COUNTRY REPORT: FRANCE

Law of 2 December 2015 Related to Risk Prevention: Towards the Renewal of GMOs Regulation in the French System?

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Introduction: Regulating GMOs in the European Context

The adoption of the French Law of 2 December 2015 related to risk prevention[2] has a specific legal background, namely European Union law.[3] Indeed, it was adopted as part of the implementation process of EU Directive 2015/412,[4] which provides for the possibility of Member States restricting or prohibiting the cultivation of genetically modified organisms (GMOs) in their territory. The Directive had been expected for years, since the enforcement of the earlier GMO Directive of 2001[5] has never been fully satisfying, not only from the point of view of Member States, but also of non-governmental organisations (NGOs) and, to a certain extent, of European Union (EU) institutions.

European GMO rules were first designed in the early nineties. From the beginning, the EU opted for a derogatory regime. That is, GMOs are not considered regular agricultural products, but specific products with a specific production process.[6] Consequently, the

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[2] Loi n° 2015-1567 du 2 décembre 2015 portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la prévention des risques (JORF 3 décembre 2015, p. 22299, available at http://www.legifrance.gouv.fr/).

[3] The scope of the Law is not limited to GMOs issues, it is also related to safety of oil and gaz operations, of certain chemical products, and greenhouse gaz emission quotas.

[4] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (JO 13.3.2015 L 68/1).

[5] 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 (OJ L 106 , 17/04/2001), p. 1-39.

[6] See Art. 2 of Directive 2001/18 '(2) 'genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'.

dissemination of GMO seeds within the territory of Member States is conditional upon prior authorisation.[7] In compliance with the precautionary principle,[8] authorisation is based on a risk assessment. Once an authorisation is delivered in one Member State, it is valid in all the Member States, in compliance with the basic principles of the single market, particularly the mutual recognition principle, according to which any product lawfully sold in one EU country can be sold in another, even if it does not meet all its technical rules or was not authorized following the same administrative procedural requirements. Such a procedure is a way to conciliate the need to ensure access to the European market (not missing the economic potential of GMO development) with product safety requirements (whose weight has increased under the pressure of public opinion).

The intervention of EU law did not remove all concerns about GMOs, but has rather strengthened them. The option for a specific regime had, paradoxically, the effect of highlighting the specificity of GMOs, especially their potential danger.[9] From then, the Member States have started developing different attitudes towards GMOs. Some are in favour of promoting a GMO culture in their territory (e.g. the United-Kingdom and Spain), whereas others have taken positions expressly against GMOs and even prohibited them in their territory (e.g. Austria and Hungary). France is intermediate. Since the 1990s, the debate on GMOs has been heated in France, with opposition from environmental NGOs and some farmers and multinationals. The position of the French government has been rather unclear. In the absence of consensus, GMOs have become a very sensitive topic in the European context as well. After the 'mad cow' crisis during the nineties and the inadequacy of the Commission to deal with this issue, GMOs have become an object of tension between

[7] Directive 90/220/EC, repealed by 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 which funds the current EU applicable regime of GMOs. The adoption of Directive 2001/18/EC was followed by the adoption of Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (JO L 268/1, 18.10.2003). These legal tools constitute the major components of the EU GMOs regime.

[8] Art. 4 of Directive 2001/18: the Member States have the obligation to 'ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs'.

[9] Damien Rousselière, Samira Rousselière, « Assiste-t-on (réellement) à une polarisation du débat sur les OGM? Une perspective internationale sur la période 2000-2010 », Revue d'économie politique 2013/4 (Vol. 123), p. 593-622, available at http://www.cairn.info/revue-d-economie-politique-2013-4-page-593.htm

the European Union Member States and the European Commission, the decision-making power of the latter being more and more challenged.

Directive 2015/412 aims to provide more opportunities to Member States to regulate GMO dissemination in their territory. Reflecting this Directive, the French Law of 2 December 2015 permits competent French authorities to prevent the dissemination of GMO seeds in the territory, even where the GMO has been validly authorised by another EU Member State. The Law states the requirements that competent authorities must comply with in order to apply to the EU for a derogation from an authorization, but stresses the fact that the application must be assessed with regard to the specific French background.

A New Opportunity to Prohibit GMO Cultivation within the French Territory

Article 20 of the Law of 2 December 2015 amends different provisions of the French Environment Code, and inserts new ones, in order to implement Directive 2015/412.[10] Noticeably, the implementation process has been very quick. Indeed, the French authorities used to be much more reluctant to implement EU Directives related to GMOs, France having been condemned already twice by the European Court of Justice.[11] Article 20 follows Directive 2015/412, implementing the new possibility for Member States to derogate from an EU authorization of a GMO. The Directive does not challenge the whole regime applicable to GMOs, but it does give new opportunities for Member States to point out their specific position towards a GMO.

Under the 2001 Directive, it was quite complicated for the Member States to derogate from an EU authorization. The only possibility was to apply for the enforcement of a safeguard clause. However, the Commission, following the opinions of the European Food Safety Authority,[12] interpreted this possibility very strictly. This enforcement procedure was not fully satisfying for the Member States, as it did not allow them to assert national specificities and national choices towards GMOs. In addition, the adoption of a safeguard clause could only be grounded on the precautionary principle, according to which the national authority shall bring new scientific evidence distinct from that submitted at the time of the application.

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[10] Amendment of the Code of Environment: Arts. L. 533-5-1, L. 533-5-2., L. 533-6; integration of new provisions: Arts. L. 533-7-1 and L. 533-8-2.

[11] Further to infringement proceedings, see Case C-419/03, CJCE, Commission v France; Case C-121/07, CJCE, Commission v France, Rec. p. I-9159.

[12] Regulation (EC) n° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002), pp. 1–24.

The adoption of Directive 2015/412 constitutes a long-time expected amendment of Directive 2001/18. It aims to leave Member States with more room to adapt the scope of an authorization. It also makes the safeguard clause just one legal basis on which Member States can implement national measures that derogate from an EU authorization. Thus, Article 20 of the Law of 2 December 2015 amended Article L. 533-5-2 of the French Environment Code to provide that during the authorization procedure, competent national authorities may demand that the geographical scope of the written consent or authorization be adjusted to exclude cultivation on all or part of their national territory.[13] In addition, Article L. 533-7-1 provides for the possibility to demand a geographical derogation once the authorization has been delivered, but only on the grounds strictly defined by Article 26 b §3 of the 2015 Directive.[14] The important point is that a Member State cannot base its demand on sanitary or environmental interests. These grounds are reviewed during the risk assessment process at the application stage and may be invoked under the safeguard clause mechanism.

Article L. 533-7-1 also provides for the procedural requirements of the Directive to be respected. From a procedural point of view, the communication of draft national measures to the European Commission opens a 75 day period during which the Commission may make comments. These comments may be taken into account by the national competent authorities. In addition, this period is a kind of suspended time, where Member State must refrain from adopting and implementing proposed derogations and operators must refrain from planting the GMO seeds which are the subject of the application. After these procedural processes, the Member State can adopt the national measure, which, according to European law, '*shall be reasoned, proportional and non-discriminatory*'[15] The time limits are strictly limited to not impair the effectiveness of the decision-making process[16]. The obligation of information is also central to preserving the functioning of the EU single market.

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[13] See Art. 26 b (1) of Directive 2015/412.

[14] Art. 26 b (3) of the Directive : '(…) provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to : environmental policy objectives, town and country planning, land use, socioeconomic impacts, avoidance of GMO presence in other products without prejudice to Article 26a, public policy.'

[15] Art. 26 b (3) of the Directive.

[16] Art. 26 b (1) : 'That demand shall be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay.'

Finally, Article L. 533-8-2 provides for the possibility for an administrative authority to revoke the national measure of derogation and reintegrate the excluded geographical area into the authorization. The authority may make a request to that effect to the authority which issued the written consent under the 2015 Directive, and then notify the decision to the Commission[17].

Directive 2015/412 opens a new way for Member States to develop a specific approach towards GMO dissemination in their territory. It leaves a wider margin of appreciation to the Member States in order to balance the different interests at stake and allow them to adapt authorizations precisely, even locally. In this way, the Directive to some extent contributes to the re-nationalization of the regulation process of GMOs. Implemented in the French system, this can lead to interesting opportunities.

Perspectives on GMO Regulation in the French System

As mentioned, the Law of 2 December 2015 does not restrict its contents to the requirements set out in the 2015 Directive. Indeed, it goes further, providing for the conditions of public information and participation in the decision-making process to adopt derogatory measures. It creates a new part in the Environment Code, Section 4 'Public participation', including Article L. 533-9. The scope of this provision is widely defined, including every decision and application authorizing GMO dissemination or derogating to such authorization. In addition, the provision requires competent authorities to provide the public with electronic drafts of their decisions and application files, for a reasonable time, depending on the type of decision[18].

Such a requirement is not new under EU law; it is fully in compliance with it.[19] The fact that the legislation expressly mentions public participation reflects French problems with GMO management, and the broader public claim for more transparency in decision-making processes. The weight accorded to evidence from scientific and advisory bodies is regularly challenged. In addition, the position of political authorities has been rather unclear, disregarding the changing of the political majority, and many decisions have not been in

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[17] Art. 26 b (5) & (6) of the Directive.

[18] Art. L. 533-9-1 of the Code of Environment.

[19] See Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26–32) ; Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC (OJ L 156, 25.6.2003, p. 17–25).

compliance with EU law. For example, in 1997, the authorization to grow a GMO corn was suspended, but not the authorization to import the GMO. One year later, the government authorized two other GMO corn crops but suspended GMO colza and beetroot for two years. The suspension of authorization of GMO corn in 1997 was challenged and upheld before the Council of State. However, after a contrary preliminary ruling by the European Court of Justice,[20] the Council of State had to cancel their support for the suspension since EU law determined that the precautionary principle could not be invoked at the national level once an authorization had been delivered, in the absence of new scientific evidence.[21] Consequently, the government delivered the authorization.[22] In 2008, France prohibited the cultivation of GMO corn MON810, the only GMO seeds currently authorized by the EU. The two administrative decisions[23] suspending its cultivation on French territory were successively annulled by the Council of State, but always after the seedling period, which was a way to limit the opportunity of cultivating concretely GMOs on French territory, at least in the short term.[24] On 15 March 2014, the Government published a third decision suspending a GMO corn. This decision was immediately challenged, with the applicants requesting the administrative decision to be overturned. By ruling of 5 March 2014, the Council of State decided not to overturn the administrative decision because the condition that the situation be an emergency was not satisfied. Even though the Council of State decided in 2013 that administrative decisions dealing with similar issues were illegal, the judge in this case considered that the context was different because there were new scientific studies. In August 2014, the European Food Safety Authority delivered an unfavourable opinion on the French position,[25] stating that the scientific report did not

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[20] CJCE Case 6/99, 21 March 2000, Association Greenpeace France e.a /Ministère de l'Agriculture et de la Pêche e.a, Rec. p. I-1651.

[21] CE, 1st October 2001, n° 225008*, Greenpeace France*.

[22] Olivier Godard, « Le principe de précaution et la controverse OGM », *Économie publique/Public economics* [on line], 21 | 2007/2, available at :
http://economiepublique.revues.org/7852

[23] See Arrêté du 7 février 2008, modifié par l'arrêté du 13 février 2008 suspendant la mise en culture des variétés de semences de maïs génétiquement modifié (Zea mays L. lignée MON 810) **;** Arrêté du 16 mars 2012 suspendant la mise en culture des variétés de semences de maïs génétiquement modifié (Zea mays L. lignée MON 810).

[24] CE, 6 November 2009, n° 313605 ; CE, 1er août 2013, n° 358103, available at :
www.legifrance.gouv.fr

[25] Statement on a request from the European Commission related to an emergency measure notified by France under Article 34 of Regulation (EC) 1829/2003 to prohibit the cultivation of genetically

contain any new information of the existence of risk. The European Food Safety Authority also found that the French Law of 2 June 2014 that prohibited any dissemination and cultivation of GMO corn violated EU rules.[26] The European Commission and Council of State have yet to assess the compatibility of the administrative decision with EU requirements, but since Directive 2015/412 has been passed their assessment will be done under the new legal conditions. Since Article 26c of Directive 2015/412 expressly provides for the possibility to adopt transitory measures,[27] the suspension decisions may be qualified as such. On 15 September 2015, the French government used this provision to notify such measures to the Commission.

Conclusion

Directive 2015/412 constitutes an interesting opportunity to clarify the relations between European and national authorities for GMO regulation in the European Union. It also brings more openness in the sharing of responsibilities between the national and European level. Such an evolution may constitute an important step towards the improvement of democratic control. Indeed, the current functioning of EU law suffers from democratic deficit, especially concerning the GMO authorization process. Giving wider discretion to Member States could be a way to reinforce democracy in the decision-making process on GMOs. It could also represent an interesting way to improve the consideration of regional specificities. The French situation, as a strict unitary State, is not comparable to that of other Member States, such as the United Kingdom, where there are different solutions with regards to GMO dissemination. Nevertheless, the new Directive may herald the beginning of a new direction with regards to the recognition of national authority, as a key actor in GMO regulation.[28]

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modified maize MON 810, *EFSA Journal* 2014; available at http://www.efsa.europa.eu/fr/efsajournal/pub/3809.htm

[26] Loi n° 2014-567 du 2 juin 2014 relative à l'interdiction de la mise en culture des variétés de maïs génétiquement modifié (JORF n°0127 du 3 juin 2014) p. 9208.

[27] Art. 26 c of Directive 2015/412 : 'From 2 April 2015 until 3 October 2015, a Member State may demand that the geographical scope of a notification/application submitted, or of an authorisation granted, under this Directive or Regulation (EC) No 1829/2003 before 2 April 2015 be adjusted. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay.'

[28] Currently, the mayor can only use its administrative police powers to prohibit GMOs cultivation on the municipal territory if there are specific local conditions. In such conditions are missing, the Council of State annuls municipal administrative decisions even grounded on precautionary principle, see for example: CE, 16 April 2010, *Azelvandre*, n° 279817. A county council could, validly, express wishes to oppose to dissemination of GMOs, see CE, 30 December 2009, *Département du Gers*, n° 308514.

Such an evolution may also be a source of new issues for the French and European Union systems. Indeed, the margin of appreciation of any Member State remains limited by at least three elements. First, national measures need to be proportionate and submitted to the indirect review of the Court of Justice. Second, they need to be in compliance with World Trade Organization law. Finally, it remains important to define the conditions of risk acceptability in a collective manner, at the European level.