7. Biotechnology

Etty, T.F.M.

published in
The Yearbook of International Environmental Law, Volume 22
2013

DOI (link to publisher)
10.1093/yiel/yvs100

Excerpted from: *Yearbook of International Environmental Law*, vol. 23. Eds: OK Fauchald, D. Hunter & W. Xi (Oxford University Press, 2013).

International Biotechnology Law and Policy: Year in Review (2012)

Thijs Etty

1. Introduction

This report summarizes the key developments during 2012 in the international governance of biosafety, agricultural biotechnology and genetically modified organisms (GMOs). This year was one of relative quiet, with no major political controversies or breakthroughs in the international law arena.

2. Global Uptake Status of Commercialized Biotech/GM Crops in 2012

GMOs have now been on the market for 17 years, and some GM crops varieties have reached nearly 100% market domination in a number of countries. According to the annual global status report by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), the extraordinary growth trend in the global uptake of GM crops continued during 2012. This year's new record of 170.3 million hectares of planted GM crops represents a 100-fold increase from the 1.7 million hectares planted in the introduction year 1996. Moreover, during the past 17 years, the accumulated worldwide hectarage has grown to 1.7 billion ha – equivalent to an area 50% larger than the total land-mass of the US or China. Despite these impressive growth numbers, the annual increase rates seems to be slowing slightly. After nearly a decade-and-a-half of double digit growth numbers, in the last two year this have slowed to respectively 8% and 6% annual increase. Perhaps this is indicative that the commercialization peak has nearly been reached and market saturation may be in sight, unless new crops and novel traits (perhaps more consumer-benefit oriented) are developed.

The ISAAA further reports that the number of countries reporting cultivation of GM crops decreased slightly from 29 to 28, of which 20 were developing countries (growing 52% of the global total). Sudan and Cuba joined as newcomers while Sweden and Germany discontinued their cultivation of GM potatoes. The top ten of GM growing countries remained virtually unchanged from previous years, led by the United States (69.5 million ha), followed by Brazil (36.6 mio ha), Argentina (23.9 mio ha), Canada (11.6 mio ha), India (10.8 mio ha), China (4 mio ha), Paraguay (3.4 mio ha), South Africa (2.9 mio ha), Pakistan (2.8 mio ha), and Uruguay (1.4 mio ha).

3. Renationalization of GMO Regulation in the European Union?

Europe continues to be largely a no-go area for GM crops, with only a rather symbolic total of 129,071 ha of GM maize planted throughout the entire continent, of which 90% in Spain, and marginal plots in Portugal, the Czech Republic, Romania and Slovakia (see ISAAA report, above). Even those small plantings may disappear if Monsanto's MON810 maize variety, approved in 1998, its pending re-authorization is not successful (the original permit expired in 2008 and the crop is currently marketed under a controversial indefinite extension rule until the EU renews the permit). The only other GM crop authorized for cultivation in the European (EU), the Amflora potato which in March 2010 was the first new GM crop to receive approval in over ten years, was definitively pulled off the market by its producer BASF in early 2012 because of lack of market interest and fierce civil society opposition. Moreover, some 10 EU Member States

have so-called precautionary 'safeguard bans' against growing GM crops, Norway has a restrictive regime and Switzerland has a full moratorium in place.

The EU Member States have for the past two years been mulling a contentious new regulatory framework, proposed by the EU Commission in July 2010 (see COM(2010)375 final, and COM(2010)380 final). According to the Commission, the scheme would leave in place the current EU-level authorization procedure for GMOs, but would provide Member States with reservations regarding GM crops the flexibility to restrict or prohibit their cultivation on their national territory. However, the proposal has been received with much skepticism and confusion and indeed, despite its ostensible simplicity and brevity, the Commission's reform package seems rather to raise more questions than it answers, in both legal and political terms. This is exemplified by the heated inter-institutional (legal) altercations that have ensued, with the expert legal services of each EU institution and many Member States shedding highly diverging light on the proposal, and providing their respective interpretations of the legal validity and solidity of the proposed reform. What is more, vocal stakeholder involvement (including civil society organizations but also, notably the biotech industry, led by EuropaBio), academic criticism, and popular media attention has further ignited this debate in the public domain. Serious doubts have been raised about the legal solidity of the scheme, in particular as regards the compatibility of such national restrictions or bans with EU and international/WTO trade law. After all, the large number of national bans under the existing regulatory framework were already subject of legal dispute in the WTO, in the *EC – Biotech Products* dispute brought by the US, Canada and Argentina against the EU and individual banning Member States. Given this large number of existing bans, the EU Commission's proposal may be no more than a codification or (ex post) legitimization of the political status quo of (re)nationalized opposition to GMOs in Europe, but some fear that it might in fact be a strategic ploy by the EU Commission to break the longstanding deadlock in EU-level decisionmaking, while offering no new legal grounds or protection to precautious Member States to ward off legal action in EU or WTO courts. It is clear that the EU finds itself at a crossroads, in deciding whether to continue down the road of EU integration (a road that has been thus far been riddled with obstacles and potholes), or whether to veer off into the direction of national differentiation (at the risk of further fragmentation and disharmony). For the moment, and for the foreseeable future, the Commission's 'Janus-faced' 'new approach' proposal seems to have further complicated this decision, and has exacerbated the political standoff, rather than to appease it. No doubt, international trade partners, most notably the complainants in the previous *EC – Biotech Products* case, will be following developments in the EU with great interest, ready to make their way back to the WTO in Geneva.

3. Cartagena Protocol on Biosafety (BSP)

The Cartagena Protocol on Biosafety (BSP) to the Convention on Biological Diversity (CBD) is the main international instrument for regulation of biosafety and GMOs. The Protocol's membership of ratifying or accepting Parties has grown to 164, with Bahrain and Jamaica joining during 2012. The BSP has been in force since September 2003.

In October 2012, the Conference of the Parties (COP) to CBD serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety convened for its sixth meeting (COP/MOP 6), in Hyderabad, India.

Meetings in the context of the BSP had in previous years taken place under increasing pressures and contention, in the build-up towards the adoption of the long-awaited supplementary protocol on liability and redress. Now that Parties were able to conclude this instrument at COP/MOP-5, in October 2010, as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety – NKLSPLR (Annex to Decision BS-V/11: International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, available at: http://bch.cbd.int/protocol/NKL_Protocol.shtml; for discussion, see last year's biosafety report in this Yearbook), the pressure was off, as reflected both in the agenda and the general atmosphere at COP/MOP-6 in Hyderabad (Report UNEP/CBD/BS/COP-MOP/6/18, 21 November 2012; see also ENB summary meeting report Vol. 9 No. 585, available at: http://www.iisd.ca/download/pdf/enb09585e.pdf).

The meeting addressed a number of standing issues on the COP/MOP agenda, including (a) compliance: Parties were to send their second round of national compliance reports, after a first round in 2007. Despite a very positive 90% submission rate, the reports showed major gaps in national biosafety frameworks, with only about half of the parties actually having implemented the core provisions of the Protocol by establishing an advance informed agreement procedure and implementing national biosafety frameworks. This led to a call on Parties to expedite efforts to put in place legal and administrative frameworks to meet obligations under the Protocol, and relatedly the need for financial resources for parties experiencing difficulties implementing the Protocol; the importance of developing public awareness programmes, etc; (b) operation and activities of the Biosafety Clearing-House (BCH); (c) financial mechanisms and resources: the COP/MOP noted with concern the drastic decline in the level of bilateral and multilateral funding available
for biosafety capacity-building activities and urged Parties to give priority to national biosafety plans and projects under the Global Environment Facility (GEF) System for Transparent Allocation of Resources (GEF-STAR) to ensure support for the BSP's implementation; (d) cooperation with other organizations, conventions and initiatives; (e) and budgetary and administrative matters. The meeting also addressed a number of substantive issues that will come/continue to dominate the agenda in the years to come, including the longstanding controversial issue of handling, transport, packaging and identification (HTPI) requirements for shipments of living modified organisms (LMOs). They key issues in the HTPI dossier are the documentation requirements for shipments of LMOs intended for direct use as food or feed (LMOs-FFPs), under Article 18(2) BSP. Arduous negotiations had previously led to the adoption of the so-called 'Curitiba rules' at COP/MOP-3 in 2006, but the question of whether a stand-alone document should be required for such shipments or whether existing documentation would suffice was ultimately deferred by Parties to COP/MOP-6, based on the experiences gained from the review of the second round of national reporting on this issue by Parties in 2012. According to the second round of national implementation reports, less than half of the parties have taken measures to meet the existing HTPI requirements. Discussions on HTPI requirements for LMOs-FFPs have again been deferred for discussion at COP/MOP-7 (which will take place either in 2014 or 2015, depending on whether the meeting frequency will be adjusted, as is being debated). Hence, discussions in Hyderabad focused on HTPI requirements for LMOs destined for contained use or for intentional release. Following discussions on whether to include references to independent documentation as types of acceptable documentation, and to the LMO-quick link tool, Parties ultimately deciding to include neither of these, instead pragmatically opting for full flexibility by allowing both/either commercial invoices or standalone documentation for HTPI purposes.

Lengthy discussions were also held about coding systems and LMO databases, and on the question of whether to include a reference to the UN Model Regulations on Transport of Dangerous Goods, but following opposition by, inter alia, Paraguay, Uruguay, Mexico, Colombia, Nigeria and New Zealand, no such reference was ultimately included – again illustrative of the conflict-averse, pragmatic stance that seems to now dominate BSP discussions. Similarly, discussions on risk assessment and risk management, in particular the revised guidance on risk assessment of LMOs (UNEP/CBD/BS/COP-MOP/6/13/Rev.1 and 13/Add.1), ended in anti-climax due to an (overly?) pragmatic approach. Despite the extensive work carried out to review the guidance by the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment as well as extensive online forums, the Parties after long discussions ultimately could not (yet) agree to endorse the guidance. Support for such progress came from, in particular the EU, Central and Eastern European countries (CEE), the African Group, Norway, China and Colombia, whereas New Zealand, Brazil, Ecuador, India, South Africa and the Philippines preferred further testing and refining of the guidance before it could be endorsed. The unsatisfactory compromise result of long and protracted negotiations was the "commendment" by the Parties of progress made on the guidance, an extension of the open-ended online forum and the (re-)establishment of a new AHTEG, to serve until COP/MOP 7. The decision explicitly reiterates (in addition to the already numerous references to its voluntary nature) that the guidance is not prescriptive and does not impose any obligations on parties and that the guidance will be tested nationally and regionally for further improvement.

After the extensive attention for liability and redress in the context of the BSP, leading up to the adoption of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (NKLSPLR) in 2010, the focus has now shifted to expediting the ratification process for this supplementary protocol. Its entry into force requires 40 instruments of ratification or acceptance, but support for the Protocol has thus far been rather modest. A total of 51 States have signed the Protocol, but only 12 had ratified it by March 2013. Only Latvia ratified the Protocol in 2011, joined in 2012 by the Czech Republic, Mexico, Sweden, Norway, Syria, Bulgaria, Lithuania, Spain, and in the first months of 2013 by Albania, Ireland, and the European Union. The CBD Secretariat has taken various initiatives to promote awareness and understanding of the provisions of the NKLSPLR, with a view to facilitating its signature and ratification, and to achieve a timely entry into force. Notably, in May 2012, it organized an inter-regional workshop on capacity needs for the implementation of the NKLSPLR, hosted by the protocol's first ratifying member, Latvia, as a follow up to four regional workshops organized in 2011.

Other substantive issues under discussion at COP/MOP-6 included (a) capacity building activities; (b) notification requirements; (c) unintentional transboundary movements and emergency measures (Art. 17 BSP); (d) subsidiary bodies; (e) monitoring and reporting; and (f) assessment and review.

Probably the most unexpected outcome of the otherwise non-eventful COP/MOP-6 meeting was the progress made on the consideration of socio-economic impacts of LMOs under the BSP. Positions on this dossier have always been quite divergent, including even on the principal point of whether socio-economic considerations are even within the scope of the BSP given its key focus on transboundary movements. However, in Hyderabad, Parties were able to reach broad consensus that socio-economic considerations require substantive engagement. Instrumental to this breakthrough seems to have been a highly successful 'regionally-balanced' workshop on capacity-building for research and information exchange on socio-economic impacts of LMOs,

which took place in November 2011, in New Delhi, India. Two weeks later, a further international workshop on socio-economic impacts of GM crops took place in Seville, Spain, co-organized by the European Commission's Joint Research Centre (JRC) and the UN's Food and Agriculture Organization (FAO). As a first concrete step on this issue (for which a guidance/guidelines is foreseen as the end-product), Parties established an AHTEG that will endeavour to develop conceptual clarity on what exactly constitutes socio-economic considerations under Art. 26 BSP. No doubt, the well-known dividedness will again firmly take root once substantive negotiations proceed on the subject, but an important, principal step was taken at COP/MOP-6 towards including socio-economic considerations under the Protocol.

Although technically not within the scope of this biosafety report, given its related relevance it is worth mentioning that the other supplementary protocol adopted at COP/MOP-5, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, is discussed in further detail in the annual report on the CBD, by Elisa Morgera and Elsa Tsioumani.

3. Aarhus Convention and Public Participation in GMO Decision-making

During 2012, there were no noteworthy developments as regards public participation in GMO decision-making in the context of the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention). Public participation in GMO decision-making has been an issue of debate under the Aarhus Convention since its inception, resulting in May 2005 in the adoption of the so-called 'Almaty GMO Amendment' to Convention by the second meeting of the Parties (MOP-2), with the objective of strengthening the rights of the public to participate in decision-making on GMOs (Decision II/1, Report ECE/MP.PP/2005/2, 12 July 2005).

However, unless and until three-quarters of the Parties ratify or accept the GMO Amendment, it will remain devoid of practical consequences for citizens and civil society. Support for the agreement appears limited. In 2012, only Ireland ratified the GMO Amendment, after no ratifications in 2011 and only one (Slovenia) in 2010. With the total number of ratifying Parties now at 27, the Almaty GMO Amendment is still one ratifying Party short of the critical mass required for its entry into force. Evidently, even then it will only be binding upon those Parties that have ratified it. In the interim, just as before the amendment was adopted, the pre-existing non-binding GMO Guidelines will continue to apply as a voluntary instrument.

Thijs Etty
VU University Amsterdam,
Institute for Environmental Studies (IVM), Department of Environmental Policy Analysis,
and
Faculty of Law, Transnational Legal Studies Department,
Amsterdam, the Netherlands