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To the State Secretary of Housing
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DATUM	July 6 2006
KENMERK	CGM/00607-03
ONDERWERP	Report Ethical and societal aspects of cisgenesis

Dear Mr. Van Geel,

COGEM has drawn up previously a technical-scientific advisory report on cisgenesis. In this report, which I hereby present to you, COGEM more closely addresses the ethical and societal aspects associated with cisgenesis.

Summary:
The societal debate on the application of genetic modification in agriculture has contributed to stimulating new developments in biotechnology. Cisgenesis is one example. In cisgenesis a plant is modified with coding DNA sequences derived from the species itself or from crossable species. With the term “cisgenic” it is indicated that one does not exceed the boundary of crossable species, meaning that the cisgenic end-product only contains genes that could also be crossed in via classic breeding. By keeping within the crossing boundaries one hopes to remove specific ethical objections as well as objections based on safety concerns. In an earlier technical-scientific advisory report, COGEM has mapped the risks of cisgenic crops for human beings and the environment. Based on this inventory, possible options for relaxing the regulation in the case of cisgenic crops were discussed.
In this report, COGEM addresses ethical and societal aspects of cisgenesis. If certain conditions are met, COGEM believes there are concrete possibilities in relation to cisgenesis for a simplified authorization procedure in restricted use and market introductions. COGEM does not expect, however, that cisgenesis will automatically be considered an acceptable form of genetic modification by all parties. Such acceptance will depend on the views those involved have on general normative issues such as the integrity of nature and the application of biotechnology in agriculture and food production, as well as on how the technique is developed and presented to society. It is also unknown how citizens and consumers in the Netherlands will actually perceive cisgenesis. In the development and implementation of regulation pertaining to cisgenesis COGEM recommends the use of interactive methods of policy design, whereby the various interested parties can articulate their views.
Because authorization involving release into the environment of GM crops takes place at the European level, possible exemption or relaxation of the regulation for cisgenesis will have to be supported by all member states. COGEM therefore advises the Ministry of VROM in this respect to start off on a national trajectory that runs parallel to the European trajectory.

Enclosed in this letter you will find a copy of the complete advisory report.

Yours sincerely,

Prof.dr.ir. Bastiaan Zoeteman

Chariman COGEM

c.c. Dr. C.P. Veerman, Minister of Agriculture, Nature and Food Quality
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Ethical and societal aspects of cisgenesis

CGM/060706-03

The Netherlands Commission on Genetic Modification (COGEM)

COGEM advices the government on the potential risks of genetically modified organisms (GMOs) and informs the Government about ethical and societal issues linked to genetic modification (Environmental Management Act article 2.3).

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Summary

The societal debate on GM agriculture has contributed to stimulating new developments in biotechnology. There is ongoing interaction among the various parties involved about the possible advantages and disadvantages. One effect of this interaction is that new applications of genetic modification are being proposed that (partly) meet specific ethical and societal objections put forward in this debate. The developers of such new techniques assume that this increases the acceptance of genetic modification and economic benefits can be realized.

Cisgenesis as reaction to societal concerns about transgenesis

Cisgenesis is an example of a technique for which the developers see great potential. In cisgenesis a plant is modified with coding DNA sequences from the species itself or from crossable species. The term "cisgenic" means that one remains within the boundary of crossable species, that is, the cisgenic end-product only contains genes that could also be crossed in through conventional breeding. Cisgenesis adds no other features to crops, than can be realised by conventional breeding. The opposite is the case in other products of genetic modification referred to by the term "transgenic." In several respects cisgenic crops show similarities with conventionally crossed crops, yet the desired features, derived from the crossable relatives, are built in quickly and efficiently with the help of genetic modification.

Ethical-societal evaluation of cisgenesis

Developers predict a larger ethical and societal acceptance of cisgenesis because the boundaries of crossing are respected. By accommodating one specific aspect of critique regarding transgenesis, however, this new technique is not yet shielded from other generally applying objections put forward by opponents with respect to the transgenic technique. On the other hand, COGEM considers it to be unjustified to fully identify cisgenesis with the "traditional" transgenic technique.

Although the intervention whereby plants are modified by means of coding DNA sequences from the species itself does remove the societal objection of violating the species boundary, this technical solution itself may give rise to a renewed pro-contra debate. This may also be the effect in part of how this technique is specifically developed and presented to society.

For the above-mentioned reasons, COGEM does not expect cisgenesis to be viewed automatically as an acceptable form of genetic modification. Some adherents of a deontological

assessment of genetic engineering will accept the argument that cisgenic products are free of genes from non-crossable relatives. However, to other deontological-oriented groups in the debate on GM agriculture, such as organic agriculture, cisgenesis will be as little acceptable as other forms of genetic modification. In consequentialist argumentation the permissibility of the transgression of outcrossing boundaries is no major criterion; from this angle, the main criteria are the utility and risks of a new technique. These various considerations, which in fact are of a general nature and are being advanced as a matter of course regarding genetic modification, will still have to be articulated in the case of cisgenesis.

Societal acceptance or approval, however, does not only depend on ethical reflection. Individuals make choices based on divergent motives and interests. So far it is hardly known whether citizens and consumers in the Netherlands will be sensitive to the arguments in favor of cisgenic crops.

Preconditions for a separate status of cisgenesis in the regulation of genetically modified organisms

Developers of cisgenic crops want government to relax the rules on genetically modified organisms (GMOs) for this particular category of GM crops because the current standards for allowing GM crops are expensive and time-consuming, while in their view no environmental hazards are to be expected in the case of cisgenic crops. COGEM, in its technical-scientific advisory report, has concluded that under certain conditions there are no technical-scientific objections against a simplified authorization procedure for cisgenic plants.

Changes in the regulation and procedures regarding cisgenesis should not conflict with other Dutch regulations and policy views. In assessing the risks of the release of GM crops into the environment, the main aspects are freedom of choice for consumers and growers, welfare, health, safety and sustainability. Welfare, health, safety and sustainability are ensured through monitoring of environmental safety and food safety. Freedom of choice is a topic that regarding cisgenesis deserves special attention.

Making adjustments in the authorization procedure concerning the release of GM crops into the environment, however, is not just a Dutch matter, as European policy is involved. This equally applies to the authorization in the field of food safety. Potential policy changes, moreover, will have to comply with European-level agreements on the coexistence of various types of

agriculture, traceability and labeling, as well as with the procedural principles of good governance.

Policy options in relation to cisgenic crops

Different ways of amending the regulation pertaining to cisgenic crops are conceivable. These various ways have divergent implications for the freedom of choice of consumers and growers, as well as for traceability and labeling. Freedom of choice is understood as both the right to stay clear of something, the negative right to refuse something, and the right to be able to positively make a specific choice. In the particular case of cisgenesis, a precondition for a possible (partial) exemption of regulation is that a file has been submitted in which it is demonstrated that the GM plant involved is in fact cisgenic. Subsequently there are two options. Cisgenic products are treated no different than products of conventional growing. In this case labeling of the products, as required for other GM crops, is not needed and freedom of choice is no issue. The second option is that there is no exemption regarding the requirement to label cisgenic products, but that there is a reduced onus of proof in the authorization procedures. In the first option molecular detection is not a problem, but traceability and visual detection on the market possibly are. In the second option there are no differences with transgenic crops in terms of freedom of choice, traceability and labeling. In the table below the implications of possible versions of policies regarding various types of agricultural products – organic, conventional, cisgenic according to the two options indicated and conventionally transgenic – are put side by side.

Type product / *Consequences for policy criteria*	*File required with authorization for market*	*Label*	*Refusal and positive choice possible for growers and consumers who reject GM*	*Molecular detection possible*	*Visual detection possible*
Organic	No	Quality mark	Yes	No	Quality mark
Conventional	No	No	Yes	No	No
Cisgenic viewed as identical to conventional	Yes	No	No	Yes	No
Cisgenic viewed as separate form of transgenic	Yes	GM-label	Yes	Yes	GM-label
Transgenic	Yes	GM-label	Yes	Yes	GM-label

Conclusions

If certain conditions are met, COGEM believes there are opportunities for simplifying the authorization procedure involving cisgenic products with respect to restricted use and market introductions. However, COGEM does not expect cisgenesis to be viewed automatically as an acceptable form of genetic modification by all parties. It depends on the views those involved have on general normative issues such as the integrity of nature and the application of biotechnology in agriculture and production. Furthermore, it is not yet known which actual views citizens and consumers in the Netherlands have about cisgenesis.

In the development and implementation of regulation involving cisgenesis COGEM recommends interactive methods of policy development, whereby the various interested parties can articulate their views. In order to move beyond the model of a pro-contra debate, a participative and integrative *science-in-society* approach, rather than a *science-and-technology-for-society* approach, will potentially be most productive. COGEM feels that policy decisions on cisgenesis that take into account the public debate as a learning process will prove socially robust. COGEM advises the Dutch Ministry of Housing, Spatial Planning and the Environment (VROM) to start off on this course. In this effort, COGEM is prepared to play a role as scientific advisory

commission. Because authorization pertaining to the release of GM crops into the environment takes place at a European level, COGEM advises the Ministry of VROM to set off on a European trajectory that runs parallel with the national trajectory.

In policy changes regarding cisgenic products the government should be aware of the implications with respect to the freedom of choice of consumers and growers, traceability and labeling. One should pay attention to opportunities for Dutch business that perhaps could be raised through specific policy adjustments. One should also be aware of possible economic damage and impediments for international sales potential as a result of (possible) mixing of non-GM products with cisgenic ones. In policy changes regarding cisgenic products the government should ensure that reduced regulation does not lead to reduced confidence in the government. Accordingly, COGEM advises the government to communicate transparently about both the specific features of cisgenesis and the adopted monitoring measures in the production chain, which secures the freedom of choice for consumers and growers alike.

The Dutch and European GMO regulations do not exist in isolation, as they also depend on developments elsewhere in the world. This is why in the case of possible changes in authorization involving cisgenic crops these global aspects and the ensuing threats and opportunities will have to be taken into consideration as well.

Finally, in adaptations of the authorization procedure, making a distinction between food and non-food crops, such as ornamental plants, should be taken into consideration. The latter are exempted from assessment on food safety and are only evaluated in terms of their environmental safety based on EU Directive 2001/18. Moreover, the ethical and societal objections against them are likely to be more limited than in the case of food crops.

1. Introduction

In de last ten years the agricultural application of genetic modification has been on the rise at a global scale[1]. The main GM crops today are corn, soy, cotton and rapeseed. From the start, however, the use of genetic modification in agriculture has met with criticism in Europe. This criticism primarily applies to crops for human consumption, but also other applications, such as for feed, pharmaceutical production or industrial goals, have been subjected to critical scrutiny[2]. The public debate does not only address potential adverse effects of GM agriculture, such as risks for humans, loss of (agro)biodiversity and economic damage to small farmers; it also deals with fundamental ethical issues, such as the permissibility of genetic modification as such[3]. Conversely, this debate has also addressed successful applications of genetic engineering in agriculture in other parts of the world, with respect to both sustainability and economic aspects. Meanwhile 90 million hectares of GM crops have been planted, without this having had demonstrable negative effects on human health or biodiversity, as proponents of GM agriculture have argued.

In Europe the growing of GM crops is permitted on stringent conditions. An elaborate system of regulation and authorization guarantees the protection of citizens against possible adverse effects of genetically modified organisms (GMOs) on the environment and human health. In risk assessment, policymakers rely on the latest scientific insights, among other things through hearing technical-scientific expert commissions such as COGEM.

So far, however, these various safety guarantees do not appear to have removed the public's concerns about GM agriculture. In an earlier report COGEM has indicated that the debate on genetic engineering in agriculture not merely involves case-specific risks[4]. Underlying themes such as the desirability of certain types of agriculture and more or less articulate views of nature and what is "natural" play a role as well. Furthermore, those who participate in the debate on GM have divergent and sometimes conflicting views on this issue that are influenced by their particular interests.

This report pays attention to one specific form of genetic modification in plants, cisgenesis. Recently COGEM has issued an advisory report which maps the technical-scientific risks associated with cisgenesis as well as the options for simplified regulation based on them[5]. The document at hand addresses the ethical and social aspects of cisgenesis. It also formulates several focal points for possible new governmental policy in this field.

2. A new application of genetic engineering in agriculture: cisgenesis

The debate on GM agriculture in the Netherlands has caused scientists and companies to look for alternative applications of genetic engineering, which may have a wider basis of social support and provide market opportunities. In genetic modification of plants, techniques are explored whereby only plant genes are used – not genes from other organisms.

A special application of genetic modification that in recent years has gained attention in the Netherlands is cisgenesis[6]. In cisgenesis a plant is modified with coding DNA sequences from the species itself or by using DNA from crossable species. The term "cisgenic" is meant to emphasize that the boundary of crossable species is not transgressed, in contrast to transgenic, whereby the crop may contain foreign genes coming from, for instance from bacteria. In an international context cisgenic plants are commonly referred to as *intragenic plants*, a term that also indicates the contrast with *transgenic*[7].

Some experts argue that cisgenic plants are quite similar to traditionally cross-bred crops and that they do not come with larger risks for human beings and the environment than conventionally crossed crops. This is why they propose to fully or partly exempt cisgenesis as a technique from GMO regulation. Such exemption could apply to the labeling requirement or the environmental risk assessment[8].

In its recent technical-scientific advisory report, COGEM has mapped the possible environmental risks of cisgenic crops in comparison to traditionally bred crops. In line with the above-described European regulations, COGEM always uses traditional breeding as frame of reference in its technical-scientific risk assessments. Moreover, this advisory report also outlines the options for relaxing the regulation for both restricted use and release into the environment (field experiments and market introductions)[9].

Risk assessment of growing GM crops in the EU

The growing of GM crops in Europe, and thus in the Netherlands, is permitted on strict conditions. Before one is allowed to produce, cultivate, or grow a GM crop and place it on the European market, an authorization procedure has to be completed. Upon the introduction of GM crops, stringent requirements are imposed on their developers with respect to risk analyses, experiments, risk management, monitoring and such.

There is a distinction between consent for restricted use and consent for release into the environment, which includes field experiments and placing GM crops on the market. One aspect of experiments under restricted use is that the spread of a GMO, such as a GM plant, must be prevented. Depending on the characteristics of the plant, specific measures are to be taken.

In a release into the environment the options for countering the spread of the plant are limited. In most cases restrictive measures are lacking here. The associated risks are therefore defined alternatively. The environmental risks of a GMO are analyzed based on a comparison with the non-modified organism (the so-called baseline). COGEM uses conventional agriculture and traditional breeding practice as baseline. Effects that might occur through application of genetic modification are compared to the projected effects of traditional breeding.

The chances of spreading of the inserted gene by GM pollen or seeds are examined, as is true of the possible changes in the plant's persistence and invasiveness. Potential adverse effects of possible occurrence of the spread of the inserted genes in the environment are also considered. Potential indirect effects –on non-target organisms for example – that could lead to disturbance of food chains or ecosystems are assessed. Similarly, potential harmful effects on soil flora are taken into account in risk analyses.

To assess the above aspects, several factors are taken into consideration. For example, the features of the inserted genes are assessed, as well as their potential effects. The characteristics of the host plant and possible (wild) relative species are also considered. Likewise, the consequences of the modification technique are evaluated. With the current modification techniques it is impossible to predict where the gene of interest is inserted in the plant. Perhaps the DNA is inserted in a coding region of the genome. This may cause either disturbance of genes or fusion of two genes, resulting in the formation of new proteins that formerly did not occur in the plant. The modification may also induce mutations. All this might cause a plant to acquire new traits, to become more invasive, to obtain an altered fitness, or to cause an effect on non-target organisms or soil organisms.

In assessing potential risks the government relies on scientific experts, including the members of COGEM. Only after it is established that the risks for human beings and the environment can be deemed to be negligibly small, consent is granted on a case-by-case basis. The European governments thus offer protection, via regulation based on the precautionary principle, against potential adverse effects of GMOs for the environment and human health.

As said, the definition of a cisgenic plant is that this plant is modified with coding sequences either from the species itself or from crossable relatives. The inserted sequences are under control by own (i.e. belonging to the gene) regulation signals and they contain their own potential introns. These functional sequences should be derived entirely from a donor plant and they should not consist of multiple DNA sections. Another condition is that as a rule the inserted functional DNA sequences can be crossed in in the plant via traditional breeding techniques. Thus the plant, based on the inserted DNA, cannot obtain qualities that cannot or do not occur in the species itself or in crossable species.

If only the introduced genes are considered, cisgenic crops present no extra risks in comparison to conventionally bred crops. In the risk assessment of GM crops, however, not only the inserted functional DNA sequences are taken into consideration, but the effects of the modification technique are evaluated as well.
In natural situations the plant genome is subject to changes. In conventional breeding, moreover, many changes are introduced in the plant genome through modern techniques, such as mutagenesis and cell and tissue culture. COGEM concludes that the changes that occur in natural conditions or that are induced in conventional breeding show similarities with the changes that occur by applying cisgenesis. Because cisgenic crops only have traits that can also be obtained through traditional breeding, COGEM has no reason to assume that the environmental risks of cisgenic plants, such as going wild and increased persistence, will be larger than those of traditionally bred crops.
Furthermore, in its analysis COGEM makes a distinction between cisgenic plants with and cisgenic plants without T-DNA borders. T-DNA borders are tiny sections of DNA that have a bacterial origin and that are also built in when applying genetic modification if use has been made of *Agrobacterium tumefaciens*. They lie to the left and right of the inserted gene. When the cisgenic plant contains no T-DNA borders, COGEM is of the opinion that the risks of cisgenesis are no larger than the risks that emerge by applying conventional breeding. Based on the technical-scientifical determination of environmental risks, COGEM deems it permitted, in experiments under restricted use, to keep such cisgenic plants (after their production) in an area to which no restrictive measures are applied in accordance with the GMO guidelines. No licence would be needed for breeding these plants. For release into the environment, as described in European Directive 2001/18/EG, COGEM, in line with this reasoning, considers exemption of

these cisgenic plants a logical next step. Field experiments in the context of the environmental risk assessment would then no longer be necessary for these plants. Field experiments continue to be required for variety registration and such. If cisgenic plants are exempted, this may have implications for the labeling requirement. Below this will be discussed in more detail.

When a cisgenic plant does contain T-DNA borders, COGEM considers the technical-scientific options for less rigid regulation to be more limited. Based on the current knowledge it is not likely that cisgenic plants, as a result of the insertion of the T-DNA border, will produce a new protein with undesirable traits that is not present in traditionally bred cultivars. However, this cannot be fully excluded. Consequently, in restricted use no regulation relaxation can take place because outcrossing should be prevented. Nor would exemption from Directive 2001/18/EG be possible with these plants. Given the theoretical chance that undesirable effects occur, a full molecular characterization continues to be indispensable.

In its technical-scientific advisory report, COGEM underscored the relevance of further examination of the concerns about the problem of new proteins in relation to adverse effects such as allergenicity and toxicity. More consultation among experts, including food experts and toxicologists, might lead to an inventory of the current knowledge and of the apparent gaps in the essential knowledge needed in this area. Based on the outcome it will perhaps be possible to arrive at a further relaxation of regulation involving cisgenic plants with T-DNA.

Advocates of cisgenic genetic engineering do not only pursue reduced regulation and a shorter development time, as having both economic and ecological benefits. They also assume that it is possible to find a broader basis of public support for this specific application of genetic modification. They expect cisgenesis to trigger less ethical and social resistance than transgenesis, whereby the species boundary is potentially violated. A closer consideration of the ethical reservations regarding applications of genetic engineering in agriculture may elucidate the extent to which cisgenesis meets them indeed.

3. Ethical perspectives on genetic engineering

Applications of genetic engineering are evaluated from the perspective of two major ethical schools, deontology and consequentialism. In a deontological approach, one argues that there are certain moral principles or tenets that should not be violated in actions. The focus is on principles – not the tangible effects of action. By contrast, in consequentialism the justness of an action is assessed based on the effects to be expected from it. Consequentialism and deontology are not the only ethical approaches advanced in relation to living nature and agriculture, as notions from virtue ethics and ethics of care may also be brought up[10,11]. Consequentialism and deontology, however, are the two major ethical approaches.

Consequentialism

A consequentialist perspective will on the one hand emphasize the favorable effects of the introduction of genetic engineering in agriculture. These include reduction of chemicals in pesticides, higher and better-quality outputs of GM crops, economic (innovation) benefits, faster and more efficient insertion of the traits desired and the possibility of producing specialties such as raw materials for the pharmaceutical industry. Consequentialist-minded pleas for cisgenesis mainly emphasize that the risks of cisgenic crops are no different than those of traditional breeding because these crops are very similar to conventionally bred ones, while the advantages of genetic modification remain in place, albeit on the basis of genes from the species itself or from crossable relatives.

In the public debate on genetic engineering in agriculture, however, a consequentialist line of reasoning may also be deployed to describe dreaded effects. These comprise the unknown and irreversible effects of the introduction of GM crops on biodiversity and the health of humans and animals, but also the fear of economic decline for farmers who lose their autonomy in part (including the *farmer's privilege*). Other arguments point to the detrimental effects of large-scale growing of GM crops on e.g. the South-American tropical rainforest. Starting from a consequentialist perspective, some also refer to the consequences of the current patenting practice, which would limit the freedom of breeders and therefore would narrow the available genetic diversity in the long term. GM agriculture thus is not only useful, but also has risks. Both sides are taken into consideration in a consequentialist evaluation.

Deontology

In deontological considerations a potential balancing of advantages and disadvantages is basically not at stake. Still, in a given situation there may be conflicting principles, the pros and cons of which are weighed in order to arrive at a decision. Common deontological objections against GM agriculture and against genetic modification in general involve rejection of not only the breaching of the species boundary, the natural crossing barrier or the species identity, but also the violation of the integrity of the organism involved[12, 13, 14]. In biotechnology based on genetic modification, according to this critical view, the organism is not regarded as a whole, as having an intrinsic value of its own that is to be respected; instead, this practice is merely geared towards utility for human beings from a purely instrumental point of view[15]. A related deontological argument against genetic modification is that it is unnatural[16]. Objections against patenting are not just expressed based on consequentialist arguments; they may also be founded on deontological considerations. In this view, life is not deemed patentable because it is no invention for which humans can claim intellectual property. Life is a given of creation.[17] Finally, the oft-voiced concern that genetic engineers are playing God is also suggestive of deontological ethics.

Ethical assessment of cisgenesis

The presumption that cisgenesis would raise fewer ethical objections than transgenesis mainly applies to deontology. Proponents view cisgenesis as a plant improvement process that is more natural because modified plants are free of genetic material from non-related organisms[18]. Cisgenesis does not violate the species boundary. Indeed, some share the reasoning that therefore cisgenesis, morally speaking, is a less objectionable form of genetic modification than transgenesis[19]. However, other adherents of deontological values, such as proponents of organic or organic agriculture, view genetic modification as undesirable action vis-à-vis living nature by definition. According to the principles of organic agriculture, the integrity of living nature – animals, plants and micro-organisms – needs to be respected. Integrity constitutes the moral dimension of what for organic agriculture is the essential standard of naturalness[20]. From this point of view respect for the integrity of living nature calls for breeding techniques that remain within the domain of life, which are, in other words, the techniques geared toward the level of the plant as a whole or, potentially, the level of cells, as smallest units of organized life. Direct intervention at the DNA level, as happens in genetic modification including cisgenesis, falls outside this scope. For organic agriculture the difference between cisgenesis and transgenesis is

not relevant because in both cases the integrity of the organism is violated. For this same reason cisgenesis is not more natural than transgenesis.

The consequentialist approach fits in more closely with the implicit assumptions – the paradigm or worldview – of everyday biotechnology than the deontological approach. Some argue there is an alliance between the two, which causes the deontological approach to become marginalized[21]. In the biotechnological paradigm, deontological considerations are interpreted as private, subjective views, which do not need to be taken very seriously. Furthermore, the general economic development mindset has a consequentialist orientation. Its downside, as regularly indicated by advocates of the deontological approach, is that the gap between the public and science is widened through the denial of the seriousness of deontological objections.

Several years ago the Dutch government declared that in each decision involving the application of biotechnology it considers consequentialism to be at issue, while it believes deontology to be at issue with respect to the autonomy and dignity of human beings, as well as the intrinsic value of animals[22]. If the government deems ethical considerations regarding GM agriculture of importance, these will then be couched in a consequentialist manner. Earlier, COGEM has stated that normative views, such as integrity and naturalness, should not be pushed aside as irrelevant[23]. In line with the integral ethical-social assessment frame presented by COGEM, such deontological arguments have to be addressed in the articulation and analysis of the issues at stake, meaning that they have to be heard prior to the actual policy development stage[24]. The deontological points of view need to be taken seriousl in the very decision of prioritizing consequentialist considerations and in legitimizing this choice.

Ethical considerations, as outlined above, are based on reflection and theorizing. For actual acceptance or rejection of technological innovations, other aspects are relevant as well. The opinions of the public are not just founded on moral-theoretical notions, but on other values and interests as well. Individuals act in part on the basis of information and trust[25]. So far little is known about whether citizens and consumers in the Netherlands indeed are sensitive to arguments advanced in favor of cisgenic crops. A current research project addresses the social acceptance of apples modified with the plant's own genes[26]. Some years ago, in the context of an EU research project, it has been studied already how the Norwegian public perceives cisgenic strawberries[27]. This revealed it was deemed more acceptable to shift genes within a single species than between species, yet at the same time one continued to be skeptical about genetic modification, regardless of the origin of the genetic material.

In short, COGEM concludes that cisgenesis will not be accepted automatically as an alternative to transgenesis. It is to be expected that at least some of those who currently oppose genetic modification processes will formulate exactly the same fundamental objections against cisgenesis as against transgenesis. After all, cisgenesis, in a technical sense is, still a form of genetic modification. Consequentialist arguments will especially address the utility and the risks of the new technique. Regarding cisgenesis such considerations will still have to be articulated. Moreover, social acceptance does not only rest in ethical reflection. Individuals make choices on the basis of divergent values and interests. It is still unknown whether the public will be sensitive to the arguments in favor of cisgenic crops.

4. Focal points of an adapted authorization policy regarding cisgenic crops

Developers have asked the government to relax the regulation on cisgenic crops. They expect less social resistance and emphasize the similarity of cisgenic and traditionally bred crops. Moreover, they consider the current authorization procedure for GM crops expensive and time-consuming. They hope that at least with respect to cisgenic crops the existing procedures are rendered less rigid.

Dutch policymakers would like to capitalize on the opportunities provided by modern biotechnology. Still, the focus on risk reduction of genetic engineering continues to be a guiding policy principle with which concerns of social utility should not interfere. Some criticize this premise, however. Based on the experience gained in genetic engineering, they feel, one might as well reflect on modes of risk control. Recently, however, in relation to modern biotechnology, the State Secretary of VROM underlined the fundamental significance of keeping the application of the assessment frame of potential risks distinct from the social-political discussion[28].

The government claims it does not wish to slow down the development of biotechnology in the Netherlands unnecessarily and therefore it puts in an effort to lessen regulation of biotechnology. In its 2005 memorandum on this issue, the Ministry of VROM has described options for making GMO regulation less rigid[29]. The European GMO regulation of restricted use makes it possible at national level to exempt cisgenic plants from the authorization requirement on restricted use. In its memorandum, the Ministry proposes to study whether such exemption of restricted use authorization for cisgenic plants is justified.

In the above-mentioned memorandum, the Ministry of VROM also describes the possibility of introducing a simplified consent procedure with a much shorter time span for meeting the various requirements. This more limited procedure, enabled by progressive insight, can be used for field experiments with GM organisms about which wide experience has been gained and of which many data relevant for risk analysis have become available. Progressive insight, the Ministry claims, may result in a growing list of organisms for which the shorter procedure will do. In time, it will perhaps be possible to introduce such simplified procedure for individual cisgenic crops about which much knowledge has been gained in the context of the risk assessment.

The above-summarized conclusions on the options for lowering the pressure of regulation regarding cisgenic crops from the technical-scientific advisory report by COGEM will play a role in the policy's further development in the Netherlands. Because the authorization with respect to the release of GM crops into the environment and their placing on the market occurs at a European level, any potential form of exemption or relaxation of the regulation for cisgenesis will have to be supported by the other member states. It is recommended the Dutch government starts off the debate on this issue both domestically and in the EU context.

Generally, authorization for GM crops is not only requested in the context of environmental safety, but also in the domain of food safety. This means that EU Regulation 1829/2003 applies, which is on risk assessment of food, feed and environmental safety of GMOs or products produced with them. COGEM, given its statutory domain of environmental safety, makes no statements on the possibilities of changing the permit practice linked to food safety and feed safety. COGEM does want to put forward the possibility, however, that in adapting the authorization it be considered to make a distinction between food and non-food crops, such as ornamental crops, because for the latter only an environmental safety assessment is required based on EU Directive 2001/18. Also, the ethical and societal objections against cisgenic non-food crops are probably smaller than in the case of food crops.

Amended regulation will have to take due account of the European-level agreements on coexistence, allowing GMO agriculture to exist in harmony alongside conventional and organic agriculture. These involve traceability and labeling. Furthermore, the policy needs to comply with the European principles of good governance. The general procedural principles of good governance are: openness, participation, effectiveness, coherence, proportionality and subsidiarity[30,31].

Moreover, possible policy changes in relation to cisgenesis should not conflict with Dutch rules and policy views. In the Dutch context, the government's 2003 memorandum on "Careful and responsible assessment" indicates which specific considerations regarding aspects of content are deemed to be applicable – within the current European frames – in the assessment of GMOs' release into the environment. And this release is the main purpose of developers of cisgenic crops. These considerations are: freedom, welfare, health and safety, and sustainability[32]. The securing of the values of welfare, health, safety and sustainability is realized through environmental safety and food safety control. In this context freedom is understood as freedom of choice. On the one hand this implies the freedom of consumers and growers to be free of

matters they do not want to have around, or a negative refusal right. On the other hand, freedom of choice figures as a positive right of consumers – specifically: whether or not to purchase genetically modified products – and the freedom of farmers to grow the things they want to grow, the products they view as potentially profitable, and so on.

In adapting the regulation one will not only have to take due account of environmental safety, food safety and the wider ethical and societal embedding of genetic engineering, but also of possible economic consequences. An amended regulation will potentially strengthen the opportunities for Dutch business and its competitiveness in relation to the current situation. The prevailing non-GM agriculture and organic agriculture, however, should not be liable to suffer. Mixing of non-GM agricultural products with cisgenic ones, or only the threat thereof, could lead to more limited sales opportunities and to a weakened trade position of the chain parties involved, such as seed producers, growers, processing industry and wholesalers.

Finally, in case of policy changes regarding cisgenesis the global dimension should not be lost sight of. The Dutch and European GMO regulation, after all, has effects elsewhere in the world, as COGEM recently has stressed[33]. And developments elsewhere in turn have consequences in Europe and thus also in the Netherlands. Therefore, any effort aimed at potentially adapting the authorization procedure involving cisgenic crops will also have to take into consideration these global aspects and the ensuing opportunities and threats.

5. Effects of policy changes regarding cisgenic crops on freedom of choice, traceability and labeling

Several exemption alternatives with respect to the current policy are conceivable, which have divergent implications for the above-mentioned criteria of freedom of choice of consumers and growers, traceability and labeling. For all cases of regulation adjustment the primary criterion for exemption will have to be that in advance a file has been submitted in which it is demonstrated that the GM plant involved is cisgenic indeed. It should be clear prior to this, however, how the species' own genes and genes of crossable relatives are defined[34].

Two scenarios are outlined for the follow-up trajectory. According to some, cisgenic products acknowledged as such and products of conventional growing should be treated equally. They also regard product labeling of cisgenic products as superfluous, even though it is required for other GM crops. In their opinion, this does not limit freedom of choice because it involves plants without foreign genes. Rather than claiming exemption of the labeling requirement, others argue for a reduced onus of proof in the authorization procedure. In cisgenic crops less rigid standards should apply than in transgenic ones because, they assume, the risks of genetic modification with the plant's own genes or genes from crossable relatives will by definition produce fewer risks.

The two proposed policy alternatives have consequences for the above-mentioned European directives and the Dutch ethical-social considerations. In the first-mentioned proposal to change the policy, molecular detection is not a problem; traceability and visual detection on the market potentially are, however. In the second proposal there are no differences concerning freedom of choice, traceability and labeling with the current policy on transgenic crops. In the table below the consequences of the possible policy alternatives regarding the various types of agricultural products – organic, conventional, cisgenic according to the two alternatives mentioned and transgenic – are put side by side.

COGEM indicates that the guarantees offered by the government in the area of the coexistence of organic conventional and GM agriculture may come under pressure in the case of a possible policy change regarding cisgenic products.[35] (Unintentional) mixing of non-GM-cultivation and its products, including seeds for sowing, with cisgenic products has to be avoided. Even if it does not result in health risks or environmental hazards, it would undermine the possibility of making a choice pro or con GM products.

Type product / *Consequences for policy criteria*	*File required for authorization for market*	*Label*	*Refusal and positive choice possible for growers and consumers who reject GM*	*Molecular detection possible*	*Visual detection possible*
Organic	No	Quality mark	Yes	No	Quality mark
Conventional	No	No	Yes	No	No
Cisgenic viewed as identical to conventional	Yes	No	No	Yes	No
Cisgenic viewed as separate form of transgenic	Yes	GM-label	Yes	Yes	GM-label
Transgenic	Yes	GM-label	Yes	Yes	GM-label

6. Policy development and public debate

In 2005 COGEM observed that despite the extensive safety guarantees, the public support for GM agriculture remains unsteady. In the report on the Farm Scale Evaluations an explanation is given as to the role the broader underlying theme's play, indicated with the term *wider issues*[36]. It involves deeper motives explaining why parties want to hold on to specific viewpoints. These underlying issues include views of nature and of what is natural, as well as ideas on sustainability, safety, responsibility for future generations, the desirability of certain types of agriculture, landscape management, food quality, etc. Citizens, farmers, scientists, nature preservationists, consumers and businesses, both individually and collectively (via their organizations) – all have views of their own on these matters. In relation to the introduction of GM agriculture, the various views and interests are currently far apart. The concerns involved are so differently defined that little common ground has been found thus far, and this hardly warrants opting for a distinctive forward direction.
While the Dutch government wants to exploit the opportunities provided by modern biotechnology, in its policy it has to account for the instability involved. Familiar policy instruments proved unfitting for a controversial topic such as GM agriculture. In Great Britain the deployment of scientific experts who assess the risks hardly contributed to confidence and a sense of safety[37]. In the report mentioned above, COGEM articulated several recommendations for enlarging the basis of public support for decisions on a technological innovation like cisgenesis. COGEM wants to reemphasize their relevance. The recommendations are:
(1) involve as many as possible interested parties and experts;
(2) do not limit the effort to specific questions, but engage underlying wider issues as well;
(3) formulate shared ambitions.

Based on the learning process gone through during this trajectory, the government may subsequently take decisions that have a broader basis in society and are hence more robust. These recommendations concerning the decision process of cisgenesis are supported by the European procedural principles of good governance, including participation and openness. In a possible policy change it is important to have an eye for the various distinctive opinions of citizens. Before policy proposals on less rigid regulation for cisgenesis are formulated, it is advisable to study whether citizens really think differently about cisgenesis than about

transgenesis. In the development of such new regulation COGEM recommends interactive methods of policy design, in which the various interested parties can articulate their views. When the Ministry of VROM decides to enter upon this path, COGEM will contribute in its role of scientific advisory commission.

Openness about the underlying concerns involved in choices made by the government is also desirable. In this context COGEM advises the government to be clear about both the specific features of cisgenesis and the control measures taken in the production chain – from seed to product for consumer – because this will secure freedom of choice. Reduced regulation should in no way lead to reduced confidence in the tenability of the government's policy.

7. Innovations only successful in a suitable context

If promising innovations are to have a chance at succeeding, major preconditions involved are public support, consumer trust and acceptance by citizens. These do not emerge through an exclusive focus on the pros and cons of a particular technological solution. What is called for is a more general debate, which in the case of cisgenesis will have to address the application of genetic engineering in agriculture. Cisgenic crops, after all, do not constitute a goal in their own right, but they are a means to realizing particular objectives. These underlying objectives which have to do with a host of issues such as business management in agriculture (cost efficiency, deployment of labor, meeting environmental objectives), concern for quality and safety of (food) products, stimulating sustainable food production, choice for consumers and growers, respect for nature, concern for biodiversity, landscape management, the type of agriculture and the balance between agriculture and nature management – also have to be addressed. This is the backdrop against which cisgenesis ought to be evaluated.

Although modification of plants through coding DNA sequences from the species itself removes the public concern of the transgression of the species barrier, this technical solution itself may give rise again to a reiteration of the pro-contra debate. Rather than being primarily an outcome of the new technique as such, this concern seems to be a result of how the technique is developed and presented to society.

The development of cisgenesis, despite its different nature as a genetic engineering technique, is still strongly related to the top-down approach of *science-and-technology-for-society*. So far the participative and integrative approach of *science-in-society* does not seem to have been followed. The intention to move beyond the pro-contra debate by developing a new technique, then, is frustrated by a science approach that precisely causes a repeat of such pro-contra debate.

COGEM does not foresee, therefore, that the societal debate on the application of genetic engineering in agriculture will vanish after the introduction of cisgenic crops in the Netherlands or Europe. There will continue to be parties and groups of citizens that resist such applications on fundamental grounds, however it still involves an innovation that at least partially eliminates elements of the moral and societal objections against genetic engineering. It is important that the policies involved take into account the projected benefits of the application of genetic engineering in agriculture for producers and consumers alike. But citizens and other stakeholders

should also be able to openly voice their underlying views, doubts and objections, something which should be accommodated and acknowledged by the government as well.

8. Conclusions

1. COGEM is of the opinion that regarding cisgenesis, on specific conditions there are possibilities to simplify an authorization procedure with respect to restricted use and market introductions. COGEM does not expect cisgenesis will automatically be regarded by all parties as an acceptable form of genetic modification.
2. COGEM considers the claim that on ethical grounds cisgenesis will gain larger public support partly justified. Its extent depends on the vision of those involved on issues such as violation of the species boundary, the integrity of nature, the application of biotechnology in agriculture and food production, patenting and such.
3. It is yet unknown how citizens and consumers in the Netherlands will actually perceive cisgenesis. In the development of special regulation on cisgenesis, it is advisable, according to COGEM, to study this issue.
4. In the development of regulation pertaining to cisgenesis and other future techniques at the interface of genetic modification, COGEM recommends interactive methods of policy design, in which the various interested parties can articulate their views and address underlying issues. Both consequentialist and deontological considerations are relevant in this debate. A participative and integrative approach of *science-in-society* is thereby most productive.

   COGEM expects that policy decisions concerning cisgenesis which take due account of the public debate as a learning process will prove socially more robust. COGEM advises the Ministry of VROM to enter upon this path. COGEM is prepared to play a role as scientific advisory commission.
5. As authorization pertaining to the release of GM crops into the environment takes place at the European level, possible exemption or relaxation of the regulation for cisgenesis will have to be supported by other member states. COGEM therefore advises the Ministry of VROM to have its national policy trafectory run parallel to the European trajectory.
6. In policy changes regarding cisgenic products, the government should pay attention to:
   a. the implications for freedom of choice of consumers and growers, traceability and labeling;
   b. the global aspects and the ensuing opportunities and threats;
   c. the possibilities and opportunities for Dutch business;

d. the potential economic damage for the sector as a result of (possible) mixing of non-GM products with cisgenic ones;
e. the possibility that a potentially reduced regulation may cause reduced trust in government among specific groups;
f. the functionality of a distinction between food crops and non-food crops, such as ornamental crops.

7. In the case of the introduction of special regulation on cisgenesis COGEM advises the government to communicate transparently on both the specific features of cisgenesis and the control measures taken in the production chain; this will secure the possibility of choice for consumers and growers alike.

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