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Report[1] on Section II.D "P*olicies and regulations in Belgium with regard to genetic technology and food security"*

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1. General introduction[6]

1.1. Use of GMO in food production

Imported GMOs are generally used to make compound feed stuffs that are fed to livestock. About 80% of compound feed stuffs contain GMOs[7]. There is currently no cultivation of GMOs in Belgium, mainly because there are no GM crops approved for cultivation that are relevant for Belgian agriculture. The different regions in Belgium have a different approach to the use of GMOs in agriculture. The Walloon and Brussels-Capital Region have implemented co-existence regulations that are meant to discourage the cultivation of GM crops[8][9]. In their vision, the use of GM crops is not compatible with the agriculture that they wish to promote[10]. In the Flemish region a different approach is taken. The Flemish government does not stimulate the use of GM crops, but is of the opinion that GM crops that are proven to be safe and have a market authorization should be available for farmers to allow a free choice. The co-existence legislation in Flanders neither encourages nor discourages the use of GM crops, but is built to enable that freedom of choice.

Overall, the public opinion in Belgium about the use of GMOs in food production is not negative, be it that in the Walloon Region it may be less positive than in the Flemish Region. A survey held by EOS magazine and a recent survey among students of Ghent University showed a rather positive attitude towards the use of certain GMOs in food production. There is however also a strong minority opinion against GMOs that attracts quite some attention.

1.2. Food security

There is no legal definition of food/feed security in Belgium, but in a White Book about Agriculture of Flanders, the crisis in food security is mentioned as one of the important external developments that need to shape agricultural research[11].

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[1] This report follows the structure of the questionnaire set out by the coordinators if this section of the Conference.

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[6] See on the general political and societal background of GMO regulation in Belgium: N. SCHIFFINO & F. VARONE, *Régulation publique des biotechnologies. Biomédecine et OGM agroalimentaires en Belgique et en France*, Gent, Academia Press, 2005, xii+ 299 pp.

[7] Data BEMEFA

[8] http://environnement.wallonie.be/legis/agriculture/qualite/qualite062.htm

[9] http://environnement.wallonie.be/legis/biosecurite/bioogm005.htm

[10] http://www.apaqw.be/

[11] http://lv.vlaanderen.be/nlapps/data/docattachments/Witboek_landb_2009_web_def.pdf

1.3. Outline of the regulatory framework relevant to biosafety.

General

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))[12] and, to a large extent, for *agricultural policy.* However, in some areas 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.[13] Requirements relating to environmental protection that 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[14]. 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).

GMO regulation

As with all EU countries, the regulations for GMOs are to a large extent dictated by the EU regulatory framework for GMOs.

The implementation of the relevant European Directives concerning GMOs and the application of the related Regulations in Belgium is a mixed competence between the regions and the Federal Government.

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[15], is a task for the *federal authorities* in as far as it deals with the "placing on the market of genetically modified organisms as or in products within the Community" (Art. 1, second indent). The regional authorities are involved as far 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" (Art. 5-11). Regional competencies are e.g. involved in the authorisation of field experiments, because there may be risks to their environment and biodiversity.

The implementation of Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 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

[12] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *Milieuzakboekje 2013,* Wolters Kluwer Belgium, Mechelen, 2013, p. 20-27.
[13] D. MISONNE et al., *Legal constraints on national measures to promote environment-friendly products,* Brussels, Belgian Science Policy, 2004, p. 13.
[14] *Ibid*., p. 14.
[15] W. XIANG, *Risk Governance of GMOs in the EU and China*, Dissertation, Ghent University, 2013, p. 118-121.

installations" that require a regional environmental permit. 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 potentially noxious installations, for example, by a system of notifications and licence requirements, and in some cases more modern instruments, such as environmental impact assessment and safety reports. This competence comprises both preventive supervision (licences, standards) and curative supervision (e.g., safety measures).

The decisions made by different administrative bodies are based on a common scientific evaluation system comprising the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB). The BAC must be consulted for the deliberate release of GMOs in the environment and the placing on the market of all GMOs and GMOs-based products; the SBB on contained use activities with GMOs and pathogens. The Council can be consulted by the Regions or the SBB for contained use activities. More information is available on the website of the Biosafety Advisory Council[16].

Federal competencies are involved as well, however, as Article 13 deals with emergency plans for such premises. The 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.

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*[17] 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, and Regulation (EC) N° 1946/2003 of the European Parliament and of the Council of 15 July 2003 on *transboundary movements of genetically modified organisms*.

Given this historically grown 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[18]:

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*[19], 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 *Biosafety and*

[16] http://www.bio-council.be/
[17] W. XIANG, *op. cit.*, p. 121- 125.
[18] More information can be found on the following website: http://www.biosafety.be/
[19] 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/

Biotechnology Unit SBB) of the Scientific Institute of Public Health (WIV-ISP). The SBB is composed of an administrative secretariat, and a multidisciplinary group of scientists.

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*[20]. This Royal Decree transposes Directive 2001/18/EC (territory covered: the whole of Belgium). This Royal Decree was adopted with some delay[21]. This delay was mainly due to disagreement on the way in which the Directive was to be transposed into Belgian law. The Minister of Consumer Affairs, Public Health and the Environment 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*[22] besides the required health environmental risk assessment. The government at the time was unable to reach an agreement on that point. The following government, without the Green parties, subsequently decided to drop this part and published the Royal Decree of 21 February 2005. A Royal Decree of 3 August 2007[23] transposes, as the deliberate release into the environment, the transport and placing on the market of genetically modified organisms is concerned, the relevant provisions of Directive 2004/25/EC on *environmental liability with regard to the prevention and remedying of environmental damage*[24].

c) The following *Regional legislation on the contained use of GMOs and pathogens* have been adopted:
- *Flemish Region*: Decree of 28 June 1985 on environmental licences (in particular Articles 19c and 22b); Regulation 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); Regulation of the Flemish Government of 1 June 1995 on general and sectorial 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 Regulation of 4 July 2002 establishing the sectorial and integral conditions for the contained use of genetically modified or pathogenic organisms;
- *Brussels-Capital Region*: Ordinance of 5 June 1997 on environmental licences; Regulation 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.

d) 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.

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[20] *Belgian Official Journal*, 24 February 2005.
[21] Belgium has in fact been condemned by the European Court of Justice for delays in the transposition of the Directive into domestic law: CJEU, C-417/30, 30 September 2004, *Commission v. Belgium.*
[22] The Federal Council for Sustainable Development, a multi-stakeholder advisory council, was also divided on this issue. While the representatives of environmental groups and development cooperation 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
[23] *Belgian Official Journal*, 20 September 2007.
[24] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.,* p. 804-805

2. Regulatory mechanisms in GMO regulation

Various regulatory mechanisms apply, depending on the application:

- Contained use of GMOs
- Deliberate release of GMOs into the environment – placing on the market for cultivation
- GMOs in Food and Feed

2.1. Contained use of GMOs

As mentioned before, in the 3 regions the contained use of GMOs is subject to the respective (regional) *environmental notification and permit systems*. In Belgium there are over 400 facilities that are approved for contained use with GMOs and/or pathogens.

In the Flemish Region e.g. *establishments* in which organisms are genetically modified or where such organisms are grown, stored, transported, destroyed, discarded or otherwise used need an environmental permit or notification. Depending on de risk level of the activities concerned, they need prior notification with the municipal government (risk level 1) or a permit of the provincial government (risk levels 2 to 4). Apart from that, for *each new contained use* of GMOs a prior notification and in some cases a consent is needed on the basis of a public notification dossier and a technical dossier, containing a risk analysis that will be assessed by the *Biosafety and Biotechnology Unit (SBB)* of the Scientific Institute of Public Health (WIV-ISP). The content of the dossiers varies according to the safety level of the planned contained use. SBB will deliver an opinion to the competent authority, being the Environmental Permitting Division of the Department for the Environment, Nature and Energy of the Flemish Region that will decide on the application. The contained use can start the day after the consent is delivered or notification has been done, depending on the risk level of the contained use. The competent authority will determine, according the risk level, the general and specific containment and protection measures on the basis of the ALARA-Principle. The approach is based on Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms. A General Regulation of the Flemish Government (Chapter 5.51 VLAREM II) determines the general conditions under which the activities can take place25. Similar provisions apply in the other regions.

Similar procedures apply in the Walloon Region and the Brussels Capital Region[26].

Safety of workers is regulated on the federal level by the Royal Decree of August 4, 1996 concerning the protection of works from risks related to exposure to biological agents at work, as amended several times. It implements Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. It is also based on risk assessment and 4 different risk levels.

2.2 Deliberate release into the environment and placing on the market of GMOs

2.2.1. Legal framework

The deliberate release of GMOs into the environment and the marketing of GMOs and products that contain GMOs, has been regulated on the *federal level*, based on the articles 132-132d of the Federal Act of 20 July 1991, by the Royal Decree of 21 February 2005 regulating the *deliberate release into*

[25] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.,* p. 806-811.
[26] http://www.biosafety.be/CU/EN/ProceduresRWEN.html and http://www.biosafety.be/CU/EN/ProceduresRBEN.html

the environment and placing on the market of genetically modified organisms as or in products[27]. This Royal Decree transposes 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,* as well as Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products and Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market.

2.2.2. Precautionary Principle

As 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[28]. Both the deliberate release of GMOs and placing on the market of GMOs 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. This assessment must be conducted according to the nature of the organism introduced, the intended use and the receiving environment. Annex III imposes more specific requirements in this connection.

2.2.3. Notification and Assessment

In the standard procedure under the Royal Decree of 21 February 2005[29], the notification dossier must be submitted to the *Federal Department of Health, Food Chain Safety and Environment*[30]. This authority investigates, together with the *Biosafety and Biotechnology Unit (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 *competent minister of the region where the deliberate release will be conducted* and to the *Biosafety Advisory Council*. At the same moment also a public consultation starts that lasts for a month. Both the deliberate

[27] The applications for approval are subject to administrative fees: Art. 5 of the Royal Decree of 13 November 2011. The Royal Decree has for its legal basis Articles 132a – 132d of the Act of 20 July 1991, which contains also the provisions concerning supervision and penalties: E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.,* p. 801 and 806.

[28] 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.

[29] Articles 15 to 18 of Directive 2001/18/EC and the Royal Decree of 21 February 2005; 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).

[30] 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)

release of GMOs and placing on the market of GMOs as or in products are subject prior to the 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.

In case of a notification for a field trial, 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 ~~or~~ takes into consideration comments 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[31]. The competent regional Minister has a veto-right and can block the authorization of the release. 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 proposed release does not comply with the conditions stipulated by the Royal Decree of 21 February 2005, the application for authorization will be refused.

2.2.4.Monitoring

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. The Minister ensures that emergency measures are taken if a serious risk occurs, such as suspending or terminating the placing on the market, and notifies the general public through 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.

New information/Safeguard clause

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 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

[31] 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.

on “its territory” (this probably means the Belgian territory). The competent authority is responsible for the EU 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).

2.2.5 Public Participation in case of a field trial

The public is informed on a request for authorisation for deliberate release of a GMO, i.e. field trial, mainly through the *official Internet sites* (Art. 11), which forms part of the general site of the Federal Department of Health, Food Chain Safety and Environment. 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. Other than 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.

2.2.6. Public participation in case of requests for authorisation of the placing on the market of GMOs

The substance of the regulations dovetails on this point with what has been provided in Articles 12 to 24 of the Directive 2001/18/EC 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 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 any 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 Belgian Government agrees/disagrees in the EU voting procedure that the GMO in question may be placed on the market.

2.2.7. Judicial review

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[32]. 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[33]. 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 particularly “on behalf of the municipality”, in the event that the municipal authority refuses to institute such an action[34].

[32] E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, p. 850.
[33] *Ibid.*, p. 893.
[34] *Ibid.*, p. 869-870.

2.2.8 Practical experiences

An overview of concluded and ongoing procedures of notifications of activities with GMOs can be found on the website of the Belgian Biosafety Advisory Council[35].

For concluded procedures, the website provides details and further links to, inter alia:

- Notifications for deliberate release of GMO's (GM plants and other) for any other purpose than for placing on the market
- Notifications for transgenic plants to be placed on the EU market under Directive 2001/18/EC - Part C
- Notifications submitted under Regulation (EC) N° 1829/2003 on genetically modified food and feed
- Notifications submitted under the Novel Food Regulation (EC) N° 258/97

There have been quite a number of notifications for deliberate release of GMOs in Belgium for purposes other than placing on the market. These concerned mainly field trials with GM plants and clinical trials with GMOs other than plants.

So far, only one authorization has been granted through Belgium for the placing on the market of GMOs, 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. The decision was delivered by the European Commission, because no qualified majority was reached at the Regulatory Committee and at the Council level.

2.2.9. Coexistence and GMO-free zones

In both the Flemish and Walloon Region a general legal framework on *coexistence of genetic modified cultures with conventional and organic cultures* has been adopted in view of the implementation of article 26a of Directive 2001/18/EC (as amended by Directive 2008/27/EC).

The Decree of 3 April 2009 of the *Flemish Region*[36], which is applicable to all cultures of GMOs in that region that would be authorised in the framework of Directive 2001/18/EC, aims to ensure the free choice of farmers between GMO, conventional and organic cultures and to avoid economic losses for conventional and organic cultures due to unintended presence of GMOs above the EU threshold value for labelling. It obliges farmers (and their contractors) who intend to cultivate GMOs to follow a specific training. They have to notify in advance the Flemish authorities and neighbouring farmers of that intention. These neighbouring farmers can object to the intended culture on the basis of a reasoned proper economic interest. The farmers who cultivate GMOs have to contribute to a Public Fund for compensation of economic losses. A Coexistence Commission, composed of representatives of various administrations and scientific experts, has to assess the objections from neighbouring farmers and the applications for compensation. All cultures of GMOs are registered in a public register. On the basis of this Decree, the Flemish Government has adopted some general rules concerning coexistence[37], as well as rules specific for maize, potatoes and sugar beet[38].

[35] http://www.bio-council.be/bac_proc_in.html
[36] *Belgian Official Journal,* 4 May 2009.
[37] B.Vl.Reg. van 15 oktober 2010 houdende de vaststelling van algemene maatregelen voor de co-existentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen, *BS* 30 November 2010.

In the *Walloon Region*, the Decree of 19 June 2008 addresses co-existence. The Executive Order of the Walloon Government, implementing the Decree[39], provides for the possibility to establish *GMO-free zones*. Such a zone consists of arable land of at least 3 farmers and covering at least 150 hectares. The concerned farmers may introduce a demand for the instauration of such a zone, and when approved, with limitations on GMO cultivation for adjacent land as a consequence[40]. Apart from that it has been suggested that 124 municipalities and the Walloon Region have declared themselves GMO-free . Such declarations have no legal consequences.

A comparison between the various systems shows that the specific rules for crops are much more stringent in the Walloon region than in Flanders. For instance the isolation distance for GM maize is in Flanders 50 meters, where in Wallonia it is 600 meters, de facto making GM maize cultivation very virtually impossible. There is also a big difference in the intent with which the Flemish and Walloon coexistence legislation was written. See „general information".

In January 2014, the region of Brussels proposed draft legislation that the around 260 hectares of agricultural land in the Brussels region will be GMO free, with reference to the costs of co-existence measures.

2.3. GMO in food production

2.3.1 Regulation (EC) No 1829/2003

This matter is regulated on the EU level by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on *genetically modified food and feed*. This Regulation provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market. It lays down EU procedures for the authorisation and supervision of genetically modified food and feed provisions for the labelling of genetically modified food and feed (Art. 1). Chapter II deals with the authorisation, supervision and labelling of genetically modified food, while chapter III does the same for genetically modified feed. Chapter IV contains common provisions for both applications.

2.3.2. Co-operation between national and EU bodies

The industrial operator can submit his application in accordance with this Regulation for all food products containing GMOs in compliance with the provisions provided for by Directive 2001/18/EC on the deliberate release of GMOs into the environment. The industrial operator can submit a single application for food and feed uses and for cultivation. This means that a GMO that has obtained authorisation can be used not only in food and animal feed but also for cultivation or deliberate release into the environment. Once the application has been made by an industrial operator, the receiving national authority concerned acknowledges receipt in writing within 14 days and informs

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[38] B.Vl.Reg. van 15 oktober 2010 houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde maïsgewassen met conventionele maïsgewassen en biologische maïsgewassen, *BS* 30 November 2010; B.Vl.Reg. van 10 november 2011 houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde aardappelgewassen met conventionele aardappelgewassen en biologische aardappelgewassen, *BS* 23 December 2011; B.Vl.Reg. van 10 november 2011 houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde suikerbieten met conventionele suikerbieten en biologische suikerbieten, *BS* 23 December 2011.

[39] A.G.w. du 7 mars 2009 relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques, *BS* 27 March 2009.

[40] Art. 30 and 31.

the European Food Safety Authority (EFSA), which is responsible for risk assessment in the food sector. The latter has 6 months in which to conduct this assessment. The Commission is responsible for risk management. On the basis of the risk assessment carried out by the EFSA, the Commission draws up within 3 months a draft decision accepting or rejecting the application. It then submits this draft to the Standing Committee on the Food Chain and Animal Health. If this committee accepts the proposal, it is finally adopted by the Commission; if it does not, the proposal is assessed by an appeal committee (NB: In the new comitology procedure, the Council of Ministers is replaced by an appeal committee. The difference between the Standing committee and the appeal committee is that the first is populated with member state ‚experts', where the second is populated with member state ‚diplomats'.). If the latter does not reach a position within three months or if it is unable to reach a qualified majority for or against, the Commission may adopt its proposal. The marketing authorisation is given for a period of maximum 10 years and is renewable.

2.3.3 Enforcement

The Regulation is in Belgium 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, more than fifty opinions have been delivered with regard to EU applications[41]. Decisions of the European Commission fall outside the jurisdiction of the Belgian courts. Such decisions can only be challenged before the EU Courts (General Court or Court of Justice) under the conditions set out in Article 263(4) of the TFEU. As is known, the Court of Justice upholds in this matter a very strict interpretation of the criterion "of direct and individual concern". It has to be seen if under the new additional criterion "a regulatory act which is of direct concern to them and does not entail implementing measures" Commission decisions such as resulting from the Regulation, can be challenged by interested parties. 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 on the validity of the decision of the European Commission (art. 267 TFEU).

2.3.4. Role of Belgian Biosafety Advisory Council

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)). In case the application covers cultivation, EFSA must consult a MS. Belgium has received a mandate from EFSA for the evaluation of 4 cultivation applications.

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 applications 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. It is current practice that all member states' biosafety advisory bodies participate in commenting to a dossier, before the EFSA opinion is formed. EFSA consults the member states. This means that in Europe more than 200 people are actively involved in assessing a dossier. In Belgium the Biosafety Advisory Council provides a formal advice after the EFSA GMO panel has formulated its opinion.

[41] http://www.bio-council.be/bac_proc_out.html#A1

2.3.5 Thresholds

A threshold value is referred to in Regulation (EC) No 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*. This Regulation covers all products which consist of GMOs or which contain (processed) products from GMOs(this includes fields as diverse as the products, which are intended for entry into the human or animal food chain, products destined for industrial processing for uses other than consumption (e.g. in the production of biofuel) or even products destined to be used ornamentally (e.g. in the production of cut flowers)) and foodstuffs and animal feed products made from GMOs. All the products covered by this Regulation are subject to compulsory labelling, which shall enable consumers to be better informed and will offer them the freedom to choose to buy products consisting of, containing or made from GMOs. Traceability enables GMOs and their products to be traced throughout the production chain. This system is based on the transmission and holding of information by each operator. All food or feed products, including those intended directly for processing are subject to the labelling obligation when they consist, contain or are made from GMOs. *Only traces of approved GMOs are exempt from this obligation if the ingredients do not exceed the threshold of 0.9 % and if their presence is adventitious and technically unavoidable*. The Member States carry out measures for the inspection and monitoring of products, including sampling and quantitative and qualitative analyses of food and feed. These measures entail the Member States being able to withdraw from the market a product that does not meet the conditions laid down in this Regulation. So far, no additional laws or regulations have been adopted at the national level with a view to the implementation of Regulation 1830/2003. Inspection is carried out by the *Federal Agency for the Safety of the Food Chain.*

2.3.6. Implementation and enforcement, controlling regime

Supervision of compliance with the conditions of authorizations 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. They have broad supervising powers, including the power to take safety measures (Art. 132a of the Act of 20 July 1991, as amended by the Act of 1 March 2007). The penalty provided for essentially consists of the right of the Minister to withdraw the 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 of the Royal Decree of 25 February 2005). Violations can be penalized by the criminal court with 1 month's to 8 years' imprisonment and a fine of 6,000 euros to 60,000,000 euros or, in case of non-prosecution, by the administrative authority with an administrative fine of at least 6,000 euros and up to 30,000 euros (Art. 132c and 132d of the Act of 20 July 1991, as amended by the Act of 1 March 2007). Inspection of Regulations 1829/2003 and 1830/2003 is carried out by the *Federal Agency for the Safety of the Food Chain*[42].

[42] http://www.afsca.be/home-en/

3. Labelling

3.1. Labelling regime

Apart from the provisions laid down in Regulation (EC) No 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.* According to Art. 11 of that Regulation Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them. No specific national rules in this respect have been adopted. However general labelling requirements are laid down in different Articles of the Royal Decree of 21 February 2005, and those provisions are subject to the sanction provisions of the Act of 20 July 1991 and the various sectorial Acts governing specific categories of goods, products or materials (Art. 49 of the Royal Decree).

3.2. Legislation addressing labelling fraud

When the labelling requirements provided for by the Royal Decree of 21 February 2005 are not observed, the sanctions of the Act of 20 July 1991, provided for in Art. 132b, apply. The competent inspectors can also seize or confiscate GMOs and products containing GMOs that are not in conformity with the regulations (Art. 132a). Similar powers are given under the Act of 24 January 1977 protecting the health of consumers with regard to food stuff and other products and under the Act of 21 December 1998 concerning product standards promoting sustainable production and consumption patterns and protecting the environment, public health and the workers. Articles 10 and 11 of the Act of 6 April 2010 concerning market practices and consumer protection contain general provisions on labelling. It contains also a section on unfair commercial practices inspired by Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market[43]. A practice is misleading if it contains false or untrue information or is likely to deceive the consumer. Unfair commercial practices can be combatted trough an action for cessation. The articles 110-118 of the Act of 6 April 2010 organise a private enforcement remedy through injunctive relief. The range of parties entitled to institute proceedings for infringement of any provisions of the act is very broad: the parties concerned the Minister of Economic Affairs, the Director-General of DG Enforcement and Mediation, trade organisations and consumer organisations. The President of the Commercial Court may order the cessation or the prohibition of any breach of the Act. In addition, the President can order that the judgement or a corrective statement should be published. Art. 123 of The Act establish an administrative warning procedure. Warnings may be issued by the Minister or the officials designated by the Minister, requesting that the undertaking concerned cease the infringement. The infringer may undertake to cease the infringement, and, where appropriate, that undertaking may be published. If the infringer dies not obey, the Minister of Director-General may initiate legal action for a cease and desist order, a settlement can be made or criminal enforcement can be started[44]

[43] B. KEIRSBILCK, *The New European Law of Unfair Commercial Practices and Competition Law*, Oxford and Portland, Hart Publishing, 2011, 702 p.
[44] B. KEIRSBILCK, *op. cit.*, 455-457.

4. Liability

4.1. Genetic technology

As *civil liability* for damage against persons, goods or economic interests is concerned, there is no specific legislation on liability for GMO-related activities. The general fault based liability of Art. 1382 of the Civil Code is applicable. A breach of a statutory duty (including duties imposed by GMOs legislation) or the general duty of care qualifies as a fault. Compensation for personal injury, direct property damage and the ensuing economic losses, is possible, provided that a causal link can be proven between these damages and the fault[45]. Pure ecological damage is not covered. However, 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 is limited. It does not alter the common fault liability for damage that is based on Article 1382 of the Civil Code[46]. At most, it may cause the liability for damage to be channelled to the notifier.

As indicated above, in the Walloon and Flemish regional legislation on co-existence there is an obligation of farmers who cultivate GMOs to compensate the economic losses that may be caused to conventional or organic cultures, including the obligation to buy the harvest that cannot be placed on the market because of (involuntary) admixture. The GMO farmers have to pay a contribution to a Fund that will compensate for the economic losses .

As *liability under public law* is concerned, the federal and regional legislation, adopted in view of the implementation of Directive 2004/35/CE 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*, is relevant[47]. De federal legislation – the Royal Decree of 3 August 2007[48] – is applicable for environmental damage that is caused by the deliberate release into the environment, the transport and placing on the market of GMOs. The regional legislation[49] is applicable when environmental damage is caused by any contained use, including transport, involving genetically modified micro-organisms. The purpose of the Environmental Liability Directive ("ELD"), and the Belgian legislation that transpose it, is to establish a so called 'administrative' framework of environmental liability, based on the "polluter-pays" principle, to prevent and remedy environmental damage, via a public law approach. The ELD aims at ensuring that the financial consequences of certain types of harm

[45] B.A. KOCH, "General Report" in B.A. KOCH (ed.), *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops. Reports*, April 2007, 45-53, http://ec.europa.eu/agriculture/analysis/external/liability_gmo/full_text_en.pdf; V. WILCOX, "Summaries of the Country Reports" in B.A. KOCH, *op. cit.,* p. 129 ; B. DUBBUISSON & G. GATHEM, "Belgium" in B.A. KOCH (ed.), *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops. Annex I. Country Reports*, April 2007, p. 32 – 50, http://ec.europa.eu/agriculture/analysis/external/liability_gmo/annex1.pdf

[46] B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 33.

[47] B. DUBBUISSON & G. GATHEM, *loc. cit.,* p. 33; W. XIANG, *op. cit.*, p. 175-182.

[48] Royal Decree of 3 August 2007 concerning prevention and remedying of environmental damage due to the placing on the market of GMOs and products containing GMOs, *Belgian Official Journal,* 20 September 2007.

[49] *Brussels Capital Region*: Ordinance of 13 November 2008 on environmental liability with regard to the prevention and remedying of environmental damage, *Belgian Official Journal*, 14 November 2008; *Flemish Region:* Decree of 21 December 2007 supplementing the Decree of 5 April 1995 containing general provisions concerning environmental policy with a Title VX Environmental Damage, transposing Directive 2004/35/EC, *Belgian Official Journal*, 12 February 2008; *Walloon Region*: Decree of 22 November 2007, amending Book I of the Environmental Code with regard to the prevention and remediation of environmental damage, *Belgian Official Journal*, 19 December 2007; E. DE PUE, L. LAVRYSEN & P. STRYCKERS, *op. cit.*, 123-142.

caused to the environment will be borne by the economic operator who caused this harm. The competent authorities shall ensure the effective implementation and enforcement of the ELD. They are for instance, in charge of specific tasks such as assessing the significance of the damage and determining which remedial measures should be taken (in co-operation with the liable operator). An operator is any natural or legal, private or public person who operates or controls the damaging occupational activity, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity. However, due to the definition and the thresholds provided for in the definition of environmental damage, it is not likely that GMOs related activities will cause damage in the sense of the ELD.

4.2. Product liability

The Act of 25 February 1991 on the liability for products with defects[50] implements directive 85/374/EEC of 25July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. GMOs, including 'primary agricultural products'[51], and products containing them, can fall under the scope of this piece of legislation if damage is caused by product that is defective. A product is understood to be defective "*when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation*"[52]. The strict liability system - channelled to the producer and provided that none of the defences is applicable - covers only (a) damage caused by death or by personal injuries; (b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 EUR, provided that the item of property: (i) is of a type ordinarily intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption[53].

[50] *Belgian Official Journal,* 22 March 1991.

[51] B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 40. The Belgian Act has not implemented the exception of *"primary agricultural products and game"* being *" the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing*" provided for in directive 85/374/EEC. The exception, provided initially in the Belgian Act, was deleted by the Act of 4 December 2000.

[52] A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation; B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 35.

[53] B.A. KOCH, *loc. cit.*, 55-56; V. WILCOX, *loc. cit.*, p. 130; B. DUBBUISSON & G. GATHEM, *loc. cit.*, p. 39 - 40.

5. Discussion

Returning to the overall topic of this report and the underlying conference, "Policies and regulations with regard to genetic technology and food security", the authors offer the following general observations.

As for all EU countries, regulation of genetic modification and of GMOs in Belgium is to a large extent shaped by the EU regulatory framework for GMOs.

The regulatory situation for GMOs in the EU knows some complexities:

- The EU regulatory framework entails Directives, Regulations, Decisions and Guidelines, each with their own objective, scope and legal basis (for example, Directive 2009/41/EC is an 'environmental protection' directive, whereas Directive 2001/18/EC is an 'internal market' directive);
- Some decisions within this framework are collective decisions, in which the Member States, EFSA and the European Commission play a role.
- The implementation on the national level, involves in many Member States various governmental levels, ranging from the national or federal level, via regional or provincial levels, to local levels. Belgium is a good example of this, whereby there is a division in competencies between the federal government and the regions[54].

As of the second half of the 90s, the part of the regulatory system addressing placing the market of GMO products, started to stagnate, and consequently the EU Member States and Institutions have revised the regulatory framework in various steps, such as:

- Directive 2001/18/EC – amendments of the original Directive on Release into the Environment
- Adoption of the Regulation (EC) N° 1829/2003 (genetically modified food and feed), and 1830/2003 (traceability and labelling)
- Adoption of Commission Implementing Regulation (EU) n° 503/2013 on applications for authorisation of genetically modified food and feed.

Despite these and other revisions, there is still much ongoing debate between the Member States and the EU institutions to further revise the regulatory framework, and the debate itself indicates that very few – if any – of the of the involved parties is content with the current system.

An often heard comment is that the EU regulatory system for GMOs is 'dysfunctional', whereby reference is made to the discrepancy between the significant R&D investments by the EU Member States and Institutions and the fact that there are so few realisations of that research, in particular in the field of agricultural biotechnology. Another discrepancy that is often referred to is that while many millions of tons of GM crops cultivated outside the EU are approved and imported for food and feed use in the EU, while European farmers are not allowed to grow those same GM crops.

Given the context of this report, i.e. the 19th International Congress of Comparative Law, the authors believe that it is appropriate to assess whether the regulatory framework itself can *a priori* not function properly, or that the regulatory framework is not implemented properly.

[54] *Supra* § 1.3.

Following up on the above statement that the EU regulatory framework knows some complexities, a first question is whether the system is, also when compared to other systems, too complex.

When compared to regulatory frameworks for GMOs in other parts of the world, we note that complexity is not unique for the EU. Regulatory frameworks in other parts of the world know similar complexities. For example, the regulatory framework of the United States entails regulations from various Government agencies, such as the EPA, the USDA and the FDA, with each their own objective, scope and definitions.

When we compare the EU regulatory framework for GMOs with EU regulatory frameworks for other topics, then we note that overall there are similar complexities in terms of mixed regulatory tools, mixed competencies etc.

The EU regulatory framework for GMOs contains an authorisation system for field trials and placing on the market of GMOs and GMO products. As with other authorisation systems, the system for GMOs contains standard elements, such as information requirements for requests/applications, rules for public involvement and confidentiality of data, time periods, procedures and criteria for decision making and the establishment of an independent and highly capable scientific body, i.e. the European Food Safety Authority (EFSA).

However, in comparing the EU authorisation system for GMOs that are medicines with the authorisation system for GMOs that are not medicines, we do note an important difference. In the decision making process for medicines (GMOs and otherwise) the positive advice of the European Medicines Agency (EMA) means approval of a medicine, whereas a positive advice of EFSA has to be voted on by a standing committee and later on by an appeal committee of member state representatives.

In summary: while leaving aside the question whether the current regulatory framework for GMOs is the best way to regulate this technology, the current system overall contains the standard elements of an authorisation system, i.e. the system can in principle function as it was designed[55]. In fact, the experiences from the early years of the regulatory system show that the system could and indeed did function as it was designed, i.e. allowing authorities to make informed decisions that involve key areas such as food security, human health and environment.

A next question is therefore how the authorisation system is applied in practice, e.g. whether decisions are taken in accordance with the legal time limits, procedures and criteria.

As various surveys suggest[56], for contained use and field trial applications, decisions are generally taken in accordance with the legal time limits, procedures and criteria.

Yet, with applications for placing on the market of GMOs and GMO products, the situation is quite different, e.g:

- For many applications for placing on the market, the legal time frames for decisions have been exceeded with many months and often with years[57].

[55] When talking about 'functioning authorisation systems' the authors refer to systems whereby decisions are taken within the legal time limits, whereby decisions are taken on the basis of the criteria laid down in the regulations, while safeguarding basic requirements for public information and confidentiality.
[56] See for example http://www.cogem.net/index.cfm/nl/publicaties/publicatie/survey-on-the-implementation-of-directive-2009-41-ec
[57] See for example: http://www.europabio.org/positions/approvals-gm-crops-eu-january-2014-update

- For many applications the EU Commission has not submitted after the EFSA opinion within the legal time frame a draft decision for a vote by Member States. In a ruling of 26 September 2013[58], the General Court confirmed that in doing so, the Commission had failed in its duties.
- Several Member States have invoked the 'safeguard clause', which allows the provisional prohibiting a GMO if there is new scientific information that suggests risk. Despite that EFSA has concluded that there was no valid scientific justification for these bans, these bans maintained.

As the above examples show, EU Member States and EU Institutions do not always comply with the regulatory system for GMOs that they themselves designed. This is disconcerting in itself, as it affects the 'Rule of Law', which touches on the question how citizens of the EU can be expected to always follow the rules, when Governments and EU institutions do not?

When we look for reasons behind the current situation, then we come to the second topic of this section, i.e. "policies".

Obviously, one of the main reasons for the current situation is that the policies of some governments and politicians are no longer the same as they were in the time when the regulatory framework was designed, when the focus was on the environment, human health, research and the internal market. For some governments and politicians, other aspects have come into the equation, such as current societal debates and preferences for certain forms of agriculture, whereby "policies" and "politics" sometimes seem intermingled. In that context, the above described difference between authorisation systems that do and authorisation systems that do not involve the possibility for politics to enter the authorisation process through standing committees and appeal committees, can become a fundamental difference with far reaching consequences.

In this perspective it is worth noting that the European Commission has presented a proposal that would allow that, after a GM crop is approved on grounds of safety, Member States can ban cultivation that GM crop in their territory, for reasons other than safety.

This proposal has received a great variety of reactions, ranging from some Governments and organisations welcoming the proposal, to criticism that the proposal would go against the Internal Market and the WTO, and that it would affect the predictability of the system that various stakeholders (e.g. farmers and research organisations) need to make investments in this area.

The legal implications of this nationalisation proposal would be an excellent topic for further discussion in the 19th International Congress of Comparative Law.

Ghent, January 2014

[58] Case T-164/10, *Pioneer Hi-Bred International vs the European Commission*.