**Avosetta Meeting on GMOs (Siena, 29-30 September 2006)**

# Belgian Report

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1. *Which is the national regulatory approach to GMO in the Member States? Is there a horizontal act on GMO or just sectoral regulations apply in the Member States?*

Environmental policy in Belgium falls largely within the remit of the three autonomous regions: the Flemish Region, the Walloon Region and the Brussels-Capital Region. This is particularly the case for *environmental protection* and *nature conservation* (Art. 6(1), III, of the Special Act of 8 August 1980 on institutional reform (further: SAIR)[1] and, to a large extent, for *agricultural policy*. However, in some areas, which are relevant to the subject matter dealt with, the federal authority is competent. Pursuant to the first point of the second paragraph of Article 6(1) SAIR, the federal Government is responsible for drawing up *product standards*. Product standards are defined as "*standards that establish the degree of pollution or nuisance which may not be exceeded in the composition or during the emission of a product, or which include specifications concerning product characteristics, methods of use, sampling standards, packaging, marking and labelling*". A product standard is applicable *when the product is placed on the market*, *inter alia*, at the time of its introduction, importation or possession, for the purpose of sale or making available to a third party, offer for sale, offer for rent, rent etc.[2] Requirements relating to environmental protection which apply *after* the product has been placed on the market, such as those concerning the use or release of products, come under the power of the Regions and not of the federal authorities[3]. In the same sense the federal authority is competent *to set standards* (and control them) concerning *the quality of primary materials used in agriculture and products derived from plants* with a view to ensure food safety during the complete production chain (Art. 6 (1) V SAIR).
The conclusion is that the implementation of the European Directives concerning GMOs and the application of related Regulations is a mixed competence.

[1] E. DE PUE, L. LAVRYSEN and P. STRYCKERS, *Milieuzakboekje 2005,* Wolters Kluwer Belgium, Mechelen, 2005, p. 23.
[2] D. MISONNE et al., *Legal constraints on national measures to promote environment-friendly products,* Brussels, Belgian Science Policy, 2004, p. 13
[3] *Ibid*., p. 14.

a) The implementation of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC is mainly a task for the *federal authorities* as it deals with the "placing on the market of genetically modified organisms as or in products within the Community" (Art. 1, second indent); also the regional authorities are concerned, however, as it deals also with "carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community" (Art. 5-11). Regional competencies are e.g. involved in the authorisation of field experiments, because risks to the environment and to biodiversity can occur.

b) The implementation of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms is mainly a competence of the regions, because the laboratories in which these activities take place are seen as so-called "classified installations" that require a regional environmental license. Indeed, the Regions are competent with regard to what is described in the SAIR as: *"the policing of dangerous, unhealthy and noxious establishments, subject to measures of internal policy concerning worker protection."* This means that the Regions are competent for the environmental supervision of companies and other noxious establishments, for example, by a system of exploitation or environmental licences, and more modern policy instruments, such as environmental effect statements and safety reports. This competence comprises both preventive supervision (licences, standards) and curative supervision (e.g., safety measures). Federal competencies are involved as well, however, as Article 14 deals with emergency plans for such premises. Federal government is competent with regard to civil protection and this comprises, *inter alia*, plans for dealing with disasters, and a coordinated action of the emergency services in the event of environmental disasters.

c) The application of Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified foods and feeds is a federal competence. The same is true for Regulation (EC) N° 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Given this division of competencies it is obvious that it was impossible in Belgium to regulate the whole issue in one piece of legislation applicable for the whole country. The solution that was chosen is a combination of a cooperation agreement between federal and regional authorities, on the one hand, and federal and regional acts and regulations on the other.

The relevant legal framework in Belgium is essentially constituted by[4]:

a) The Cooperation Agreement of 25 April 1997 between the Federal State and the Regions on the administrative and scientific coordination concerning biosafety. This cooperation agreement concerns not only GMOs and GMMs, but also organisms that are human pathogens. The Cooperation Agreement establishes a common scientific evaluation system for all biosafety-related matters. It is composed of the *Biosafety Advisory Council*[5], which is charged with the task of evaluating the biosafety of activities or products for which GMMs, GMOs or parts thereof are used and of the contained use of human pathogenic micro-organisms, and with offering advice in the context of the Cooperation Agreement. The secretariat of the Council is assumed by the *Service of Biosafety and Biotechnology (SBB)* of the Louis Pasteur Scientific Institute of Public Health. The SBB is composed of an administrative secretariat, a multidisciplinary group of scientists and a laboratory for biosafety research and expertise (territory covered: the whole of Belgium).

b) The Royal Decree of 21 February 2005 regulating the deliberate release into the environment and placing on the market of genetically modified organisms as or in products[6]. This Royal Decree transposes Directive 2001/18/EC and enforces Decision 1830/2003 (territory covered: the whole of Belgium).
This Royal Decree was adopted with some delay[7]. This delay was mainly due to disagreement on the way in which the Directive was to be transposed into Belgian law. The then Minister of Consumer Affairs, Public Health and the Environment, M. Aelvoet of the Green Party, had framed a preliminary draft which in some respects went further than what was prescribed by the Directive. One of the controversial points was that for each individual application to authorize field experiments, an assessment also had to be made of the *ethical aspects*[8] besides the required health environmental risk assessment. The government at the time was unable to reach an agreement on that point. The new government, without the Green parties, subsequently decided to drop this part.

[4] More information can be found on the following website: http://www.biosafety.be/

[5] Royal Decree of 2 September 2005 appointing the members of the Biosafety Advisory Council, *Belgian Official Journal*, 6 October 2005. The Council is composed of 12 active and 12 deputy members. Half the members represent the various relevant federal and regional ministers, the other half are representatives of the scientific communities. For more info, see http://www.bio-council.be/

[6] *Belgian Official Journal*, 24 February 2005. The Royal Decree has for its legal basis Article 132 of the Act of 20 July 1991, which contains the provisions concerning supervision and penalties: E. DE PUE, L. LAVRYSEN and P. STRYCKERS, *o.c., p.* 501

[7] Belgium has in fact been condemned by the European Court of Justice for delays in the transposition of the Directive into domestic law: ECJ, C-417/30, 30 September 2004, *Commission v. Belgium.*

[8] The Federal Council for Sustainable Development, a multi-stakeholder advisory council, was also divided on this issue. While the representatives of environmental groups and Third World organizations, consumer organizations, trade unions and some representatives of the scientific community supported the idea, a case-by-case ethical assessment was dismissed by the representatives of the employers' organizations. See: Federal Council for Sustainable Development, Opinion of 15 October 2002, www.frdo.be

c) The following Regional legislation on the contained use of GMMs and pathogens have been adopted:
- *Flemish Region*: Decree of 28 June 1985 on environmental licences (in particular Articles 19c and 22b); Decision of the Flemish Government of 6 February 1991 establishing the Flemish Regulations governing environmental licences (VLAREM I) (in particular Articles 1, 30°, 57b to 57i and Section 51 of Annex 1 and Annexes 15, 16 and 17); Decision of the Flemish Government of 1 June 1995 on general and sectoral provisions relating to environmental safety (VLAREM II) (in particular Chapter 5.51 and Annexes 5.51.3 – 5.51.5);
- *Walloon Region:* Decree of 11 March 1999 on environmental licences; Walloon Government Decision of 4 July 2002 establishing the sectoral conditions for the contained use of genetically modified or pathogenic organisms;
- *Brussels-Capital Region*: Ordinance of 5 June 1997 on environmental licences; Decision of 8 November 2001 of the Brussels-Capital Government on the contained use of genetically modified and/or pathogenic organisms and on the classification of the installations concerned.

We should also mention the Act of 28 April 2005 amending the Act of 28 March 1984 on patents as regards the patentability of biotechnological inventions, which transposes Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions into Belgian law.

*2. Executive competencies in the Member States: which national authority is responsible for the area of Dir. 98/81 and Dir. 2001/18 and for the area of Reg. 1829/2003 and Reg. 1830/2003?*

The main supporting authorities for the implementation of the Directives and Regulations in question are the aforementioned *Biosafety Advisory Council*[9] and the *Service of Biosafety and Biotechnology*.

Depending on the subject, advice is given to the competent federal or regional authorities.

With regard to the deliberate release into the environment and putting on the market of genetically modified organisms as or in products (Directive 2001/18/EC), the *Biosafety Advisory Council* delivers its opinion to the *Federal Minister or Ministers responsible for Public Health and the Environment*[10]*,* who are empowered to grant the requisite prior written authorizations.

With regard to the contained use (Directive 90/219/EEC), the *Service of Biosafety and Biotechnology*[11] delivers its opinion to the bodies that are competent for notifications and

[9] http://www.bio-council.be/
[10] In the present government, these portfolios are divided over two ministers, which means that a joint decision is required each time.
[11] In 2005, the SBB dealt with 90 dossiers, corresponding to 206 operations (Activities – Annual Report drawn up by the Biosafety Advisory Council – Period January 2005 to December 2005, p. 9). In the period 1992-2002, 414 dossiers concerning 1265 operations were dealt with (Activities – Annual Report drawn up by the Biosafety Advisory Council – Period May 2003 to December 2004, p. 24). In 2003, 96 dossiers concerning 300 operations and, in 2004, 142 dossiers concerning 443 operations were dealt with (*ibid.*, p. 12)

authorizations in accordance with regional law. For the Flemish Region that is the *Environmental Licences Section of the Department of the Environment, Nature, Land and Water Management*[12]. In the Walloon Region the competent authority is, depending on the risk level, the Mayor and Aldermen of the municipality concerned (risk level 1) (notification only) or the *Direction Générale des Ressources Naturelles et de l'Environnement (DGRNE)-Division de la Prévention et des Autorisations* (risk levels 2, 3 and 4)[13] (environmental licence for up to 10 years). In the Brussels-Capital Region we have the *Brussels Institute of Environmental Management*[14].

*3. Implementation and enforcement of Directive 2001/18/CE on the deliberate release into environment of GMO:*
*a) What about risk assessment, management and the concept of precaution?*
*b) Which is the impact of the complex, multi-level EC law procedure for the release of GMO in domestic administrative systems and organizations? In particular, which are the procedures of authorization? Are the scientific bodies involved in such a process and what is their influence on the competent authority's decisions?*
*c) What about self-monitoring and supervision by administrative bodies and public entities (NGOs, etc.)? How the safeguard clause is applied?*
*d) How are transparency and participation dealt with? What about the access to information on GMOs?*
*e) How is the court review? Is the legal standing of third parties and associations allowed?*
*f) Which is the nature of the penalties fixed according to Art. 33 (criminal, administrative, civil sanctions)?*

a) Like the Directive (Article 1), the Royal Decree of 21 February 2005 (Article 1) provides that the objective of the decree is, "in accordance with the precautionary principle", to protect human health and the environment when carrying out the activities covered by the Directive and the decree[15]. Both the deliberate release of GMOs and placing on the market of GGOs as or in products are subject to the prior written authorization of the competent federal ministers (Articles 3 and 4). In order to obtain such authorization, a notification must be submitted along with a health and environmental risk assessment of which the requirements in terms of content are specified in Annex II. That same Annex also makes reference to the precautionary principle. In his risk assessment, the notifier must ensure that an accurate assessment is made on a case-by-case basis of the potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms. This assessment must be conducted according to the nature of the organism introduced and the receiving environment. Annex III imposes more specific requirements in this connection.

[12] E. DE PUE, L. LAVRYSEN and P. STRYCKERS, *o.c.*, 502; http://www.mina.be/
[13] http://mrw.wallonie.be/dgrne/dppgss/index.htm
[14] http://www.ibgebim.be/
[15] In its opinion, the Federal Council for Sustainable Development had pointed out that the provisions in the preliminary draft Royal Decree should specify more accurately in which cases the precautionary principle applies. According to the Federal Council, once every possible kind of harm and the probability of such harm have been identified, the resulting situation allows a conventional risk assessment. This situation does not fall within the scope of the precautionary principle. The conditions for the risk assessment are therefore applicable. On the other hand, the precautionary principle applies in cases that are characterized by scientific uncertainty (or ignorance). In those cases, (any provisional) scientific knowledge is inadequate to determine every possible risk of serious or irreparable harm or damage.

b) In the standard procedure[16], the notification dossier must be submitted to the *Federal Department of Health, Food Chain Safety and Environment*[17]. This authority investigates, together with the *Service of Biosafety and Biotechnology (SBB)*, the admissibility of the dossier within 15 days after receipt thereof. If the dossier is found admissible, a European identification number is assigned and a copy of the dossier is sent to each of the relevant *regional ministers* and to the *Biosafety Advisory Council*. The *Biosafety Advisory Council* delivers an opinion within 65 days; this opinion is communicated to the competent authority and the relevant regional minister(s). Where appropriate, the Biosafety Advisory Council, in delivering its opinion, takes into consideration the comments of the competent authority or of the other Member States, and relevant comments by the public. The competent authority subsequently submits a decision to the relevant federal Ministers, who decide in agreement with the territorially competent regional Minister[18]. The Ministers or their representatives adopt a reasoned decision within 90 days following the admissibility decision of the notification. This decision may consist in authorizing the release, subject to the conditions under which such release may take place; the authorization decision lays down at least the conditions put forward by the territorially competent regional minister. If the release does not comply with the conditions stipulated by the Royal Decree of 21 February 2005, the application for authorization will be refused.
So far, two authorizations have been granted to *Transgene* (clinical experiments on humans) and *Pfizer Animal Health Group* (clinical experiments on animals)[19] respectively in accordance with the new procedure. On the basis of the previous Directive, 158 dossiers for plants and 7 for non-plants were examined[20]. The GMO databases show for the 1999-2005 period 41 authorizations for field experiments with plants and for the 1997-2003 period 7 authorizations for clinical experiments with micro-organisms[21].

c) The notification comprises a technical dossier which must contain a *monitoring plan* in accordance with the applicable parts of Annex III in order to identify the effects of the GMO or GMOs on human health and the environment. It also comprises the *planned self-monitoring measures*, information concerning the monitoring, the remediation measures, waste processing and the planned emergency measures. Annex III to the Royal Decree imposes more specific requirements in this connection. Supervision of compliance with the conditions of authorization is entrusted to the *Directorate-General for the Protection of Public Health: Medicines* for medical GMOs and to the service of the *Federal Department of Health, Food Chain Safety and Environment* designated by the minister for the other GMOs. Article 42 of the Royal Decree contains the safeguard clause. This clause provides that if the competent federal Minister, on the basis of new or additional information which has become

[16] Articles 15 to 18; in addition, there are also so-called differentiated procedures for special cases (e.g. GMOs that meet the criteria of Annex V and with which sufficient experience has been gained in the context of release into certain ecosystems).
[17] More particularly: Federal Public Service (FPS) Health, Food Chain Security and Environment - Service Denrées alimentaires, Aliments pour Animaux et Autres Produits de Consommation (http://www.biosafety.be/gmcropff/EN/CADREN.html)
[18] This agreement is deemed to have been given if the territorially competent regional Minister has not communicated any written objection to the authorization to the competent authority within ten working days after receipt of the opinion of the Biosafety Advisory Council.
[19] http://www.bio-council.be/bac_proc_out.html#A1
[20] Annual Report drawn up by the Biosafety Advisory Council – Period of May 2003 to December 2004, p. 24-25.
[21] http://www.biosafety.be/Menu/BiosBelg.html

available after authorization has been granted and which may have an impact on the assessment of the health or environmental risks, or on the basis of the reassessment of the existing information in the light of new or additional scientific knowledge, has sufficient reason to assume that a GMO as a product or in products that has already been the subject of a proper notification dossier and of a written consent that was delivered in accordance with the Royal Decree or by virtue of a different licensing system of a Member State, poses a risk to human health or to the environment, the Minister may provisionally restrict or prohibit the use or sale of that GMO as a product or in products on "its territory" (this probably means the Belgian territory). The Minister ensures that emergency measures are taken if a serious risk occurs, such as interrupting or terminating the placing on the market, and notifies the general public over the Internet site. Before taking such a decision, the Minister offers the authorization holder the opportunity to give his comments verbally or in writing, except in duly justified cases of extreme urgency. The competent authority notifies the Biosafety Advisory Council, the European Commission and the other Member States of the actions that have been taken and states the reasons for the decision. The competent authority is responsible for the Community procedure intended to take a decision regarding a modification or withdrawal of the conditions of authorization. For this purpose it shall, where appropriate, request the opinion of the Biosafety Advisory Council (Art. 42).

*d) The public is informed* chiefly over the *official Internet sites* (Art. 11), more particularly the Internet site of the competent authority which forms part of the general site of the Federal Department of Health, Food Chain Safety and Environment, the Internet site of the SBB, the Internet site of the Biosafety Advisory Council, or the Internet site of the Supervisory Office (Art. 2, 21°). Within 5 days from the date of the letter confirming the admissibility of the notification, the competent authority organizes a *consultation of the public*. This consultation period lasts 30 days. During this period, the competent authority publishes the following information on the Internet site: the notification, except the confidential data; the summary of the notification and the information intended for the general public. In the case of clinical trials with human medicines, the publication on the Internet must not infringe privacy or medical secrecy. Except in the case of clinical trials, the competent authority sends a copy of the notification, except the confidential data, to the mayor of the municipality or municipalities where a deliberate release is planned. Immediately upon receipt of this notification, the mayor informs the general public by posting a "notice of consultation" at the town hall. This notice remains posted for the whole duration of the public consultation. Throughout the consultation period, the notification, except the confidential data, is accessible to the public during the opening hours of the town hall and at least once a week until 8 pm or on Saturday morning, in the place which the municipal authority has designated in the notice of consultation. The public can transmit its comments to the competent authority over the Internet site or by letter. Within 10 days following the public consultation, the competent authority informs the relevant federal Minister and the regional ministers of the observations made by the public and passes the observations in connection with biosafety on to the Biosafety Advisory Council (Art. 17). The Biosafety Advisory Council must investigate the comments by the public, and a summary is made of the public consultation as part of the decision report that is submitted to the competent Ministers (Art. 18(1)). Since the decision of the competent Ministers must be properly reasoned, it will also need to specify to what extent the comments of the public have been taken into consideration (Art. 18(3)). No later than one month after the decision, the following information is published on the Internet site: the opinions, decisions and amendments, and the reports of the competent authority and the supervisory office. The public can also consult the full

notification, except the confidential data, by simple request to the competent authority (Art. 21). Article 43 provides that the Minister, the regional Ministers, the Supervisory Office, the Biosafety Advisory Council and the SBB must not divulge to third parties any confidential information that was notified or exchanged under the Royal Decree or Directive 2001/18/EC; they must also protect intellectual property rights relating to the data received. The notifier may indicate the information in the notification, the disclosure of which might harm his competitive position and which should therefore be treated as confidential. Verifiable justification must be given in such cases. It is the competent authority which, after consultation with the notifier, decides which information will be kept confidential, and informs the notifier and the competent regional ministers of its decision. Article 43(4) provides that in no case the following information may be kept confidential: general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses; methods and plans for monitoring of the GMO or GMOs and for emergency response; health and environmental risk assessment and the opinions of the Biosafety Advisory Council. As was already said, confidential information will not be made public, but will form a separate attachment to the notification to which the competent authorities naturally do have access.

e) The decision on the notification, the withdrawal of an authorization and a provisional restriction or a provisional ban in the context of the safeguard clause are administrative legal acts that can be challenged by an action for annulment and an action for suspension before the *Council of State*. The Council of State carries out a legality review. This review not only involves testing such individual decisions against higher legal standards (European law, Constitution, statutes and Royal Decrees), but also against the formal obligation of justification and the principles of good government. Both substantive and formal aspects are concerned. Both natural and legal persons who can prove an interest can bring such an action within 60 days after they have been notified of the challenged decision. For the Council of State, the interest in question must be a personal, direct, positive and legitimate interest. There must always be an individualized connection between the applicant and the challenged legal act. The act in question must be prejudicial, in other words, it must cause a certain disadvantage to the person bringing the action. However, it can concern a minor material or even purely moral interest[22]. There is little doubt that the neighbouring residents or farmers of a test field have a sufficient interest. Public (e.g. municipal authority) or private legal entities (e.g. non-profit conservation organizations) can take action before the Council of State. In the latter case, it is examined whether the organization has the necessary authority to defend the collective interest which it has defined in its bylaws, in other words, whether it is sufficiently representative[23]. When the Council of State annuls a decision, the administrative procedure must be resumed and the administrative authority is bound by the judgment of the Council of State. Consequently, it will have to make sure that it does not commit the same breach again.
In the case of a manifest infringement or a serious risk of infringement of this legislation, an *action for suspension* may be brought before the President of the Court of First Instance. This can also be done by non-profit organizations which have been incorporated for at least three years and which can prove that there is an actual activity going on that corresponds to their corporate purpose and that this activity is connected with a collective environmental interest which they seek to protect. Individual citizens can indirectly also bring such an action, more

[22] E. DE PUE, L. LAVRYSEN and P. STRYCKERS, *o.c.*, 850.
[23] *Ibid.*, 893.

particularly "on behalf of the municipality", in the event that the municipal authority refuses to institute such an action[24].

f) Supervision rests with the above-mentioned supervisory bodies. The penalty provided for essentially consists of the right of the Minister to withdraw his or her consent. Such withdrawal can be resorted to if the conditions for obtaining the authorization are not or no longer satisfied, and no alternative settlement is arrived at between the holder of the authorization and the Minister or his representative, where appropriate after the opinion of the Biosafety Advisory Council has been sought. Authorization can also be withdrawn if incorrect or misleading information has been given, on the basis of which the authorization had been granted. Before withdrawing an authorization, the Minister offers the authorization holder the opportunity to give his comments verbally or in writing, except in duly justified cases of extreme urgency (Art. 24). Violations can be penalized by the criminal court with 1 month's to 2 years' imprisonment and a fine of 5,500 euros to 255,000 euros or, in case of non-prosecution, by the administrative authority with an administrative fine (Art. 132, Act of 20 July 1991) of at least 5,500 euros and up to 27,500 euros.

*4) Authorisation of the placing on the market of GMOs*
*a) Authorisations for GMOs other than food and feed: what about risk assessment, management and the concept of precaution? Is the benefit resulting from GMO use considered as a factor to be balanced against the expected risk? Does the risk assessment take into account that the GMO may be released under very different climatic and geographical conditions? Is the public involved? Do the authorities issue general authorisations, or do they restrict authorisations to specific climatic and geographical conditions? Are there third party rights of standing to challenge an authorisation?*
*b) Authorisations for GM Food and Feed under Regulation 1829/03:*
*a) What is the national practice in relation to the EC authorisation procedure? Are there national risk cultures expressed in the consultation procedure? How are transparency and participation dealt with?*
*b) Which is the legal standing in relation to the Commission authorization?*
*c) Role of the EFSA in providing the European scientific opinion on an application: should there not be a possibility for national scientific agencies, bodies etc. to comment on an application? Should EFSA be obliged to distribute that opinion together with its own opinion?*

a) The substance of the regulations dovetails on this point with what has been provided in Articles 12 to 24 of the Directive and the accompanying Annexes. The procedure involves public consultation. Article 32 provides that, in order to simplify the public consultation procedure organized by the European Commission, the competent authority should publish a summary of the notification on the Internet site as soon as the summary of the notification has been forwarded, along with information that is intended for the public. From the date of this publication, the public has 30 days in which to present observations to the European Commission, and the full notification, except the confidential data, can be consulted by simple request to the competent authority. Within five days after receipt of the observations made by the public, the competent authority informs the Minister of the observations by the

[24] *Ibid.*, 869-870.

public and passes the observations in connection with biosafety on to the Biosafety Advisory Council for an opinion. In delivering its opinion, the Biosafety Advisory Council must take into account the relevant observations of the public (Art. 31(3)). The Biosafety Advisory Council must also take into consideration the observations made by the other Member States, in accordance with the procedures for exchange of information. The relevant federal Ministers ultimately decide whether and under which conditions the GMO in question may be placed on the market, or whether the GMO must not be placed on the market. The decisions taken by the Ministers are administrative legal acts which may be challenged in court in the same way as decisions concerning deliberate release into the environment (see above under 3(e)).

So far, only one authorization has been granted, more particularly for the "commercial release of MS8, RF3 and MS8xRF3 oilseed rape", to Bayer Crop Science. The authorization has been given for import and processing for nutritional purposes; no authorization has been given for cultivation. Meanwhile, the EFSA has delivered a favourable opinion. The case is currently pending before the European Council because no qualified majority was reached in the Regulatory Committee[25].

b)

aa) The Regulation is enforced by the same authorities as those that intervene in the national procedures. The websites show the applications for authorization and the public consultations and inquiries under way by a link to the European website. The opinions of the Biosafety Advisory Council are published on its own website. So far, two opinions have been delivered with regard to notifications by *Monsanto* (one British and one Belgian)[26].

bb) Decisions of the European Commission fall outside the jurisdiction of the Belgian courts. Such decisions can only be challenged before the European law courts under the conditions set out in Article 230(4) of the EC Treaty. As is known, the Court of Justice upholds in this matter a very strict interpretation of the criterion "of direct and individual concern". The matter can also arise before a national court of law. That Court must then of course refer the case to the European Court of justice for a preliminary ruling of the validity of the decision of the European Community.

c) The Regulation provides that the EFSA may ask the appropriate food assessment body of a Member State or a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out assessments (Art. 6(3)(b) and (c)). The national competent authority receives the applications for authorization and the EFSA informs the European Commission and the other Member States of the applications (Art. 5(2)(a) and (b)). Although the Regulation does not say so in so many words, the purpose of those notifications could not be other than to allow the competent authorities to express their views on the matter during the course of the procedure, either in the form of an opinion to the EFSA, or through the public consultation procedure, or by taking part in the Committee referred to in Article 35. In practice, the Belgian Biosafety Advisory Council delivers an opinion. So far, the Biosafety

[25] http://www.biosafety.be/gmcropff/EN/TP/SBB_NotificationC_BE_96_01.html
[26] http://www.bio-council.be/bac_proc_out.html#A1

Advisory Council and the Service of Biosafety and Biotechnology have evaluated five EFSA dossiers: one Belgian, three British and one Danish.
The Regulation can still be improved on this point by explicitly providing for the possible participation of national scientific institutions in the preparation of the opinion of the EFSA and by obliging the EFSA to incorporate in an attachment to its own opinion the opinions it has received.
On 11 May 2006, the Biosafety Advisory Council delivered an opinion on the problems in the procedure and made the following suggestions:
" *–The applicant and EFSA should address more explicitly potential long-term effects and biodiversity issues in their risk assessments, underpinned by the necessary expertise in the EFSA GMO Panel;*
*- The current guidance notes developed by EFS should be completed with guidance summarising for the applicants some generally recognised valid research protocols whereas allowing at the same time flexibility and rapid adaptation to new scientific knowledge; the statistical protocol for data analyses should be provided;*
*- The EFSAnet should be practically improved in order to facilitate the download, the use and the upload of information by the national scientific bodies;*
*- Interaction between the EFSA GMO panel and national experts should be improved in a realistic way with a view to resolving possible diverging scientific opinions between EFSA and Member States, in a collective, interactive and iterative learning process with continuous feed backs;*
*- The scientific opinions of the EFSA GMO panel should be written according to scientific standards, providing detailed scientific justification and addressing, when relevant, scientific uncertainties;*
*- The public should be better informed through comprehensible and easy accessible information;*
*- Each proposal should be based on scientific arguments."*[27]

*5) Coexistence:*
*a) What have MS done in order to protect non-GM agriculture/processing/trade/consumption? Focus on GM free zones, coordination of agricultural practices, liability, implementation of art. 31(3) of Dir. 2001/18*
*b) Have MS established a scheme ensuring GM free zones? How does the special impact assessment based on Art. 6(3) Habitats Dir. work?*

a) The Belgian authorizations of field experiments usually impose a minimum distance between the test fields and GM-free fields. The Royal Decree of 21 February 2005 provides that the notification of a deliberate release for other purposes than placing on the market must contain a signed declaration of *civil liability* (Art. 13(1)(f)). This declaration reads: *"I, the undersigned notifier,…, hereby assume full civil liability for any damage caused to human and animal health, property or the environment as a result of the tests"*. The scope of this clause, however, is limited. It does not alter the common fault liability for damage that is based on Article 1382 of the Civil Code. At most, it may cause the liability for damage to be

[27] Opinion of 15 May 2006 by the Belgian Biosafety Advisory Council on the procedures followed by the European Food Safety Authority (EFSA) for the scientific evaluation and the risk assessment of genetically modified organisms (GMO) for food and feed use and on the European decision rules pertaining to the marketing authorisations given to these GMOs (English - ref. BAC_2006_SC_375), http://www.bio-council.be/docs/BAC_2006_SC_375.pdf

channelled to the notifier. Article 31(3) of Directive 2001/18/EC is implemented through the public registers on the *Belgian Biosafety Server*.

b) In Belgium there is no policy aimed at establishing GM-free zones. In the Flemish Region, the correct transposition of Article 6 of the Habitats Directive remains problematic. Whereas Article 6(3) and 6(4) of the Habitats Directive speaks of "any plan or project", Article 36c(3) of the Decree of 21 October 1997 (the so-called "Habitat Test") speaks of "a licensable activity […] a plan or programme". The concept of "licensable activity" is defined as "an activity for which a licence, permit or authorisation is required by law, decree or decision". A "plan or programme" is "a document in which policy intentions, policy developments or large-scale public, private or mixed activities are announced and which is drawn up and established, amended or reviewed on the initiative or under the supervision of the Flemish Region, the provinces, the public utilities, the intermunicipal partnerships and/or municipal authorities, and/or of the federal government, or for which co-financing is available from the European Community or the Flemish Region or the Flemish Community in the context of international cooperation, insofar as the intended plan or programme is likely to have a significant environmental or safety impact on the territory of the Flemish Region". Some authors believe that gaps would arise in the arrangement due to the fact that a plan or programme refers more to large-scale affairs. Furthermore, plans which fall between the two concepts, such as development plans or management plans, would not be covered by the arrangement, and wrongly so. In addition, not all interferences in the protected areas are licensable. A similar problem arises in the Walloon Region, where the law speaks of "any plan or project for which a licence is required" (Art. 29(2) of the Act of 12 July 1973). There can be no doubt, however, that an application for authorization of field experiments in the Birds and Habitats areas or that could have an adverse impact on such areas will have to undergo an appropriate assessment in accordance with the respective regional legislation implementing the Habitats Directive.

*6) How GMO traceability and labelling issues are dealt with in the Member States' legislation (Reg. 1829/2003, Dir. 2001/18, Reg. 1830/03)? Do national systems of verification exist? How do they work? Which are the penalties introduced by national legislators?*

So far, no additional laws or regulations have been adopted at the national level with a view to the implementation of Regulations 1829/2003 and 1830/2003. Inspection is carried out by the *Federal Agency for the Safety of the Food Chain*[28]. No penalties have been reported so far.

*7) How are Member States implementing Directive 2004/35/EC on Environmental Liability with specific reference to GMOs?*

Although preliminary studies have been carried out with respect to the transposition of Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, the requisite transposition legislation at the federal and regional levels is still in full

[28] http://www.afsca.be/

preparation. In a competence review[29] carried out in the context of the Impact Study of the Directive on Liability for Environmental Damage (I.R.A.M.)[30], it was investigated to what extent the Directive should be transposed at the federal or the regional level, more particularly also insofar as GMO-related activities are concerned.

[29] R. SLABBINCK, S. DE LODDERE and L. LAVRYSEN, "Bevoegdheidsonderzoek" in H. BOCKEN, L. LAVRYSEN, G. VAN HOORICK, F. MAES, R. SLABBINCK, G. GONSAELES, T. VAN NIEUWERBURG, L. GOETHALS*, Impactstudie richtlijn aansprakelijkheid milieuschade (I.R.A.M.): voorbereiding van de omzetting van EG Richtlijn Milieuschade*, Ghent , University of Ghent , 2005, 292 p. + annexes

[30] http://www.mina.be/front.cgi?s_id=802