicide has the same effects in the country of cultivation as in Norway (see questions 5a and 5b, economy and society)
- it has been decided in international treaties that the herbicide to which the plant is resistant should be prohibited (see question 5c, economy and society)

The questions as to whether approval of a GMO application is compatible with the political objectives of Norway's North-South policy, the political objectives for protection of biodiversity and Norway's role as a leading example and bridge-builder, as well as with its food policy objectives, make it possible to carry out a more holistic assessment of the sum effects of individual decisions: what direction do we want to take, and what will be the overall effect of individual decisions regarding genetically modified plants on our objectives in areas such as nutrition, food and regional development policy? These questions should also be seen in conjunction with the question of whether the HR crop prevents conversion to other agricultural systems in the future. It is the sum total of the answers to these questions that determines whether a decision supports Norway's policy objectives.

Possible approaches to assessing whether genetically modified crops contribute to sustainable development

There are several possible approaches to assessing whether genetically modified plants contribute to sustainable development. One option is to draw up checklists with criteria or parameters that must be measured to determine whether a GMO can be approved. Using international treaties which contain a sustainable development requirement may be another alternative. A third method may be to require that the GMO is certified under international certification schemes.

At present, there are no treaties on the sustainable use of GMOs. Nor are there any certification schemes, either Norwegian or international, for trade in genetically modified crops. However, the treaties and certification schemes already in use could be used as a starting point for designing national assessment systems.

International treaties may be used in two ways: either to require that GMO producer countries meet the conditions set out in international treaties in order for a GMO to be approved, or as a source of inspiration to establish Norwegian requirements. The UN Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture (the Plant Treaty of the Food and Agriculture Organization of the United Nations (FAO)) are examples of international treaties that are founded on the principle of sustainable development. In the socio-economic area, there are treaties such as the ILO's Worst Forms of Child Labour Convention.

There are several hundred certification schemes for organic food and feed in the world. In addition, there are a number of certification schemes for ordinary food. Codex Alimentarius, which was established by FAO and the World Health Organisation (WHO), is a set of food safety standards and guidelines.[116] GLOBALG.A.P. is another standard, developed by the meat industry.[117] For the past few years, the Codex Alimentarius Commission has been engaged in establishing a certification scheme for the production of food from genetically modified organisms, but has not yet completed this work. The process of following up the Cartagena Protocol on Biosafety to the UN Convention on Biological Diversity may also provide a basis for future GMO certification schemes.

FAO is also drawing up guidelines for assessing whether food production and agricultural systems are sustainable.[118] The organisation has presented guidelines containing methods and indicators for measuring whether production is sustainable, and several institutions have carried out pilot studies. The guidelines may be used to assess entire value chains, including production, processing and sales, whether production is conventional (not organic nor GMO), organic or based on genetically modified organisms. This work could also be used as a starting point for Norway's own assessment systems, and may prove to be useful for a potential future GMO certification scheme.

The Norwegian sustainability indicators and GMOs

In connection with the follow-up of the work of the Brundtland Commission, each country undertook through Agenda 21 to establish national sustainability indicators.[119] These indicators are intended to measure the state of sustainability within national borders.

After conducting an official study, Norway established its set of indicators in 2005.[120] This set has subsequently been changed slightly, and currently contains the following indicators:[121]

(1) Norwegian official development assistance
(2) Total imports from developing countries
(3) Norwegian emissions of greenhouse gases
(4) Emissions of NO_x, NH_3, SO_2 and NMVOC
(5) Nature index for open sea and coastal waters
(6) Nature index for terrestrial ecosystems
(7) Standards of maintenance for protected buildings
(8) Total energy use per unit of GDP
(9) Spawning stock for selected fish species
(10) Irreversible loss of biologically productive areas
(11) Potential exposure to substances harmful to health and the environment
(12) Net national income per capita by sources of income
(13) Trends in income distribution
(14) Generational accounts
(15) Level of educational attainment
(16) Disability pensioners and long-term unemployed as a percentage of the population
(17) Life expectancy

A possible approach to assessing whether a genetically modified organism contributes to sustainable development is to examine the various indicators in relation to the GMO in question. Several of the indicators may be relevant: (2) Total imports from developing countries, (6) Nature index for land ecosystems, (11) Potential exposure to substances harmful to health and the environment and (12) Net national income per capita by sources of income (this is relevant if the GMO increases profitability in one or more industries).

Calculation of the Norwegian indicators
Statistics Norway is responsible for calculating the indicators according to a specific system and for publishing an annual report.[122] The concept of sustainable development may be interpreted as meaning that consumption measured per inhabitant in a given year must not exceed a level that makes it possible to choose the same consumption per inhabitant in all subsequent years.[123] This is contingent on the resource base being maintained.

The resource base encompasses both resources that are measurable based on their economic value, and resources that must be measured on the basis of physical values. The rationale is that as long as each country conserves its resource base, the global resource base will also be conserved. All the resources to which a cash value can be assigned are included in the national wealth. This means manpower, human capital, machinery and other capital equipment, financial capital, agriculture, forestry, aquaculture, fishing of natural stocks, wind- and water-based power resources, oil and gas reserves and mineral reserves.

To achieve sustainable development, efforts must be focused on keeping national wealth constant or increasing it. Due to population growth, and the fact that we are consuming a growing proportion of our oil and gas resources, national wealth per capita is decreasing. To counteract this trend, part of the revenues from oil and gas resources must be invested in other types of capital, such as human capital (the population's knowledge and skills). Another solution is to improve management of renewable resources, i.e. agriculture, forestry, fishing and wind- and water-based power resources.

A question that is relevant to ask in connection with GMOs is whether they can increase the value of some of the renewable resources.[124] This could occur, for example, if the revenues from farming are greater than before once the cost of input factors is deducted.

Many resources, such as biological diversity, drinking water and clean air, are not included in national wealth because it is extremely difficult to measure the cash value of services that are not traded on a market. This has two unfortunate consequences. First, it results in the undervaluation of national wealth. Second, negative changes may appear to be positive, and vice versa. For instance, national wealth may increase as a result of rationalisation of agriculture, which increases the value of this sector. However, the rationalisation process may have reduced ecosystem services by reducing biological diversity. Because such changes are not registered as a market transaction, they will not be included in Statistics Norway's calculations.

FACT BOX

Herbicides – active ingredients

Glyphosate

Glyphosate acts by binding to, and accordingly inhibiting, the enzyme EPSPS (5-enolpyruvoylshikimate-3-phosphate-synthetase). EPSPS acts as a catalyst for the formation of aromatic amino acids. When EPSPS no longer functions, these amino acids are not formed, and the plants die.

Glyphosate-resistant plants are the most widely cultivated genetically modified plants in the world. The most usual way to create these plants is to insert the gene that codes for the EPSPS protein in the CP4 strain of the soil bacterium *Agrobacterium*. This version of EPSPS is called CP4 EPSPS. CP4 EPSPS binds glyphosate in a manner that does not inhibit the formation of amino acids (see also chapter 3.1.1.1.1). As a result, the glyphosate is de-activated, and the formation of amino acids takes place as before. There are also examples of plants into which a gene has been inserted that codes for the enzyme GOX (glyphosate oxidoreductase), which breaks down glyphosate.

The most common glyphosate products on the market contain glyphosate salts that ensure that the substance is highly water-soluble to make it as effective as possible. The most common are isopropylamine salts.

Glyphosate, which is best known under the brand name Roundup, is the most widely used herbicide in the world. Its use is also permitted in Norway in many connections: in agriculture, along railway lines and roads, and in private gardens.

Glufosinate ammonium

Glufosinate ammonium (short form: glufosinate) inhibits the plant enzyme glutamine synthetase. Glutamine synthetase catalyses the formation of glutamine from glutamate and ammonium. When glutamine synthetase becomes inactive, the plant no longer makes glutamine, and ammonium accumulates. This prevents photosynthesis, and the plant dies.

Glufosinate-resistant genetically modified plants are already being cultivated. The gene for the enzyme PAT or the enzyme BAR is inserted into these plants. These enzymes break down glufosinate ammonium.

Glufosinate ammonium is best known under brand names such as Finale and Basta. Herbicides containing glufosinate ammonium are no longer permitted for any area of use in Norway, and are being phased out in the EU.

Dicamba

Dicamba (3,6-dichloro-2-methoxybenzoic acid) and 2,4-D (see below) belong to a family of herbicides that simulate the effects of the plant hormone auxin, a hormone that affects plant growth. These herbicides cause much more DNA, RNA and protein to be produced, particularly in the growth zones of the plant. This in turn affects cell division, with the result that the fluid-transporting channels break down and the leaves wither. Dicamba is absorbed through leaves and roots and then disseminates through the whole plant. The herbicide is toxic to dicotyledons, but has little effect on monocotyledon cereal plants and grasses.

Monsanto plans to market a type of soybean that is resistant to both dicamba and glyphosate from 2014. They have inserted a gene from the soil bacterium *Streptophomonas maltophila*, which causes the soybean plant to make a protein that breaks down dicamba into components that should not harm the plant.

Dicamba has been approved for use in grass fields and cereals in Norway under the product name Banvel.

2,4-D

2,4-D (2,4-dichlorophenoxyacetic acid) is similar in structure and mechanisms to dicamba. Like dicamba, 2,4-D mimics the effects of the plant hormone auxin, and affects cell division so that the leaves wither.

In 2010, Dow Agro-Sciences completed the development of genetically modified maize, soybean and cotton that were resistant to 2,4-D. As of November 2013, however, the plants had not yet been approved for cultivation in any countries. The company has inserted a gene from the soil bacterium *Ralstonia eutropha* into the plants. The gene codes for an enzyme that breaks down the herbicide into components that should not harm the plants. The gene was obtained from resistant soil bacteria in areas where 2,4-D had been used.

2,4-D is approved for certain areas of use in the EU, but has been prohibited in Norway since 1997 as a hazard to health and the environment.

The AOPP group

The AOPP, or APP group (aryloxy phenoxy propionate) is a group of herbicides that inhibit the enzyme acetyl CoA carboxylase, which plays an important part in the synthesis of fatty acids. The genetically modified soybean that has been made resistant to 2,4-D is also resistant to some herbicides in this group.

Isoxaflutole

Isoxaflutole belongs to a group of herbicides that inhibit HPPD, an enzyme that is important, among other things, for producing tocopherol and plastoquinone in plants. Plastoquinone is important for photosynthesis, and without it leaves bleach and the plants die.

A variety of soybean from Monsanto that is resistant to isoxaflutole was approved in the USA in 2013. This soybean contains an inserted gene that codes for a bacterial version of HPPD from *Pseudomonas fluorescence* that is not inhibited by isoxaflutole. An amino acid has been altered from the version produced by the bacterium, with the result that the plant tolerates the herbicide even better.

Isoxaflutole has long been approved in the USA for limited use on maize. Isoxaflutole has been approved for some areas of use in the EU, but has not yet been assessed in Norway.

Imidazolinone

The herbicides in the imidazolinone family inhibit the enzyme AHAS (ALS). This enzyme is necessary to the formation of branched chain amino acids, and without AHAS plants die.

Bayer CropScience has applied for approval for a type of soybean that tolerates herbicides in the imidazolinone family. This soybean contains an inserted modified gene for AHAS from thale cress (*Arabidopsis thaliana*). This version of AHAS is resistant to the imidazolinone herbicides. Pioneer Hibred has also developed soybean and maize that tolerate this type of herbicide.

Some imidazolinone herbicides have been approved for certain areas of use in the EU, but not in Norway.

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