GMO regulation in the Netherlands

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Questions 1-2; National regulatory approach to GMO in the Member States; Executive competencies in the Member States

The European directives on GMO's have been implemented in the Netherlands by the *Besluit genetisch gemodificeerde organismen Wet milieugevaarlijke stoffen*[2] or, in translation the *Decree on Genetically Modified Organisms* (hereafter: GMO Decree). The GMO Decree is a so called 'Royal Decree' based on Article 24 of the *Environmental Dangerous Substances Act*.

The Dutch GMO Decree does not intend to provide for more 'stringent' standards than the Directive. According to the Dutch government, the legal basis of Directive 2001/18 (Article 95 EC) does not allow for more stringent standards and no use have been made of either paragraph 4 or 5 of Article 95.

According to Article 8 of the GMO Decree a license is required for undertaking a deliberate release of GMO's. Competent authority is the Minister for the Environment. This provision has to be read in conjunction with Article 23 GMO Decree, which contains a general prohibition for the deliberate release of GMO's without a license.[3]

If the authorization covers aspects related to the responsibilities of the Minister for Agriculture the decision has to be made 'in accordance' with the Minister for Agriculture. In practice this means that the Minister for Agriculture is almost always involved in the decision-making procedure.

If the authorization covers aspects related to the responsibilities of the Minister for Public Health, this minister needs to be consulted.

Question 3; Implementation and enforcement of Directive 2001/18

The application for a license should be accompanied by an environmental risk-analysis. The Minister for the Environment, deciding upon the application, should take into account all available data related to the risks for man or the environment. According to Article 26 of the *Environmental Dangerous Substances Act* can the license only be refused "in the interest of the protection of man and the environment".

Application procedures; Public Participation and Access to Environmental Information

The GMO Decree knows two kind of procedures with respect to application-procedures for the deliberate release of GMO's:

-for trade purposes (introduction of GMO's on the market as products or in products; Paragraph 3.3 of the GMO Decree);

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[2] *Staatsblad* 1990, 53, with latest amendments in *Staatscourant* 2005, 320.

[3] Article 23, par. 2 provides for exceptions to this license-requirement of which activities for the 'contained use' is the most important one. Activities with GMO's confined to certain institutions like labaratories etc. are exempted, but those institutions must be licensed, by regional or local authorities, in accordance with the *Wet milieubeheer* (Environmental Management Act). In other words, with respect to contained use not the activity as such is licensed but the establishment in which the activity is carried out.

-for ‘other’ purposes[4] (Paragraph 3.2 of the GMO Decree).
With respect to decisions for deliberate release for ‘other purposes’ one can say that, according to Article 26(3) of the EDSA, in principle the standard public law procedures are applicable. The decision-making procedure and public participation is subject to the so called ‘uniform public preparatory procedure’ of Division 3.4 of the General Administrative Law Act (GALA) and of Division 13.2 of the Environmental Management Act. According to this procedure draft-decisions, together will all relevant documents pertaining to the decision, will be deposited for inspection by the public (everyone) for a period of 6 weeks. The communication of the draft shall be given in one or more newspapers or free local papers, or in any other suitable way, prior to the deposit of the application for inspection. As the decision is given by the Minister, notification is also required in the official state gazette (*Staatscourant*). Only the substance of the draft need be stated. Interested parties may state their views on the application or the draft either orally or in writing, at their discretion. The time limit for stating such a view is 6 weeks and commences on the first day of public inspection.

In view of mixed (national/Community) nature of the decision-making procedure with respect to decisions trade purposes (introduction of GMO’s on the market as products or in products) the Dutch legislator had to decide that the standard rules on public participation are not applicable (Article 27 GMO Decree). For this the GMO Decree follows closely the rules on public participation of the Community. The notification will be displayed for public inspection, leading to the national assessment report and subsequently in the Community phase of the procedure. Notification will be done by the Joint Research Centre of the European Commission.
With respect to ‘market dossiers’ and the procedures of Article 24 Directive 2001/18, the ministry for the Environmental, although not obliged by the directive, will display those dossiers for inspection by the public in its library. A notification to this end will be made in de *Staatscourant* and on their website.
The GMO Decree contains a specific provision for marketing-authororisations of which the Commission has expressed its concern. Article 30 of the Decree provides that in those circumstances the national procedure will be stayed. This to enable the procedure of Article 30(2) Directive 2001/18 to be followed. The complete authorization-procedure for marketing purposes can last for 225 days, much longer that the maximum of 120 days for the authorization for other purposes.

The precautionary principle
The precautionary principles is not in so many words explicitly transposed into Dutch GMO legislation. It only makes a reference to Annex II of the Directive. Before the Council of State the question rose to which extent a license can be refused on the basis of the precautionary principle. As said above according to Article 26 of the *Environmental Dangerous Substances Act* can the license only be refused “in the interest of the protection of man and the environment”. The Council of State argued however that Article 26 can be interpreted consistent with the Directive. That means that also implies that the precautionary principle must be read into “the protection of man and the environment” of Article 26 EDSA.[5]
For example, it emerged from a decision of the Dutch Council of State that Directive 2001/18 on the deliberate release into the environment of genetically modified organisms had not been

[4] A currently no gm crops are grown commercially in the Netherlands decisionmaking for ‘other’ purposes concern in particular a limited number of small-scale field trials only.
[5] Council of State 28 June 2004, M&R 2004/10, nr. 104 and Council of State 21 December 2005, M&R 2006/2, nr. 20.

transposed into Dutch law, specifically the Environmentally Dangerous Substances Act.[6] Under that Act, authorisation had been granted for small-scale trials with flowering genetically modified rape. Pursuant to the second paragraph of section 26 of the Act, the authorisation could only be refused 'in the interest of the protection of man and the environment'. According to the court this statutory framework provided sufficient basis for the court to interpret in the light of the directive. The obligations set out in the directive, including the precautionary principle and the duty to carry out a specific environmental risk assessment in accordance with the criteria of Annex II of the directive, were 'read into' the national law. Clearly, this means that applicants are confronted with obligations arising out of a directive that has not been transposed.
There is now some debate in the Netherlands whether European law requires to amend Article 26 EDSA to include more specifically a reference to the precautionary principle.

With respect to authorisations for GMOs other than food and feed the current GMO Decree contains wider possibilities to issue general authorizations and is not confined individual/specific authorizations (Article 24 (3)).

Involvement scientific bodies
The so called *Cogem*[7] – established by the Environmental Management Act (Article 2.25-2.40) – can provide the Minister for the Environment for scientific advice on notifications for contained use and applications for deliberate release. It can do so either upon request from the Minister or *ex officio*. The Cogem advice is not part of the formal licensing procedure. Details on their work can be found at www.cogem.net.

Access to court
All interested parties who have been taken part in the application-procedure have access to the Council of State (*Raad van State*) in an annulment-procedure against a license (and its conditions) granted by the Minister for the Environment. The limit of such an appeal is 6 weeks after the final decision has been taken. Interim-procedures are available as well. My guess is that all licenses issued have triggered an appeal at the Council of State. My impression is also that the judicial review exercised by the Council of State can be characterised as 'procedural': did the Minister take into account all relevant data; was the risk-assessment exercised in a thorough, scientific sound and objective manner; was the reasoning provided by the Minister complete and did the reasoning 'carry' the final decision? On substantive issues the Council of States takes deference to the position of the Minister. In particular with respect to the question whether the deliberate use of GMO's is *acceptable* relating to the risks for man and the environment, the Council acknowledges that the Minister enjoys "a certain degree of discretion". There is debate in Dutch legal circles to what extent this deference is in line with in particular Recital 47 of the Directive that 'the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment'. It is in anyway a pity that the actual provisions in the Directive – for instance Article 4(1) – are formulated in a less stringent way.

Penalties
Violating the licensing requirements of the GMO Decree is considered to be a criminal offence in the meaning of Article 1a *Wet op de economische delicten* (Act on economic offences). Maximum penalties can range from imprisonment (for intentional acts max. 6

[6] Council of State 28 June 2004, M&R 2004/10, nr. 104 (with note by Jans).
[7] Commissie genetische modificatie; Commission genetical modification.

years) to fines up to 45.000 Euro (if I understood our criminal law correctly). However, I could not find any judgment relating to the criminal enforcement of the GMO Decree. Furthermore, the Minister for the Environment has the option to apply the 'standard' administrative sanctions (revoking license, etc.).

Dutch Policy on Coexistence

Co-existence refers to the simultaneous existence of genetically modified crops next to conventional and organic crops. Commission Recommendation (EC) 556/2003 encourages Member States to work out national strategies and methods to deal with co-existence.
A few years ago, the Dutch Ministry of Agriculture, Nature and Food Quality and the Ministry of Housing, Spatial Planning and the Environment launched a broad public debate on outcrossing and co-existence. Various scenarios for co-existence were discussed with stakeholding organisations during this debate. The Ministry of Agriculture used the outcome of the debate to draw up a Dutch policy on co-existence, which was published in October 2003. Co-existence is primarily a practical problem and in view of the Government's policy of deregulation, the Dutch Government would prefer a system of self-regulation for co-existence issues.
The aim of this so-called co-existence consultation was to realise a sector approach to co-existence; an approach drawn up and supported by all stakeholder representatives, which would make it possible for conventional, organic and genetically modified crops to exist side by side in the Netherlands. In 2004 this committee issued their report Co-existence in the Primary Sector.[8] The committee concludes its assignment with the following recommendations:

General

1. The links in the chain preceding and following primary production are important for the realisation of co-existence in the primary sector and for the success of coexistence in the chain.
2. The agreements and arrangements in this report, which may be regarded as a covenant, are part of an integral package. It is vital that all components of this package are implemented.

Specific

3. In the interests of freedom of choice, every effort should be made to prevent cross-contamination. Crops should be cultivated in a way that minimises the chance of losses resulting from admixture. The crop and farm management obligations formulated in this covenant are appropriate instruments for achieving this aim, provided they are proportionate and reasonable.
4. The committee has reached agreement between the stakeholders concerning: the acquisition of knowledge, the exchange of information and crop adaptations between farmers, the registration requirement for GM growers, measures that tie in with the code of Good Agricultural Practice and separation distances. Compliance with these measures could be assured with a system of certification of GM growers. The measures concerning crop production and farm management could be incorporated in the system of certificates (arable crops, feed manufacturing). The implementation of compulsory notification, separation distance and GAP measures should be incorporated in a co-existence regulation.
5. The committee laid down separation distances for three crops on the basis of the latest scientific information. At this time, however, little information is geared specifically to the

[8] The report is available, upon request, in PDF-format, from me.

Dutch context of crop farming, in particular as regards fodder maize. Further research geared to the Dutch situation is necessary.
6. Farm-level measures must go hand in hand with monitoring. The aim of monitoring is to evaluate the measures' effectiveness, so that they may be adapted if necessary.
7. The stakeholders have agreed that every effort should be made to prevent cross contamination disputes being taken to court. The agreements in the covenant aim to prevent this from becoming common practice. The committee feels that those who fail to comply with the agreements, resulting in proven damage, should be held to account for the losses resulting from admixture on the basis of current liability legislation. The covenant sets out each party's obligation in avoiding admixture and hindrance. Those who have carried out their part of the agreement in good faith should be indemnified from liability for losses resulting from cross-contamination (income loss and costs of analyses).
8. A compensation fund should be created per cultivar to cover losses. Under certain conditions, injured parties may qualify for compensation of income losses resulting from cross-contamination.
9. The government and all relevant parties in the chain (per cultivar) should contribute to the fund.
10. Market exclusion can have serious consequences for GM-free growers, but at the same time it might be impossible to identify a liable party. Every effort should be made to minimise the threat of market exclusion. The committee is certain that this can be achieved by: strict co-existence measures combined with control and enforcement, monitoring and if necessary adjustment of measures, research, educating market parties and consumers. The committee believes that these conditions will be realised adequately with this covenant. It will also be important to harmonise co-existence strategies.
11. An agreement on rapeseed was not drawn up due to time constraints, the low degree of urgency for this crop and the complexity of this crop. Co-existence agreements would therefore have to be made before GM rape could be introduced commercially.
12. The coexistence agreements will be evaluated after three years of implementation, starting from the 2005 growing season. The agreements will not expire after three years, but may be adapted with the agreement of all the parties involved following the results of the evaluation. Interim adjustments may also be possible on the basis of new scientific evidence. All adjustments should be made by consensus only.
13. A satisfactory solution for ' resulting damage', for example to the status of a farm after GM contamination, is yet to be developed. As yet, there is no policy to deal with a farm losing GM free certification, including organic certification.

The committee makes the following recommendations:
1. in the short term, cultivation and farm management measures should be incorporated in cultivation certificates (food safety for the arable sector, GMP 11 for feed production) and their implementation should be supported by a regulation, to be drawn up in the near future;
2. The Ministry of Agriculture and the Ministry of Environment should arrange for the technical facilities for GM crop registration before 1 February of the year of cultivation;
3. The structure and functioning of a compensation fund and the conditions under which a farmer may qualify for compensation need to be worked out;
4. The IRMA will make an estimate of the required scope of the fund;
5. In the short term, a monitoring protocol must be drawn up, including all the elements identified by the committee;
6. All stakeholders must make a serious effort to generate support for the implementation of co-existence agreements and measures, at the very least among their own grassroots;

7. Third parties should also be informed of co-existence and the coexistence agreements now made concerning GM cultivation. If necessary, active extension by for example allotment associations should ensure that the agreements are complied with;
8. All field trials allowed by the Ministry of Environment should take account of the separation distances agreed by the committee members;
9. In view of the Dutch Government's wish to enable coexistence and to facilitate self-regulation, it should

- seek to close the knowledge gap by commissioning research in the short term, to provide more field data on separation distances especially for fodder maize. In particular, research is needed on the effectiveness of separation distances for fodder maize in combination with separate harvesting of non- GM plating rows. Research should also be carried out into the possibilities for minimizing separation distances and for a uniform approach to this matter;
- contribute financially to the cost of managing the compensation fund and act as guarantor;
- contribute financially to the monitoring programme;
- support the co-existence agreements made in the Netherlands and give its approval to the European Commission regulation and fund;
- contribute to the dissemination of knowledge on GM cultivation and associated regulations;
- contribute to campaigns informing consumers and market parties about coexistence.

10. The Dutch Government should closely follow developments in neighbouring countries regarding their coexistence strategies and maintain open lines of communication in order to prevent problems arising in border zones.
11. The Dutch Government should lobby for harmonisation of European coexistence strategies.

The government found the report and its proposals balanced and realistic and was looking forward for the implementation.

Liability
There are no specific provisions on this in the Dutch GMO legislation. This means that the standard provision on liability in the Dutch Civil Code is applicable. However, the issue of liability for nuisance and economic loss resulting from co-existence is an important point of discussion.[9] The following aspects will be relevant. When GM crops are first introduced, the GM farmer will be regarded as the 'newcomer'. The question of who is responsible for compensating nuisance or loss will depend on whether 'unlawful action' was taken by the farmer which led to the loss or damage. When the introduction of a new crop leads to a conflict of interest between GM farmers and non-GM farmers, the court will most certainly consider the matter of liability on the basis of:
- oldest rights;
- nature, severity and duration of the nuisance and resulting loss;
- the public importance and interests served by the activities which caused the nuisance;
- the possibilities for measures which can be taken to prevent losses;
- local circumstances.

It is not conceivable to assume liability in cases of loss resulting solely from market attitudes.

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[9] See also the proposals in the previous paragraph.