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Institute for Independent
Impact Assessment in
Biotechnology



Free trade – Opening the door to genetic engineering in agriculture

Impact of CETA and TTIP on EU regulations in the agricultural sector –
a critical assessment

Christoph Then
Study on behalf of the
Alliance 90/The Greens parliamentary group
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Summary: CETA and TTIP as a threat to EU standards in protection of consumers and the environment

The EU is currently holding talks with Canada and the USA on new bilateral free trade and investment agreements. Negotiations have already concluded on The Comprehensive Economic and Trade Agreement (CETA) with Canada and a comprehensive treaty text was presented at the end of September. Negotiations are also underway with the USA on the Transatlantic Trade and Investment Partnership (TTIP). The European Commission alone is conducting the negotiations, in accordance with the Treaty on the Functioning of the European Union (TFEU), on the basis of the mandate given to it by the European Parliament and the Council. It is not yet clear whether the Member States will eventually also become Contracting Parties and the agreements will require ratification by Member State parliaments. According to public statements from Berlin and Brussels, the EU intends on principle to maintain or even enhance its consumer and environmental protection standards. Conversely, the industry and the negotiating partners Canada and the USA are openly seeking to lower those standards, which – especially in the field of agricultural genetic engineering – they regard as serious obstacles to trade.

On the basis of the known CETA text, which is also regarded as a blueprint for TTIP, it has to be assumed that in the medium term we are facing the threat that the standards of environmental and consumer protection in the field of agricultural genetic engineering will be lowered. It is to be assumed that both the German Federal Government and the EU Commission are aware of these consequences, even though this is not currently being discussed in public.

Differences between genetic engineering regulations in the EU, Canada and the USA

Over the past few decades, civil society has played an active part in the political debate on genetic engineering, as a result of which provisions on the protection of GM-free agricultural and food production, labelling and freedom of choice have been enshrined in EU law. Furthermore, the precautionary principle has created a rational basis for dealing with scientific uncertainty. At present, there are considerable regulatory differences between the EU and the respective negotiating partners on issues such as:

- Approval as a political decision or as an administrative act:
In the EU it is not an authority but the political body that decides on approvals and, where appropriate, approval requirements. That makes it clear that responsibility for approvals lies with the political body. Moreover, it allows decisions to be taken on grounds other than only the risk aspect. In the USA and Canada, however, it is the respective authorities that are responsible for decisions of this kind.
- Mandatory approval for genetically modified plants:
The US and Canadian systems relating to GMOs are not consistent, because the legislator does not distinguish between genetic engineering and other production procedures. In those two states – unlike in the EU – genetically modified plants can be put on the market without any approval examination because they fall through the cracks of the system. Given the development of new technologies to modify the genotype, it is to be expected that the cracks in the US mandatory approval system will continue to widen.
- Mandatory labelling:
Consumers and farmers in the USA and Canada cannot know whether food or feed is produced from genetically modified plants because these are not labelled as such.

Summary: CETA and TTIP as a threat to EU standards in protection of consumers and the environment**› Management of scientific uncertainties:**

In the EU, account must also be taken of uncertainties in the context of risk assessment and approval procedures. In the USA (to put it simply) GM plants are considered safe until proved otherwise.

› Protection of GM-free agriculture:

The USA and Canada do not have legal rules to protect GM-free agriculture or to prevent the uncontrolled spread of GMOs into the environment. The EU does have legal provisions of that kind, even if they may seem inadequate.

In addition to differences in genetic engineering regulations, there are also comparative differences between the EU, the USA and Canada with regard to patent law, with particular reference to whether plants and animals can be patented. In Europe it is forbidden to patent plant varieties and animal species or breeding techniques. The German Federal Government wants to see some of the bans become stricter in Europe. These patent-law bans are important in terms of agricultural genetic engineering because company buyouts and the corresponding patent applications are strong drivers of the concentration process in the seed industry. Whether CETA and/or TTIP will make it easier to obtain patents cannot be ascertained at this point. It may well be, however, that even the start of the TTIP negotiations will mean that the German Federal Government can no longer call as planned for a Europe-wide ban on the patenting of conventional plant and animal breeding. The opening of negotiations is producing a legally binding effect.

WTO Plus: New mechanisms put pressure on EU regulations

As regards CETA, the agreements in the biotechnology sector are based on the outcome of a dispute settlement procedure before the WTO (World Trade Organization). Canada, jointly with the USA and Argentina, had brought an action before the WTO seeking to facilitate market access for genetically modified plants. CETA and TTIP can be regarded as a resumption by other means of the WTO dispute procedure.

The signature of CETA would, however, worsen the situation in important areas. The EU would abandon positions it had still officially upheld during the WTO dispute. Moreover, the measures proposed under CETA go far beyond the standards for dispute settlement procedures applicable in the framework of WTO:

According to the text of the CETA agreement, the trading partners seek to create a close network of cooperation at a wide variety of levels. Barriers to trade arising from the various regulatory approaches are to be removed as far as possible. The Contracting Parties would, however, still have the same right to introduce their own environmental and health protection rules. But these standards must remain within the framework set by CETA, which considerably restricts the real margin for play.

There is no mention of aspects such as the precautionary principle, measures to protect GM-free agriculture or binding food labelling to protect the consumer's freedom of choice, which means they do not form an object of or a common basis for further negotiations. Rather, the objectives of the agreement are directed unilaterally at economic interests.

The agreed objectives include more efficient approval procedures, examining alternatives to the existing marketing authorisation rules, avoiding differences between the respective provisions, and boosting competitiveness.

With a view to achieving them, talks and consultations are to be held on a regular basis. The talks will focus on areas such as drafting common norms for approval processes. Furthermore, a variety of joint bodies are to be set up, such as the Regulatory Cooperation Forum (RCF), which in most cases will probably not meet in public. These bodies would create a kind of shadow government of experts responsible for examining whether not only existing but also future legal standards are compatible with the free trade agreement. From a democratic point of view, these bodies are problematic in a similar way to the planned arbitration tribunals: competences that were originally transferred from the national parliaments to the EU will be shifted from there to entities that operate as a kind of ‘higher power’ or ‘supreme technical inspectorate’. Although the public will have very little power to monitor them, they will have a considerable impact on the democratically elected institutions.

Nor should the role of the planned arbitration tribunals with regard to the protection of investors be underestimated. The definition of investments chosen under CETA is very broad and comprehensive. It is not unlikely that indirectly at least these tribunals will be able to put pressure on EU environmental and consumer protection standards, which could weaken not only legal standards but also administrative acts. Unlike under the WTO’s Dispute Settlement Understanding (DSU), it is not States but only companies that have the right to bring an action before these tribunals.

Even the ongoing talks are beginning to have a legal effect

The EU has become involved in a legally binding process simply by opening negotiations. The result is that even the grant of a mandate produces what is called a ‘regulatory chill’, which may result in a standstill with regard to the relevant regulatory issues. Even the ongoing CETA and TTIP negotiations make it more or less impossible to, for example, expand the mandatory labelling of various food production processes. That affects, among others, the German Federal Government’s plans to label the products of cloned animals or animals fed with GM plants. It probably also affects the planned ban on patenting plant and animal breeding.

Consequences of signature

Following the signature of CETA, which is also regarded as a blueprint for TTIP, it is to be expected that the agreed objectives and mechanisms will lead in the medium term to a lowering of EU standards to protect GM-free agriculture such as measures to prevent contamination and maintain clean seed.

Changes can also be expected with regard to approval procedures. Firstly, it may be assumed that the precautionary principle will be driven further and further into the background. Secondly, it is doubtful whether in future the approval procedures will still cover all aspects of genetic engineering. Today this process is already widely backed by campaigns spearheaded by the genetic engineering industry, partly in an attempt to suggest that there is a ‘consensus’ about the safety of genetically modified plants, with a view to influencing the setting of future standards.

There is, therefore, a risk that this change to the ‘rules of play’ will cancel out the standards set by the EU following years of political debate. Looking to the future, society will certainly lose some of its policy-making freedom. Under these framework conditions, policy-makers will have no alternative but to obey the rules of free trade and all other areas of policy-making will be subject to the primacy of economic interests.

Recommendations for political action

Unlike what is suggested in various public statements, the signature of CETA and TTIP would make it impossible to maintain existing standards in the EU. The planned agreement in fact fundamentally changes the rules of play. There is no consideration, at least in the present CETA text, of ethics, freedom of choice or the precautionary principle.

If environmental and consumer protection standards are to be maintained and developed, they should have been specifically excluded from the scope of the CETA agreement. At the very least, important foundations of EU regulations such as the precautionary principle and consumer freedom of choice should have been mentioned specifically as the basis of CETA. That is not the case, however. For that reason alone, and from the perspective of environmental and consumer protection, the CETA agreement that has already been negotiated should not be signed.

In the case of the TTIP negotiations, the errors of CETA could theoretically still be avoided. This means that sensitive areas such as environmental and consumer protection in the food production sector should be entirely excluded from the agreement. Unless this can be specified in the negotiating mandate and the negotiations are conducted accordingly, the only way to prevent deterioration in the status quo is to break off the talks.

1. Introduction

1.1 Impact assessment

The Alliance 90/The Greens parliamentary group in the German Bundestag tasked Testbiotech to examine the potential impact of the planned CETA and TTIP free trade agreements on the agricultural genetic engineering sector, focusing in particular on the following issues:

- › Which passages of the CETA text are relevant to biotechnology?
- › What are the regulatory differences between the EU, Canada and the USA with regard to agricultural genetic engineering?
- › What impact will the current negotiations and, where appropriate, the conclusion of the free trade agreements have on EU genetic engineering regulations?

1.2 The background to CETA and TTIP

In May 2009 the European Union and Canada opened negotiations behind closed doors on the ‘Comprehensive Economic and Trade Agreement’ (CETA). October 2013 brought the first statement that the negotiations had been politically concluded, and the text reached the public in August 2014.¹ At the EU-Canada summit on 26 September 2014 in Ottawa it was once again declared that the negotiations were politically concluded, but the text was not initialled. That same day the EU Commission put the text of the agreement on the Internet.² The agreement with its annexes takes up more than 1 600 pages and is due to be signed in 2015, although there is still some dispute as to whether the EU Member States need to approve it or whether the approval of the EU institutions, i.e. the Commission, the Council and Parliament, will suffice.

The European Union and the USA have been negotiating the ‘Transatlantic Trade and Investment Partnership’ (TTIP) agreement behind closed doors since July 2013. No text is available to date and only as a result of public pressure has the EU Commission’s negotiating mandate granted by the EU Council been published some 14 months later.³ Texts and public statements in which the two negotiating partners set out their positions do, however, exist (see below).

The negotiations on these free trade agreements are – like the EU-South Korea Free Trade Agreement – the first the EU has conducted on the basis of the Treaty on the Functioning of the European Union (TFEU).⁴ That treaty gives the EU Commission the power to negotiate such agreements without the direct participation of the Member States as soon as the European Parliament and the Member States have given a mandate to that effect.

¹ Initially only via unofficial sources such as the ARD: www.tagesschau.de/wirtschaft/ceta-101.html (Deutsch)

² See http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf

³ Only after public protests more than a year after the start of the negotiations: www.euractiv.com/sections/trade-industry/ttip-negotiating-mandate-finally-declassified-309073

⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:C:2012:326:FULL&from=EN>

The public is monitoring the negotiations with a very critical eye, partly because the relevant documents are only being published very late if at all. It was not until the end of September 2014, when it was announced at an EU-Canada summit that the CETA negotiations were concluded, that the text was officially published. Until then there had been little possibility of holding a wider and informed debate.

1.3 Different expectations of the negotiating partners

According to public statements from Berlin and Brussels, the EU intends on principle to uphold or even improve its consumer and environmental protection standards. Accordingly, Federal German Chancellor Angela Merkel stated that the negotiations were even aimed at greater environmental protection, greater consumer protection.⁵ And EU Trade Commissioner Karel De Gucht, who was responsible for the talks until October 2014, emphasised that genetic engineering laws would not be changed.⁶ The same assurance was given by the new EU Commissioner Cecilia Malmström, who guaranteed that European standards of environmental and consumer protection would not be lowered.⁷

Conversely, the expectations of the industry and the negotiating partners Canada and the USA are openly focused on lowering these standards, which they regard, especially in the field of agricultural genetic engineering, as major obstacles to trade. They are equally critical of EU approval procedures and of the mandatory labelling of GM food and feed.

With regard to agriculture, the USA lists the following among the official negotiating objectives:⁸

'A successful T-TIP would eliminate tariff barriers, resolve disagreements over existing unwarranted non-tariff barriers and reduce costs associated with regulatory differences.'

Of special interest here is agricultural genetic engineering:

'The EU's non-tariff barriers to U.S. agricultural products must also be addressed in the negotiations. Long delays in reviews of biotech products create barriers to U.S. exports of grain and oilseed products.'

Underlying the US positions are also the interests of the biotech and agro-industry, which is active on both sides of the Atlantic. There is no doubt about its demands and the environmental associations Greenpeace⁹ and Friends of The Earth Europe¹⁰ for example, have published collections of quotations to that effect. Here the interests of the biotech industry, as communicated via, for example, their EU umbrella association EuropaBio, are no different from the positions of the agro-industry, as upheld in the USA. The national delegations that are officially opposed and hold contrary positions are, therefore, influenced on both sides of the Atlantic by powerful lobbying associations that share identical interests and objectives.

5 www.welt.de/print/welt_kompakt/article128157426/Merkel-wirbt-fuer-Abkommen-mit-den-USA.html (Deutsch)

6 <http://uk.reuters.com/article/2014/02/28/uk-eu-usa-trade-idUKBRE1RoNR20140228>

7 <http://www.heute.de/eu-handelskommissarin-malmstroem-im-interview-zu-ttip-transparenz-verbessern-35830046.html> (Deutsch)

8 Why trade promotion authority is essential for U:S: agriculture and the transatlantic trade and investment partnership, April 2014, <http://www.fas.usda.gov/sites/default/files/2014-04/tpa-ttip.pdf>

9 www.greenpeace.de/themen/transatlantische-handels-und-investitionspartnerschaft-saegt-eu-standards (Deutsch)

10 www.foeeurope.org/sites/default/files/gm_food_eu-us_trade_deal.pdf

1. Introduction

In this context, the question also arises of how opposed the contracting parties' respective negotiating positions actually are. Although there are considerable differences in terms of their legislative demands (see below), the EU Commission and the USA have been trying for years, for instance in bodies such as the Transatlantic Economic Council (TEC)¹¹ and the Doha Development Agenda (DDA)¹², to improve cooperation in the field of biotechnology. Talks on these subjects are also being held with Canada in the framework of the WTO.¹³ ¹⁴ A critical analysis is, therefore, also necessary to establish the extent to which the publicly stated negotiating objectives and positions are consistent with the strategies actually pursued.

It should also be remembered that there are increasing calls in the USA for the labelling of GM plants.¹⁵ The industry is bringing actions against initiatives of this kind¹⁶, giving a foretaste of the dispute settlement procedures available under CETA and TTIP (see below).

These transatlantic cross-overs between positions show that the debate about the free trade agreements is not only bringing States face to face but also that a powerful agricultural lobby is confronting large sections of civil society. In the final analysis, there are economic interests – more or less pronounced – on both sides of the Atlantic – that want to preserve GM-free agriculture and food production.

11 Transatlantic Economic Council (TEC), see

http://ec.europa.eu/research/biotechnology/eu-us-task-force/index_en.cfm

12 See negotiations on trade and the environment in the framework of the Doha Development Agenda (WTO trade round since 2001), www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_e.htm#tradeenvironment

13 World Trade Organization, its precursor was the General Agreement on Tariffs and Trade, GATT.

14 <http://trade.ec.europa.eu/doclib/press/index.cfm?id=536&serie=325&langId=en>

15 <http://www.vtrighttoknowgmos.org/>

16 <http://www.usatoday.com/story/news/nation/2014/06/12/lawsuit-challenges-vermonts-gmo-labeling-law/10402301/>

2. Differences between genetic engineering rules in the EU, Canada and the USA

Ever since the USA and the EU agreed in February 2013 to open negotiations on a free-trade agreement known as the Transatlantic Trade and Investment Partnership (TTIP), there have been discussions about whether the EU's genetic engineering rules could become a stumbling block for such an agreement. EU legislation¹⁷ stipulates, among others, as follows:

- the precautionary principle must always be observed with regard to the release or authorisation of genetically modified organisms (GMOs),
- all GMOs must undergo risk assessment before being placed on the market,
- risk assessment must be clearly distinguished from risk management,
- it is mandatory to label GMO-produced food and feed.

The EU rules on the management of food production risks are based on EU Regulation 178/2002, which lays down that the precautionary principle must be applied to ensure a high level of protection of human health and the environment. The precautionary principle also forms the basis of risk assessment and risk management with regard to the release and placing on the market of genetically modified organisms (GMOs) in the EU (Article 1, Dir. 2001/18). Accordingly, the precautionary principle applies in particular to cases where there is some scientific uncertainty and lack of lack of information with regard to risk assessment, because there is no clear evidence either of the risks or of the safety of products. Under the precautionary principle, GMOs may in fact be released or placed on the market even if there is still some uncertainty about their actual risks to human health and the environment, although adequate precautionary measures must then be taken, such as labelling, monitoring, measures to prevent their uncontrolled spread and contamination and, where appropriate, measures to remove the GMOs from the environment.¹⁸

The USA, on the other hand, does not have any specific genetic engineering legislation¹⁹ and the products in question are only examined on a case to case basis. For instance, GM plants that produce insecticides are checked in accordance with the provisions of the pesticide laws. Similar criteria are applied in Canada. In the USA at least, genetically modified plants can also be placed on the market without any form of testing (see Chapter 5.2.3, 'EU Approval procedures').

2.1 Basis of EU rules and the precautionary principle

The current EU rules date back to a legislative process that began in 2000, following various repeated food crises (e.g. BSE and dioxin contamination. According to the Commission's White Paper²⁰, which set out the new rules for the first time, these crises revealed serious weaknesses in the system applied to date:

¹⁷ EU Directive 2001/18, EU Directive 1829/2003.

¹⁸ Krämer, L., 2013 Genetically Modified Living Organisms and the Precautionary Principle, legal dossier commissioned by Testbiotech, www.testbiotech.de/node/904

¹⁹ See also: Mudgal, S. et al. (2014) Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP), IP/A/ENVI/2014-03 PE 536.293
[http://www.europarl.europa.eu/RegData/etudes/STUD/2014/536293/IPOL_STU\(2014\)536293_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2014/536293/IPOL_STU(2014)536293_EN.pdf)

²⁰ EU Commission, WHITE PAPER ON FOOD SAFETY, COM (1999) 719 fin., http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf

‘Community and Member State food safety systems have been under unprecedented pressure during recent feed and food emergencies. These emergencies have exposed weaknesses which call for action by the responsible authorities (Commission, Member States and the Parliament (...)’

The new system should, therefore,

‘(...) aim at the early identification of potential hazards to prevent crises arising rather than reacting to them.’

Among others, the precautionary principle should, therefore, be applied:

‘Where appropriate, the precautionary principle will be applied in risk management decisions.’

In 2000 the Commission also published a Communication on the precautionary principle²¹, in which it takes the view that the precautionary principle can also be applied under the WTO rules:

‘The Commission considers that the Community, like other WTO members, has the right to establish the level of protection – particularly of the environment, human, animal and plant health, – that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.’

Accordingly, the precautionary principle is based on the most comprehensive possible scientific risk assessment, which clearly identifies the degree of uncertainty:

‘The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.’

Yet a decision cannot always be taken on the basis of the scientific assessment because the degree of uncertainty cannot always be identified conclusively:

‘However, in some situations the scientific data are not sufficient to allow one to apply these prudential aspects in practice, i.e. in cases in which extrapolations cannot be made because of the absence of parameter modelling and where cause-effect relationships are suspected but have not been demonstrated. It is in situations like these that decision-makers face the dilemma of having to act or not to act.’

That is why a clear distinction is drawn in the EU between risk assessment on a scientific basis, coordinated by the EFSA European Food Safety Authority, and risk management, i.e. political decisions on approvals (EU Commission and EU Member States). These have to take aspects other than scientific certainty into account and, where appropriate, also set out requirements or issue bans:

‘The appropriate response in a given situation is thus the result of an eminently political decision, a function of the risk level that is ‘acceptable’ to the society on which the risk is imposed.’

Mainstreaming the precautionary principle, together with measures to ensure transparency, traceability and labelling, and measures to protect GMO-free agriculture are achievements it took European civil society many years of debate to attain. They are based on scientific findings, while also offering policy-makers the necessary margin for play for decisions that enable them to take active precautionary measures. These rules go beyond questions purely of risk assessment. They offer not only some protection against risks but also freedom of choice and legal certainty to producers who are opposed to genetic engineering.

21 Communication from the Commission on the precautionary principle, COM (2000) 1 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:en:PDF>

2. Differences between genetic engineering rules in the EU, Canada and the USA

2.2 Differences between genetic engineering rules

There is a wide range of differences between genetic engineering regulations in the EU and in the USA/Canada. Table 1 gives a brief overview of some areas.

Table 1: Overview of differences between genetic engineering rules in the EU, the USA and Canada

Subject	EU	USA	Canada
Separation between risk assessment and risk management	There is a strict institutional separation between scientific risk assessment (EFSA, European Food Safety Authority) and risk management (political decision-making).	There is no strict institutional separation between risk assessment and risk management (decision on approvals).	There is no strict institutional separation between risk assessment and risk management (decision on approvals).
Separation between risk assessment for health and the environment risk assessment for health and for the environment.	The European Food Safety Authority EFSA is responsible for both environmental and consumer protection.	The Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have different competences with regard to environmental risks, food safety and labelling: APHIS is responsible for ensuring that organisms (not just GMOs) do not become pests, the EPA examines whether GM plants containing substances effective against pests are effective (similar to pesticides). The FDA examines food safety.	The Canadian Food Inspection Agency (CFIA) and Health Canada have different responsibilities for environmental risks, food safety and labelling.
Basis of approval procedures	Regulation is specific and process-based. The decision whether an approval process must be initiated depends on the production process used.	No specific legislation on GM plants. The approval requirement is based not on the production process but on the characteristics of the products. GM plants that present no evident risks can be put on the market without approval testing.	No specific legislation on GM plants. The approval requirement is based not on the production process but on the characteristics of the products. In general, plants with novel traits must undergo a risk assessment. GM plants without novel traits are not regulated.
Criteria for approval decisions	The decision on approval may also include aspects (ethical or socio-economic criteria) that were not taken into account in the risk assessment.	The approval decision does not include aspects that were not also taken into account in the risk assessment.	The decision on approval does not include aspects that were not also taken into account in the risk assessment.

2. Differences between genetic engineering rules in the EU, Canada and the USA

Subject	EU	USA	Canada
Evaluation of precautionary principle	The precautionary principle and uncertainties in risk assessment are emphasised as an important regulatory basis.	The precautionary principle has no pronounced impact.	The precautionary principle has no pronounced impact.
Approval of stacked events (combinations of GM plants created by cross-breeding)	Stacked events must undergo risk assessment.	Stacked events are only subject to risk assessment in certain cases.	Stacked events are only subject to risk assessment in certain cases.
Contamination with non-approved GMOs	Zero tolerance applies to food (although for plants already approved in other regions a 0.1% tolerance applies to food).	Where GMOs would have required approval, they must be removed.	Where GMOs would have required approval, they must be removed.
Seed purity	Seed that is not labelled as GM may not be contaminated with GM seed.	Conventional seed may be contaminated with GM seed if that seed has been approved.	Conventional seed may be contaminated with GM seed if that seed has been approved.
Uncontrolled spread of GMOs	On principle the uncontrolled spread of GMOs in the environment must be avoided.	If GMOs have been approved, they may also spread beyond the field and into the environment.	If GMOs have been approved, they may also spread beyond the field and into the environment.
Ensuring GM-free agriculture and measures (coexistence rules).	Special provisions on coexistence are designed to protect GM-free agriculture. They include clearance rules, a cultivation register, liability rules and labelling.	There are no provisions on protecting GM-free agriculture from GMOs that have already been approved.	There are no provisions on protecting GM-free agriculture from GMOs that have already been approved.
Labelling	Food and feed produced from GMOs must be labelled as such.	Food and feed produced from GMOs are not subject to any general labelling requirement.	Food and feed produced from GMOs are not subject to any general labelling requirement.

2. Differences between genetic engineering rules in the EU, Canada and the USA

In summary the effect of these differences is as follows:

- › Institutional separation between risk assessment and risk management (approval decision): In the EU, the decision on approval and where appropriate on approval requirements is taken by the political body rather than by an authority.
- › Institutional separation between the environment and the health sector: In the USA, a different authority is responsible in each case, in the EU the competence lies with the European Food Safety Agency EFSA.
- › Products subject to the approval procedure: here the system in the USA and Canada is not consistent since it does not distinguish between genetic engineering-processes and other production processes nor, therefore, does it include all the relevant products. GM plants may also be placed on the market without being subject to approval examination.
- › Labelling: in the USA and Canada there is no transparency for consumers and farmers as to whether food and feed was produced from GM plants.
- › Risk assessment: in the EU account must also be taken of uncertainties in the context of risk assessment as possible obstacles to approval. In the USA, on the other hand, it is assumed that products are safe until otherwise proven (GRAS concept: 'generally recognised as safe'), although there is provision for comprehensive compensation and complaint procedures.
- › Protection of GM-free agriculture and the environment. The USA and Canada provide for measures to prevent contamination with non-approved GMOs. In cases where GM plants have been approved however, there are no generally applicable rules to protect GM-free agriculture or their uncontrolled spread in the environment.

Alongside genetic engineering regulations, differences in patent law relating to plant cultivation and animal breeding also have a substantial impact on further developments in the context of agricultural genetic engineering.²² Seed patents in particular encourage a massive concentration process in the seed industry, which benefits agricultural firms such as Monsanto.²³ GM plants and animals are nearly always also patented. This development is the subject of much dispute in Europe, and the German Federal Government is therefore planning, under the coalition agreement, to restrict the patenting of, in particular, conventional plants.²⁴ That is why we need to examine the extent to which CETA and TTIP could lead to changes in this respect. The following gives an overview of some of the differences:

- › In the USA, species protection plays a secondary role in the sector of plant cultivation. Patents are granted for plant species on a regular basis.
- › In Canada, no patents are granted for plants (and animals), isolated DNA sequences may, however, be patented. As a result, patent protection also covers GM plants that contain such genes.
- › In Europe, the patenting of plant varieties and animal species as well as of predominantly biological breeding processes is prohibited. Nevertheless, patents are granted for GM plants and to some extent also for conventionally bred plants and animals. This practice is disputed and according to the German Federal Government's coalition agreement it is to be changed.(see below).

²² Differences relevant to CETA also exist with regard to medicines, but are not discussed here.

²³ See e.g. <https://www.msu.edu/~howardp/seedindustry.html>

²⁴ <https://www.cdu.de/sites/default/files/media/dokumente/koalitionsvertrag.pdf>

3. The WTO dispute settlement procedure for genetic engineering and its significance for TTIP and CETA

The differences in the regulatory framework governing agricultural genetic engineering between the USA and Canada on the one hand and the EU on the other have been causing disputes for years. As early as 2003 the USA, Canada and Argentina brought an action before the WTO on the grounds of delays in EU approval for GM plants.²⁵ The action was based in particular on the WTO standards for sanitary and phytosanitary measures (SPS) and technical barriers to trade (TBT). These standards are more than 20 years old. There is reason to doubt that they can play a significant role in a modern environmental and consumer policy.

The agreement on sanitary and phytosanitary measures (SPS) lays down which regulations are admissible in order to protect the health of humans, animals and plants. These regulations may have a direct or indirect effect on international trade. SPS measures may be taken where this is necessary to health protection. In this context, the SPS agreement provides that members must base their measures on the existing international standards of the Codex Alimentarius, the International Office of Epizootics (IOE) and the International Plant Protection Convention (IPPC). These measures are coordinated internationally and therefore define on principle the necessary level of protection. A member state may only resort to more stringent requirements where it can demonstrate on the basis of a risk assessment and scientific evidence that they are necessary.²⁶

The WTO agreement on Technical Barriers to Trade (TBT) aims to prevent the creation of unnecessary technical barriers to trade and promote mutual recognition and harmonisation. The goal is to guarantee members the right to take specific measures to achieve a justified objective while at the same time preventing protectionist measures. Under the TBT agreement, the technical regulations and conformity assessment procedures must not be more trade-restrictive than necessary to fulfil a legitimate objective. They must also be transparent and non-discriminatory.²⁷

In 2006, the WTO Dispute Settlement Panel ruled at first instance in favour of the plaintiffs in a number of areas. The EU decided not to appeal and did not dispute the first instance ruling.²⁸ Unlike in the case of the WTO hormone dispute between the EU and the North Americans, no penalties were imposed. Since then, neither the EU nor the plaintiffs in the form of the USA, Canada and Argentina have changed their positions officially. Instead, the dispute was resolved by direct talks between the EU and Canada in 2008 and then also with Argentina in 2010.

The EU Commission published the following information on the case:²⁹

The European Commission has held regular discussions on biotech-related issues with the three complainants in this case – Canada, Argentina and the United States - since the adoption of the WTO panel report in 2006.

Similarly to the settlement reached last year with Canada, the settlement reached with Argentina provides for bi-annual meetings between competent services of the European Commission and Argentinean authorities regarding the application of biotechnology to agriculture and related trade issues of mutual interest, including:

25 DISPUTE DS291, DS 292, DS 293, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm

26 See: <http://www.bmwi.de/DE/Themen/Aussenwirtschaft/Handelspolitik/wto,did=615546.html> (Deutsch!)

27 See: <http://www.bmwi.de/DE/Themen/Aussenwirtschaft/Handelspolitik/wto,did=615546.html> (Deutsch!)

28 Cf, Greenpeace: Genetic Engineering and the WTO: an Analysis of the Report in the 'EC-Biotech' Case.

Amsterdam 2006. <http://www.greenpeace.org/international/en/publications/reports/genetic-engineering-and-the-wto/>

29 <http://trade.ec.europa.eu/doclib/press/index.cfm?id=565&serie=325&langId=de>

3. The WTO dispute settlement procedure for genetic engineering and its significance for TTIP and CETA

- › *The follow up of the authorisation processes of genetically modified products of interest to the Parties, both in the EU and Argentina;*
- › *The measures related to biotechnology which may affect trade between Argentina and the EU, including measures adopted by the EU Member States;*
- › *Specific issues which arise in the context of requests for authorisation submitted to regulatory evaluation;*
- › *The exchange of information on the trade impact of asynchronous authorisations of genetically modified products;*
- › *The evaluation of the economic and trade outlook of future authorisations of genetically modified products;*
- › *The renewal of authorisations of genetically modified products;*
- › *The exchange of information regarding other relevant issues in the field of agriculture biotechnology, including new legislation in the field in the field of biotechnological agriculture, or coordination mechanisms to solve eventual cases of adventitious presence of non-authorized GMOs in shipments of authorised products.*

This dialogue is aimed at an exchange of information that would contribute to avoiding unnecessary obstacles to trade (...)

The outcome of the procedure is relevant to the discussion about TTIP and CETA for the above reasons and more. The CETA text refers explicitly to the WTO procedure between the EU and Canada (WT/DS292). The CETA standards relating to environmental and health protection are explicitly based on the WTO's SPS and TBT rules. Furthermore, the outcome of the dispute settlement procedure between the EU and Canada³⁰ is specified as the basis for the biotechnology agreement.

That means that TTIP and CETA can be regarded as a continuation of the WTO dispute procedure by other means. Since the US complaint to the WTO was not resolved,³¹ it can be assumed that the interests behind that complaint continue to have an effect on the current TTIP negotiations.

This is also clear from a report published in 2013 by the United States Trade Representative on the SPS strategy of the USA.³²

In 2003, the United States challenged the EU's de facto moratorium on approvals of U.S. agricultural products derived from modern biotechnology, such as certain corn and soybean varieties, as well as marketing prohibitions that individual EU Member States had imposed on agricultural biotechnology products that the EU had previously approved. In 2006, a WTO panel found that EU and Member State measures

30 WTO dispute European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS292)

31 DS291, http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm

32 The EU is not the only problem for the USA: In the USA's view, 50 countries are currently infringing the WTO's SPS rules: 'Argentina, Australia, Bahrain, Bolivia, Bosnia and Herzegovina, Brazil, Chile, China, Colombia, Croatia, the Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, the European Union, India, Indonesia, Israel, Jamaica, Japan, Kazakhstan, Kenya, Korea, Kuwait, Kyrgyzstan, Macedonia, Malaysia, Mexico, Morocco, New Zealand, Norway, Peru, Philippines, Russia, Saudi Arabia, Serbia, Singapore, South Africa, the South African Development Community, Sri Lanka, Switzerland, Taiwan, Thailand, Turkey, Ukraine, Uruguay, and Vietnam.' 2013 REPORT ON SANITARY AND PHYTOSANITARY MEASURES, United States Trade Representative, <http://www.ustr.gov/sites/default/files/2013%20SPS.pdf>

were inconsistent with WTO rules. This dispute remains unresolved. (...) The United States continues to press the EU for fundamental improvements in its regulatory system with the goal of normalizing trade in agricultural products derived from modern biotechnology.'

In the case of Canada too, it is likely that the interests that came to light in the WTO complaint remain as topical as ever. After the parties have agreed to cooperate following the WTO procedure, Canada now wants to safeguard this outcome through CETA, make the cooperation process binding and promote it, and also widen the range of issues covered.

The CETA text has the following to say here:³³

'The Parties agree that cooperation and information exchange on issues related to biotechnology products are of mutual interest. Such cooperation and exchange of information will take place in the bilateral Dialogue on Biotech Market Access Issues which was established as part of the Mutually Agreed Solution reached on 15 July, 2009 between Canada and the European Union following the WTO dispute European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS292). The dialogue covers any relevant issues of mutual interest to Canada and the EU (...).'

33 Article X.03: Bilateral Cooperation on Biotechnology.

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

In order to assess the effects of CETA on the agricultural genetic engineering sector, it is not enough simply to study the specific passages on biotechnology. Indeed, general provisions such as those on cooperation between the authorities are also highly relevant.

CETA contains provisions on widely different product groups and sectors such as agricultural products, rules of origin, the electrical and motor vehicle industry, financial markets, and telecommunications. Alongside product-related or sector-specific chapters there are also general rules on, for example, international dispute settlement tribunals, customs requirements, copyright, employment law, investment protection, sanitary and phytosanitary measures (SPS), and technical barriers to trade (TBT), as well as on cooperation between authorities (regulatory cooperation) and political talks and bilateral cooperation (dialogues and bilateral cooperation). CETA also establishes a range of new bodies that are to have an advisory function and in some cases also decision-making powers.

4.1 General provisions

General provisions of relevance to the biotechnology sector include provisions on investment protection, cooperation between authorities, uniform criteria for market access, establishing joint bodies and scientific and research cooperation. They are briefly described below.³⁴

4.1.1 Investment protection

Since the effects of the dispute settlement tribunals are already the subject of detailed public discussion³⁵, they need not be described in further detail here. The main criticisms concern lack of transparency, no obligation to exhaust national legal remedies, lack of independence of the dispute settlement tribunals and lack of legal review options.³⁶

In disputes before the criticised Investor State Dispute Settlement (ISDS) tribunals, claims may be made either under the ICSID (International Centre for Settlement of Investment Disputes) rules or the UNCITRAL (United Nations Commission on International Trade Law) arbitration rules or any other arbitration rules on agreement of the disputing parties.³⁷ Unlike the WTO dispute settlement procedures, which are conducted between individual states, the ISDS mechanisms are designed solely to give additional rights to foreign investment undertakings.

These dispute settlement tribunals could lead to a flood of claims directed not only against legal provisions and regulatory standards but also against administrative acts³⁸ such as authorisations for trial

³⁴ The quotations below are taken from the 'Consolidated Text' of CETA that the EU Commission forwarded to the German Bundestag on 26. September 2014.

³⁵ See e.g. "Verkaufte Demokratie, Wie die CETA-Regeln zum Schutz von Investoren das Allgemeinwohl in Kanada und der EU bedrohen", http://power-shift.de/wordpress/wp-content/uploads/2014/11/Studie-CETA_November-2014_verkaufte-demokratie.pdf (Deutsch!)

³⁶ Krajewski, M., (2014) Modalities for investment protection and Investor-State Dispute Settlement (ISDS) in TTIP from a trade union perspective, Friedrich Ebert Stiftung, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2519995

³⁷ Investment. Article X.22: Submission of a Claim to Arbitration, p. 169

³⁸ Prof. Dr. Markus Krajewski, Anmerkungen zum Gutachten von Dr. Stephan Schill zu den Auswirkungen der Bestimmungen zum Investitionsschutz und zu den Investor-Staat-Schiedsverfahren im Entwurf des CETA auf den Handlungsspielraum des Gesetzgebers vom 22.9.2014, http://www.gruene-bundestag.de/fileadmin/media/gruenebundestag_de/themen_az/EU-USA_Freihandelsabkommen/Thesenpapier_Klageprivilegien_in_CETA.PDF (Deutsch!)

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

releases or the grant of approvals. CETA defines the concept of investments very broadly. Accordingly, share, stocks and equity participation in an enterprise, concessions for the exploitation of natural resources and also intellectual property rights (patents) are regarded as relevant investments.³⁹ That means it will be a question, case by case, of how the claims are justified. For instance claims submitted in order to protect the investment of equity participation in an enterprise could also have an effect on applicable standards of environmental and consumer protection.⁴⁰ As a result of their interaction with objectives and mechanisms set out in the Agreement over and above the dispute settlement tribunals (see below), this will certainly put considerable pressure on existing EU environmental and consumer protection norms, which will have clear implications at least in the medium term.

4.1.2 SPS and TBT

With regard to environmental and consumer protection, CETA is based mainly on the WTO standards relating to sanitary and phytosanitary measures (SPS) and technical barriers to trade (TBT).

With regard to SPS, a Joint Management Committee is to be set up to continuously monitor observance of these standards.⁴¹ This forum is to identify opportunities for closer cooperation and discuss at an early stage any relevant measures planned by the trading partners.

In the passages on TBT, the trading partners undertake to ensure that their respective technical regulations are compatible.⁴² Labelling requirements must not be more trade-restrictive than necessary.⁴³ Once again, a joint committee is to be set up to monitor conformity with the common standards.⁴⁴

4.1.3 Cooperation between authorities and rules of cooperation

The trading partners want to create a close network of cooperation at a variety of levels. For instance they will agree, among others, planned measures in the framework of multilateral environmental agreements.⁴⁵ With regard to the Convention on Biological Diversity for example, the EU and Canada could in future negotiate common positions in the run-up to conferences.

The rules on cooperation are summarised in the section entitled 'Regulatory Cooperation'.⁴⁶ It provides as follows, with regard to environmental and consumer protection standards:

*'The Parties commit themselves to ensuring high levels of protection for human, animal and plant life or health and the environment in accordance with the TBT Agreement, SPS Agreement, GATT 1994 and GATS.'*⁴⁷

39 Investment, Article X.3: Definitions, p. 149-150.

40 See also: Gerstetter et al. (2013), Legal implications of the EU-US trade and investment partnership (TTIP) for the Acquis Communautaire and the ENVI relevant sectors that could be addressed during negotiations, IP/A/ ENVI/ ST/2013-09, PE 507.492, <http://www.ecologic.eu/10074>

41 SPS, Article 15, p. 105.

42 TBT, Article 4, technical regulations, Seite 87.

43 TBT, Article 7, Marking and Labelling, Seite 88.

44 TBT, Article 8: Management of the Technical Barriers to Trade Chapter, Seite 88/89.

45 Trade and Environment, Article X.3: Multilateral Environmental Agreements, Seite 386.

46 Reg Coop, p. 396.

47 Reg Coop, Article X.2: Principles, p. 396.

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

Barriers to trade arising from different regulatory measures are to be eliminated where possible:

*(...) the Parties commit themselves to further developing their regulatory cooperation in light of their mutual interest in order to: (a) prevent and eliminate unnecessary barriers to trade and investment; (b) enhance the climate for competitiveness and innovation, including through pursuing regulatory compatibility, recognition of equivalence, and convergence; and (c) promote transparent, efficient and effective regulatory processes (...)*⁴⁸

The Contracting States do, however, still retain the right to introduce their own environmental and health protection rules. Those standards must, however, be compatible with the CETA rules, which considerably restricts their actual margin for play. Aspects such as the precautionary principle, measures to protect non-GM agriculture or the obligation to label food in order to protect consumer freedom of choice are not mentioned and are therefore neither an objective nor a part of the common basis for further negotiations.

The agreed objectives of cooperation do, however, include enhancing the efficiency of approval procedures, identifying alternatives to existing instruments of marketing authorisations, avoiding unnecessary regulatory differences and improving competitiveness.⁴⁹

To that end, ongoing discussions and consultations are to be held, with the aim, among others, of agreeing common standards for authorisation processes.⁵⁰ A joint body is also to be set up, the Regulatory Cooperation Forum (RCF), cooperating directly with the trading partners' authorities with a view to standardising the respective procedures. This forum will also review in advance regulatory initiatives, whether in progress or anticipated.⁵¹ A body comparable to the RCF is discussed in the TTIP context under the title of 'Regulatory Cooperation Council'. This Council is to be made up of representatives of authorities and trade together with the Secretariat-General of the EU Commission and the US Office for Information and Regulatory Affairs (OIRA). In future, the creation of bodies such as RCF and RCC is likely to lead to a situation where 'legislation incompatible with regulations of the other party needs at least special justification'.⁵²

48 Reg Coop, Article X.2: Principles, p. 396.

49 Reg Coop, Article X.3 Objectives of Regulatory Cooperation, p. 397.

50 Reg Coop, Article X.4 Regulatory Cooperation Activities, pp. 398–406.

51 Reg Coop, Article X.6: Role and Composition of the Regulatory Cooperation Forum, p. 400.

52 BUND: Das Gemeinwohl ist nicht ver(frei)handelbar. Kein transatlantisches Freihandelsabkommen TTIP auf Kosten von Mensch und Umwelt. Berlin, BUND Positionen 62, 2014. On the Internet under: http://www.bund.net/fileadmin/bundnet/publikationen/sonstiges/140807_bund_sonstiges_ttip_position.pdf (Deutsch!)

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

4.1.4 Joint bodies

Cooperation will be based on a whole range of joint bodies. Some have already been mentioned. The high number of proposed bodies (see Table 2) – most of which will not meet in public – already suggests that civil society will not be able to monitor or influence their activities without drawing on considerable resources. For EU Member States too, these new bodies imply the need for significantly more resources with the risk of potentially overextending at least the smaller states.

Table 2: Overview of several planned CETA bodies relating to environmental and consumer protection

CETA body	Responsibility
Committee on Trade in Goods mit Untergremium für Landwirtschaft ⁵³	Trade promotion.
Joint Management Committee for Sanitary and Phytosanitary Measures ⁵⁴	Monitoring and implementing WTO SPS norms.
Management of the Technical Barriers to Trade Chapter ⁵⁵	Monitoring and implementing WTO TBT norms.
Civil Society Forum ⁵⁶	The only body providing specifically for public participation with regard to sustainability and trade.
Panel of Experts ⁵⁷	A group of experts that can be convened to consider environmental protection issues.
Regulatory Cooperation Forum ⁵⁸	Responsible for promoting close cooperation between authorities on all market access issues.
CETA Joint Committee ⁵⁹	A body of representatives of the Contracting States that has ultimate decision-making power within the scope of the agreement.

4.2 Specific provisions on biotechnology

CETA places special emphasis on cooperation in the biotechnology sector. Chapter 10 – Dialogues and Bilateral Cooperation – emphasises the need to strengthen cooperation in the common interest:

‘Building on their well-established partnership and shared values, the Parties agree to develop their cooperation on issues of common interest. Their efforts will in particular be aimed at: (a) Strengthening bilateral cooperation on biotechnology through the bilateral Dialogue on Biotech Market Access Issues; (...)’

⁵³ Trade in Goods, Article 14 Committee on Trade in Goods, p. 25.

⁵⁴ SPS, Article 15 Joint Management Committee for Sanitary and Phytosanitary Measures, p. 105.

⁵⁵ TBT, Article 8: Management of the Technical Barriers to Trade Chapter, p. 88/89.

⁵⁶ Trade and SD, Article 5: Civil society forum, p. 373.

⁵⁷ Trade and Environment, Article X.15: Panel of Experts, p. 392.

⁵⁸ Reg Coop, Article X.6: Role and Composition of the Regulatory Cooperation Forum, p. 400.

⁵⁹ Administrative and Institutional Provisions, Article X.01: The CETA Joint Committee, p. 447.

4. Which CETA provisions may affect EU legislation in the agricultural genetic engineering sector?

Cooperation is to cover all areas of biotechnology and be directly linked to the WTO dispute settlement procedure. The issues mentioned specifically include:

- › Approval procedures
- › Rules governing contamination
- › Dismantling barriers to trade, especially on the part of the EU
- › Cooperation on legislative initiatives

Article X.03: Bilateral Cooperation on Biotechnology

1. *The Parties agree that cooperation and information exchange on issues related to biotechnology products are of mutual interest. Such cooperation and exchange of information will take place in the bilateral Dialogue on Biotech Market Access Issues which was established as part of the Mutually Agreed Solution reached on 15 July, 2009 between Canada and the European Union following the WTO dispute European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS292). The dialogue covers any relevant issues of mutual interest to Canada and the EU, including, among others:*

- a. Biotechnology product approvals in the territory of Canada or the EU as well as, where appropriate, forthcoming applications of commercial interest to either side;*
- b. the commercial and economic outlook for future approvals of biotechnology products;*
- c. any trade impact related to asynchronous approvals of biotechnology products or the accidental release of unauthorised products, and any appropriate measures in this respect;*
- d. any biotech-related measures that may affect trade between Canada and the EU, including measures of EU Member States;*
- e. any new legislation in the field of biotechnology; and*
- f. best practices in the implementation of legislation on biotechnology.*

2. *The Parties also note the importance of the following shared objectives with respect to cooperation in the field of biotechnology:*

- a. exchanging information on policy, regulatory and technical issues of common interest related to a product of biotechnology; and in particular information on their respective systems and processes for risk assessment for taking a decision on the use of a genetically modified organism;*
- b. promoting efficient science-based approval processes for products of biotechnology;*
- c. cooperating internationally on issues related to biotechnology such as low level presence of genetically modified organisms;*
- d. engaging in regulatory cooperation to minimize adverse trade impacts of regulatory practices related to biotechnology products.'*

The text does not refer to strengthening environmental and consumer protection, the precautionary principle or consumer freedom of choice, i.e. issues very important to the EU. Instead, the specifically mentioned objectives of the agreement are directed solely at economic interests.

5. Discussion: The effects of CETA and TTIP

Under the CETA provisions, differing environmental and health protection standards may be directly, but in any case indirectly contested by submitting claims to the international courts of arbitration.⁶⁰ Below it will be shown that the agreements will also have substantial implications for EU standards even without appeals to arbitration panels. The biotechnology provisions are directly aimed at aligning or revising the respective standards.

5.1 The envisaged agreement goes beyond the WTO standards

The proposed cooperation in the field of biotechnology is to be based on the outcome of the WTO dispute settlement procedure. It is fully expected that the CETA and TTIP rules in this regard will go beyond the WTO standards since the WTO only authorises bilateral agreements if they are aimed at closer economic integration between the participating states over and above the level achieved under the WTO.⁶¹ That already makes it clear on principle that TTIP and CETA cannot just be a case of ‘and so on’ but in fact represent a ‘WTO plus’.

Here it should also be remembered that some of the WTO standards must be regarded as obsolete. The 1994 trade-restricting measures provided for under WTO legislation and set out in Article XX GATT go back to much earlier versions (GATT 1947), to a time when modern environmental and consumer protection standards had not yet been developed. Instead of improving these standards with a view to strengthening environmental and consumer protection, however, the CETA agreement waters down environmental and consumer rights even more.

With regard to the object of dispute under the WTO dispute procedure, the EU would be doing an about-turn with the signature of CETA. Instead of defending its standards, as it was still endeavouring at least in part to do under the WTO dispute settlement procedure, it is now agreeing to a binding process in which it is in a weak legal starting position. The position of Canada and (with regard to TTIP) the USA, on the other hand, becomes much stronger. They can threaten to continue the dispute procedure not just under CETA and TTIP but also under the WTO.⁶² It may be assumed that under these conditions EU standards in the agricultural genetic engineering sector will tend to fall.

In the comparable WTO dispute on the approval of ‘hormone-treated meat’, the EU followed a different line and managed to uphold its position. Even though the Panel found against it, the EU adhered to its position and defended it even in the face of penalties,⁶³ resuming the proceedings at a later date.⁶⁴ The planned signature of CETA will certainly have consequences that go far beyond the WTO dispute settlement procedure (WT/DS292):

60 Krajewski, M., (2014) Modalities for investment protection and Investor-State Dispute Settlement (ISDS) in TTIP from a trade union perspective, Friedrich Ebert Stiftung, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2519995

61 www.wto.org/english/tratop_e/region_e/regatt_e.htm

62 Prof. Dr. Peter Tobias Stoll, Dipl. jur. Hagen Krüger, 2014. Agrar- und verbraucherpolitische Auswirkungen des Comprehensive Economic and Trade Agreements (CETA) zwischen der EU und Kanada, https://www.gruene-bundestag.de/fileadmin/media/gruenebundestag_de/themen_az/EU-USA_Freihandelsabkommen/Stoll-Krueger_CETA-Kurzstudie.pdf (Deutsch!)

63 www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm

64 www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm

1. Unlike in the framework of WTO, in this case concrete measures and objectives such as accelerated approval procedures are agreed and are binding.
2. The range of issues that can be negotiated under CETA is significantly wider than under the WTO procedure and now covers all issues in the biotechnology sector, including labelling and measures to protect GM-free agriculture.
3. The planned agreements have problematic implications for the margin for play with regard to future legislative processes. The draft legislation in question would first have to be submitted to the specific CETA bodies for consultation, before being put to the vote by the elected parliaments. These bodies examine the proposed legislation in terms of the specifically formulated CETA objectives. The WTO, on the other hand, merely provides for the general notification of the legal texts in question, without reference to the specific objectives in the biotechnology sector.
4. Under the WTO procedure, only certain cases actually give rise to WTO dispute settlement procedures and the establishment of the appropriate bodies. In the case of both the CETA and the TTIP agreements, provision is made for recourse to dispute settlement mechanisms and bodies designed to ensure observance all the agreed rules on a continuous basis.⁶⁵
5. While WTO dispute settlement procedures are reserved only to States, under CETA and TTIP firms that are in certain positions and that may even be obliged to do so under company law, or even individual investors⁶⁶ can file claims for compensation.

5.2 Examples of the effects of CETA and TTIP

The planned free trade agreement is having an effect even before its signature. The negotiations are already producing a deterrent 'chilling effect'. This can be demonstrated by examples such as the cloning of animals for food supply. CETA and TTIP can be expected to have other potential effects on food labelling and the standards of EU approval procedures.

5.2.1 Cloning animals for food supply

The European Parliament has been calling for some years now for not just the cloning of working animals but also imports of products from cloned animals and their offspring to be regulated.⁶⁷ This is mainly because of ethical reservations, since the cloning process causes huge health problems for the cloned animals and their surrogate mothers. For the same reasons the EU Commission's advisory group on ethics (European Group on Ethics in Science and New Technologies, EGE) is also opposed to the cloning of animals for food supply.⁶⁸

⁶⁵ Unpublished report by the Research Services of the German Bundestag, EU-Kennzeichnungspflicht für Lebensmittel aus mit GVO gefütterten Tieren, PE 6 – 3000 – 141/14, 15. August 2014, leaked by PowerShift – Verein für eine ökologisch-solidarische Energie- & Weltwirtschaft e.V., 19.11.2014.

⁶⁶ www.spiegel.de/wirtschaft/unternehmen/yukos-russland-verliert-rechtsstreit-gegen-ex-eigentuermer-a-983167.html (Deutsch!)

⁶⁷ European Parliament resolution of 3 September 2008 on the cloning of animals for food supply, P6_TA-PROV(2008)0400

⁶⁸ EGE, The European Group on Ethics in Science and New Technologies to the European Commission (2008): Ethical aspects of animal cloning for food supply, opinion number 23, http://ec.europa.eu/european_group_ethics/publications/index_en.htm

In this connection, in 2010 Karel De Gucht, the EU Commissioner who was responsible for the CETA and TTIP negotiations until 31 October 2014, circulated what is known as a non-paper warning of substantial implications for trade with the USA.⁶⁹ In it he warns urgently against measures to restrict or ban imports of the products in question. According to him there is little or no alternative to importing these products, since a ban would lead to serious problems for trade with the USA:

Imposing an import ban on the offspring of cloned animals will lead to serious problems with the US and Latin America and will also have a great impact on EU agricultural production if our food exports will be banned as a regulatory measure.

To begin with the US, immediate measures that they could adopt immediately as a reaction to a ban on offspring of cloned animals could include the denunciation of the MoU on Hormones⁷⁰ and going back to Carousel sanctions, hitting our exports for a value of approximately 250 million euros per year. Like in 2008, sanctions would be targeted on Member States and sectors where damage will be greatest. The US would also likely restart litigation on all pending SPS disputes, such as poultry AMT⁷¹ or GMOs, as well as challenging the measures on cloning.

Such backlash in US relations would quickly jeopardise the progress made over the last few years on DDA⁷² and TEC⁷³.

This non-paper, which is notable for its dramatic tenor, has a significant bearing on the discussions about TTIP and CETA for a number of reasons:

- It shows in exemplary fashion the significance of biotechnology processes for transatlantic trade. If, for instance, the EU required that cloned animals must be fully labelled as such or be banned from being placed on the market, this could be regarded as in breach of the CETA provisions and have far-reaching implications. That is all the more true in that the CETA agreement makes no provision for the introduction of legally binding labelling, which would promote freedom of choice.
- It is argued that the appropriate protective measures cannot be implemented because that would lead the USA to reactivate WTO dispute settlement proceedings that are already pending or initiating new proceedings. Yet although there is certainly some debate in the framework of WTO on ethical margins for play⁷⁴, the CETA agreement makes no reference to regulations of that kind.
- It becomes clear that transatlantic talks such as those under the Transatlantic Economic Council (TEC), which in legal terms still fall far below the level of binding agreements, can yet have a strong deterrent ‘chilling effect’.

69 http://www.testbiotech.org/sites/default/files/Non_Paper_EU_Commission_Cloning_online.pdf

70 Memorandum of Understanding, on imports of hormone-treated meat, https://www.ustr.gov/sites/default/files/asset_upload_file254_15654.pdf

71 Antimicrobial treatments (AMT), and other animals for slaughter.

72 Doha Development Agenda (current trade round and the follow-up to WTO negotiations).

73 Transatlantic Economic Council (TEC), see http://ec.europa.eu/research/biotechnology/eu-us-task-force/index_en.cfm

74 See e.g. WTO Director-General Pascal Lamy, Ministerial Segment – Panel on Biodiversity and Trade – Convention on Biological Diversity 8th Meeting of the Conference of the Parties (Cop-8) 26-29 March 2006, http://www.wto.org/english/news_e/sppl_e/sppl22_e.htm; see also Article GATT XX, which on paper at least permits trade-restrictive measures ‘necessary to protect public morals’.

The wording of the non-paper must also be considered in relation to the ongoing CETA and TTIP negotiations. Canada's negotiations on CETA date back as far as 2009. In 2010 the EU Commission launched a strategy paper announcing negotiations on free trade agreements with the USA.⁷⁵ It may, therefore, be assumed that De Gucht's Opinion was also aimed at ensuring that neither the ongoing nor the planned free trade negotiations are jeopardised.

5.2.2 Objectives set out in the coalition agreement

CETA and TTIP do not just affect existing standards but also have implications for future regulations in particular. The German Federal Government's 2013 coalition agreement⁷⁶ lists a number of issues in the field of biotechnology and agriculture on which political progress is needed: a ban on cloning working animals, ban on patenting conventional breeding, compulsory labelling of products originating from animals fed with GM plants, zero tolerance of the contamination of food, and the protection of GM-free seed. The coalition agreement provides as follows:

'At European level, we advocate a ban on animal cloning and on the import of cloned animals and their meat. We strive for mandatory labelling for the offspring of cloned animals and their meat.'

'We advocate mandatory EU labelling of products from animals fed on genetically modified plants.'

'We believe in zero tolerance of unauthorised genetically modified constituents of foodstuffs – and also seed purity.'

'The existing ban on patenting conventional breeding methods, animals and plants obtained from such methods as well as their products and the material intended for producing them should be implemented and the relevant European regulations tightened up.' (unofficial translation)

5.2.2.1 Preventing broader labelling rules

Presumably the first two aims could no longer be implemented under the CETA provisions. These offer no margin for new, binding labelling rules aimed at giving consumers greater freedom of choice. It may be assumed that the German Government no longer has any room for action in these areas even before the signature of CETA and during the TTIP negotiations. The drafting of EU legislation to that effect would be contrary to the binding declarations by the EU and the German Federal Government that they intend to sign CETA and negotiate TTIP to a successful conclusion. This also follows from a report by the German Bundestag's Research Services on the labelling of foodstuffs.⁷⁷ It states as follows with regard to the Federal Government's statements of intention:

'Against the background of the WTO legal provisions and the objectives set out in the TTIP agreement and CETA, secondary legislation on mandatory labelling could be described as an obstacle to trade that is incompatible with the objectives of the CETA and TTIP negotiations at issue.'

75 EU Commission, 2010, Trade as a driver of prosperity, SEC(2010) 1269, http://trade.ec.europa.eu/doclib/docs/2010/november/tradoc_146940.pdf

76 <https://www.cdu.de/sites/default/files/media/dokumente/koalitionsvertrag.pdf>

77 Unpublished report by the German Bundestag's Research Services, 'EU-Kennzeichnungspflicht für Lebensmittel aus mit GVO gefütterten Tieren', PE 6 – 3000 – 141/14, 15. August 2014, leaked by PowerShift – Verein für eine ökologisch-solidarische Energie- & Weltwirtschaft e.V., 19.11.2014.

In the view of the German Research Services, even the start of the negotiations on the free trade agreements will mean that draft legislation on the matter can no longer be initiated. Accordingly, such draft legislation is incompatible with the negotiating mandate given in the framework of CETA and TTIP:

‘During the negotiations, the Council and the Commission have a duty to do their utmost to ensure that trade agreements are compatible with EU law (...), The introduction of a broader labelling mandate for products from animals fed with GMO foods meant, however, that new legislation must be enacted and requires the Commission to propose legislation to that effect, where appropriate at the request of the Council (...). That is why the Commission’s obligation to successfully conclude the negotiations on a TTIP agreement and on CETA could lead it to (...) refrain from submitting a legislative proposal.’

Member States also find they have significantly less scope for action:

‘With regard to the EU’s exclusive competence, conversely for the Member States this implies (...) the requirement not to take measures that could jeopardise the achievement of the objectives of the EU Treaties. (...) could lead to (...) to the requirement that Member States may not take any measures that have a significant adverse impact on the measures adopted or to be taken for their implementation. In accordance with a standstill clause, Member States may not take any action that could weaken the EU’s international negotiating position or bind the EU in advance by creating a fait accompli.’

Moreover, the conclusion of the free trade agreements would very likely bring complaints:

‘In view of the objective of the substantial removal of non-tariff barriers to trade under the planned TTIP agreement and CETA, extending the labelling requirement to products of GM-fed animals following the conclusion of the agreements would carry the risk of complaints from the USA and Canada in accordance with the standards of the TBT and SPS agreements.’ (unofficial translations)

That means it will not be possible to implement the German Federal Government’s plan while the CETA and TTIP negotiations continue or even after the agreements have been signed. Unless the EU negotiating line is substantially revised, consumers will, therefore, have no freedom of choice in future either with regard to animal products from animals descended from cloned animals or fed with GM plants.

5.2.2.2 Risks to GM-free agriculture and food production

Zero tolerance of contamination with non-authorized GMOs in food and maintaining GM-free, clean seed form part of existing EU standards, which the German Federal Government has committed itself to uphold under the coalition agreement.

Signature of CETA will not necessarily bring about an immediate lowering of existing standards. Since, however, it has been agreed under CETA to hold talks about this question, the future of these standards is uncertain. Canada (and where appropriate the USA) can argue pursuant to CETA that these measures are not concerned with demonstrable risks to human health and the environment but are precautionary measures to protect GM-free agriculture. There is, however, no provision for measures of that kind under CETA.

The consequences would be serious. If, for instance, the contamination of seeds with GMOs was authorised, that would make GM-free agriculture impossible in the Member States in the long term. Abolishing the distinction between cultivation and processing systems in the EU would also mean that the EU food industry lost the potentially important competitive advantage of GM-free agriculture.

Topical cases also show that removing the distinction between forms of production can have considerable adverse effects on international trade. US maize exports are currently seeing sales decline considerably; with exports to China affected most. The US harvest includes a GM strain of maize (technical name: MIR162, brand name: Agrisure Viptera) made by the Syngenta company, which is not authorised in China and was not listed separately in the US harvest. Agricultural trading companies such as the Cargill group in the USA, which are suffering substantial economic losses as a result, have already announced that they are suing Syngenta for damages, which are likely to come to at least US\$ 1 billion.⁷⁸

5.2.2.3 Circumventing the bans in patent law

With regard to patenting plants and animals, the text of CETA leaves some margin for interpretation by interested circles and their patent lawyers. On the one hand it regards patents as investments, while on the other it establishes that the revocation of patents does not constitute expropriation.⁷⁹ Regulations in this sector must be compatible with the WTO⁸⁰ and are to be reviewed after three years.⁸¹ That does not create adequate legal certainty as to whether the Federal Government's proposal can be successfully implemented.

With regard in particular to customary patent protection in the USA, this also produces clear conflicts between objectives as well as the corresponding legal and political hurdles for TTIP. In this context it may well happen that even the beginning of the TTIP negotiations means that the Federal Government can no longer call as planned for a Europe-wide ban on conventional animal and plant cultivation. As has been shown, the very fact of negotiations beginning has a legally binding effect.

5.2.3 EU approval procedures

Even without the signature of CETA and TTIP, EU approval of GM plants is already marked strongly by economic interests. In 2014, for instance, when the EU feed industry considered that EU approvals were not progressing fast enough, their umbrella organisations called for the rapid approval of eight different GM crops.⁸² At an EU Commission meeting that discussed possible approval, EU trade Commissioner De Gucht announced that the USA could speed up imports of apples and pears from the EU to the USA if GM crops were approved.⁸³ Some EU Commission members had sought in advance to agree a 'deal' with the USA, which, however, was not implemented by the time of the meeting. This case shows the extent to which EU approval of GM plants is already being steered by economic interests and arrangements made behind closed doors. That is why some sections of civil society are also calling for the test standards to be tightened significantly.⁸⁴

The closer cooperation between the EU and its transatlantic trade partners, which is a goal of the free trade agreements, will substantially increase the pressure on the EU approval procedures.

78 <http://www.reuters.com/article/2014/11/19/adm-syngenta-ag-lawsuit-idUSL2NoT92P520141119>

79 Investment Section 4: Investment Protection, Article X.11: Expropriation, p. 159

80 Since the TRIP agreement of the WTO does not require patents for plants and animals, these could, therefore, be excluded from patent protection.

81 Investment, Declaration to Investment Chapter Article X.11 Paragraph 6, p. 183

82 www.feednavigator.com/Regulation/EU-feed-industry-on-edge-as-it-awaits-approval-of-eight-GM-crops

83 <http://ec.europa.eu/transparency/regdoc/rep/10061/2014/EN/10061-2014-2098-EN-F1-1.Pdf>

84 http://www.boelw.de/uploads/media/141008_BOELW_Studie_Risiken_mit_amtlichem_Siegel.pdf (Deutsch!)

Changes can be expected both to the legal framework conditions and to the risk assessment requirements. 2015 already offers an opportunity to lower the risk assessment requirements: in 2013 the Commission submitted new requirements (Commission Implementing Regulation (EU) No 503/2013) relating to the risk assessment of food and feed produced from genetically modified plants.⁸⁵ Whether these requirements will suffice for a real risk assessment cannot be discussed here. They represent a move towards tighter test requirements compared to current practice.⁸⁶

The regulation requires, *inter alia*:

- › feeding trials of GM plants over a 90-day period;
- › improved statistical methods for comparisons with conventional plants;
- › more stringent requirements on the use of comparator and control groups during release trials.

These requirements are to be reviewed again in 2015. Should CETA be signed by then, it is not unlikely that they will be revoked and replaced by less stringent ones.

Since CETA does not place much emphasis on the precautionary principle, on principle that agreement shifts the burden of proof to the disadvantage of the EU. Canada (and where appropriate the USA) could require according to the straitjacket of CETA (and where appropriate TTIP) that the EU submits the appropriate evidence of the harmful effects of GM plants in order to justify its test standards. Under CETA, approval based on the precautionary principle could, therefore, be replaced in part or wholly by an evidence-based approval examination. An approval examination would then – regardless of the procedures – be admissible only for products where evidence of a specific potential risk already exists.

Under these framework conditions, there is the problem that legislators and authorities come to depend on the test results available in each case. Shortcomings in risk research, uncertainty in risk evaluation and references to the limits of current scientific knowledge are then no longer deciding factors in the approval examination. The requirements relating to approval examinations and where appropriate rejection of applications would have to be justified by tests providing clear evidence of potential risks. Yet test results of this kind are often not available for various reasons.

- › Genetic engineering continues as before to rely on only partially validated basic knowledge. The scientific understanding of the mechanisms of heredity and gene regulation is subject to constant changes. This means that new questions arise continually about the risks involved, as in the case of the risk assessment of miRNA,⁸⁷ which is absorbed with nutrients from the gut as a biologically active messenger substance. With regard to risk assessment, in some cases the decisive questions may not be asked and necessary testing methods not used for adequately examining a risk.
- › Risk assessment of GM plants is a highly complex area. Unlike in the case of procedures that work with closed systems, in this case the behaviour of organisms and populations under at times very different environmental conditions has to be assessed. GMOs often show surprising reactions to changing environmental influences.⁸⁸

85 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF>

86 However, they have not been applied to date. All approval applications submitted by the end of 2013 are examined according to the assessment system applicable at the time.

87 <http://www.efsa.europa.eu/en/events/event/140604.htm>

88 Zeller S.L., Kalininal, O., Brunner, S., Keller B., Schmid B. (2010) Transgene x Environment Interactions in Genetically Modified Wheat: <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0011405>

- › Some of the effects of GM plants only become apparent in cases of extensive cultivation, after a period of many years or on very close examination. For years the industry disputed the idea that cultivating glyphosate-resistant GM plants would lead to weeds becoming resistant to the herbicide glyphosate⁸⁹ – as has since been proved beyond doubt.⁹⁰
- › In many cases risk examination is interest-driven. This applies both to national research programmes, which are often geared more to encouraging innovation and competition than to a critical examination of the risks, and to external contract research commissioned by the industry. There is detailed evidence of how research can be misused for the sake of economic interests, as in the case of, for example, the tobacco industry⁹¹ – similar mechanisms can be found in the biotechnology sector.⁹²

The industry has long since recognised the potential advantage of these weaknesses in an evidence-based approval system. It propagates the view on both sides of the Atlantic that there is no ‘consensus’ on the safety of GM plants and that the precautionary principle is therefore obsolete. This allegation, where the choice of words is a deliberate reminder, although the other way round, of the debate about climate change, is loudly trumpeted on both sides of the Atlantic. The implication is that there will always be doubters, but surely the scientists had reached a common consensus.

There is good evidence of the methods used to instrumentalise science.⁹³ Depending on the economic interests at stake, either doubts are sown (e.g. climate change) or it is suggested that a product is safe (e.g. by the tobacco industry and the genetic engineering industry).

Apparently independent experts also disseminate statements of this kind, like the EU Commission’s outgoing Chief Scientific Advisor Anne Glover.⁹⁴ These arguments are set out in detail in, for example, the report of the European Academy Scientific Advisory Panel (EASAC, 2013). The EASAC report was published almost exactly at the same time the TTIP negotiations began in June 2013. Its approach is clearly based quite heavily on the perspective of the industry.⁹⁵ This is clear, for example, from the fact that the authors describe the introduction of new GMOs as a priority.

‘Priorities include introducing insect-resistance and herbicide-tolerance into wheat, barley, oil seed rape, soybeans, potato, vegetable brassicas and other horticultural crops.’

The EASAC authors advise abandoning the existing EU genetic engineering regulations based on the precautionary principle and moving towards the practice of countries such as Canada and the USA that restrict their risk assessment to case-by-case testing of individual products. The core demands of the

89 See Then, C. & Boeddinghaus R. (2014) Das Prinzip industrielle Landwirtschaft in der Sackgasse, eine Studie Im Auftrag Der Grünen / Europäische Freie Allianz und Martin Häusling, MEP, www.gruene-europa.de/fileadmin/dam/Deutsche_Delegation/Broschueren/140926BroschureSuperWeeds_Web_.pdf (Deutsch!)

90 www.weedscience.org

91 Oreskes & Conway Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming, Bloomsbury Publishing, 2010

92 <http://www.testbiotech.org/node/1109>

93 Oreskes & Conway (2014) Oreskes & Conway Merchants of Doubt, Bloomsbury Publishing, 2010

94 <http://www.testbiotech.org/node/1090>

95 EASAC (2013) Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture, EASAC policy report 21, www.easac.eu/fileadmin/Reports/Planting_the_Future/EASAC_Planting_the_Future_FULL_REPORT.pdf

EASAC report are as follows: gene technology should no longer be regarded as a risk technology and the existing regulations should therefore be relaxed. They regard the precautionary principle in particular, which forms the basis of EU risk assessment, as obsolete. The EASAC authors argue that enough experience has now been gained with GM plants to show that they pose no risks. Nor should all GMOs be subject to risk assessment any more, but only individual products where it is known that they pose risks and may cause damage:

'(...) in common with other sectors, the aim should be to regulate the trait and/or the product but not the technology in agriculture. The regulatory framework should be evidence-based. There is no validated evidence that GM crops have greater adverse impacts on health and the environment than any other technology used in plant breeding (...).'

If the views of the EASAC authors were accepted that would mean:

- Replacing the precautionary principle with an approval system that only examines already proven damage to human health and the environment,
- Abolishing uniform approval procedures for GMOs,
- Abolishing uniform labelling for GMOs, which implies less transparency and freedom of choice for farmers and consumers.

That means the position of the EASAC authors fits seamlessly into the agreement negotiated under CETA. The example of GM plants that come on the US market without approval procedures shows the consequences this could have⁹⁶ According to the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture, genetically modified, herbicide-resistant grass does not need to be tested under approval procedures – even though grasses are extremely liable to proliferate beyond control. Accordingly, there is no need even to test the safety of a GM pineapple marketed by the Del Monte company, which has an altered content of anthocyanins (certain colourings that are also important to vitamin content). So these products can be placed on the market without any risk assessment, do not need to be labelled and do not come under any product traceability system. Meanwhile, following trial releases, GM grass is now spreading out of control in the USA, with unforeseeable environmental implications.⁹⁷

5.2.4 Suspension of mandatory approval for new genetic engineering technologies?

Hitherto, any use of genetic engineering processes in the EU has required the appropriate risk assessment. With a view to the impacts of TTIP and CETA, however, account must also be taken of more recent technical developments that have not yet been regulated. This problem can also be illustrated by looking at the report of the European Academy Scientific Advisory Panels (EASAC 2013). The report also presents new technologies designed to make it possible to edit genomes in a more targeted – and sometimes more radical – manner than is possible with existing genetic engineering processes. One method used is 'genetic-scissors', which cut the genes at a specific point and can also insert additional DNA. The new technologies are particularly relevant to risk assessment because in recent years artificial

96 Camacho A., Van Deynze, A., Chi-Ham C., Bennett A.B. (2014) Genetically engineered crops that fly under the US regulatory radar. *Nature biotechnology*, 32(11): 1087-1091.

97 <http://www.stop-the-spread-of-transgenes.org/>

DNA synthesis processes have also evolved continually. This also makes it possible to create synthetic DNA sequences that do not exist in this form in nature.⁹⁸

The EASAC authors also believe that new technologies will be available in future that will offer new, radical methods of genetically modifying plants.

'Further ahead, scientific discovery worldwide may enable much more radical options for GM crops involving highly polygenic traits (...).'

At the same time, however, the EASAC authors advocate the complete exclusion of at least some of the new processes from GMO legislation:

'(...) there is a need for urgent action to agree the status and regulation of New Breeding Techniques and, in particular, to confirm which products do not fall within the scope of the legislation on genetically modified organisms.'

The exclusion of certain processes from mandatory regulation can systematically undermine the EU's process-based approval and labelling system. Since CETA stipulates that proposed new rules must on principle first be submitted to the trading partners' joint forums, a dynamic could arise where new GM processes are on principle tested less thoroughly than is currently the case.

5.3. Other effects

Other effects relate to arrangements made within the framework of multilateral environmental agreements and legislation on pesticides.

As shown earlier, the Contracting Parties should also agree their negotiating positions within the framework of multilateral environmental agreements. This could lead to significant adjustments to the negotiations within the framework of the Convention on Biological Diversity (CBD). To date, the Contracting Parties often set very different priorities here, which means, for instance, that in certain cases the interests of the developing countries can prevail. If this balance were altered by arrangements made between the EU and Canada or the EU and the USA, that would have a considerable impact on the future of the agreements. Moreover, the USA never ratified the CBD agreement but thanks to TTIP it may now be able to make its positions prevail indirectly via the EU.

Under the legislation on pesticides, the Contracting Parties agreed that data submitted with a view to the approval of plant protection products must be treated in confidence for at least ten years.⁹⁹ This regulation is contrary to the recent case law of the European Court of Justice, according to which documents of this kind must be open to the public.¹⁰⁰

98 Then, C., (2014) Free trade for 'high-risk biotech' ? Future of genetically engineered organisms, new synthetic genome technologies and the planned free trade agreement TTIP – a critical assessment, Testbiotech, www.testbiotech.org/node/1007

99 IPR, Article 11 Data Protection on Plant Protection Products, p. 347.

100 <http://curia.europa.eu/juris/liste.jsf?jsessionid=9ea7d2dc30dbc219e99d345b4ff48cbda91946064440.e34KaxiLc3qMb40RchoSaxuMb3jo?num=T-545/11&language=en>

6. Conclusions

On the basis of the published CETA text it has to be assumed that the planned free trade agreements are certainly aimed at lowering the standards of environmental and consumer protection in agricultural genetic engineering. It is likely that both the German Federal Government and the EU Commission are aware of these consequences, even though this is not currently being discussed in public.

Simply by opening the negotiations the EU is tied to a legally binding process. As a result, even the negotiating mandate produces a 'regulatory chill', which can lead to a standstill on the relevant regulative issues. Even the current CETA and TTIP negotiations make it more or less impossible to expand the mandatory labelling of various food production processes. That also affects the Federal Government's plans to label the products of cloned animals or animals fed with GM plants.

After the signature of CETA, which is widely regarded as a blueprint for TTIP, it is likely that on the basis of the agreed objectives and mechanisms the EU standards for the protection of GM-free agriculture, such as measures to prevent contamination and maintain clean seed, will have to be lowered in the medium term.

We may also expect changes to approval procedures. Firstly, we may assume that the precautionary principle will become increasingly secondary. Furthermore, it is questionable whether all GM processes will even be covered by approval procedures. This trend is already being backed by campaigns largely driven by economic interests, which try to suggest that there is a 'consensus' about the safety of GM plants as a means of influencing the setting of future standards.

Nor must we underestimate the role of the planned dispute settlement tribunals in protecting investors. The definition of investment chosen under CETA is a very broad and comprehensive one. It is not unlikely that pressure can also be exerted on environmental and consumer standards via these dispute settlement tribunals, which may adversely affect not only legal standards but also administrative acts. Unlike under WTO law, in the case of these private dispute settlement tribunals it is not States but companies and their investors that have the right to submit claims.

For a long time now, however, there have been fears of the consequences not just of the planned dispute settlement tribunals but also and more particularly of the objectives agreed in the biotechnology sector, with the aim of harmonising legislative standards.

The large number of new bodies will also encourage governance structures that can be effectively steered by, in particular, powerful economic actors. Within these bodies, the interests of financially strong market participants and lobby groups will predominate because they can appoint their own experts to as many of them as possible, systematically monitor their activities and steer them in a certain direction. The imbalance that produces between the powerful agricultural industry and the interests of the wider public cannot be corrected by specifically opening some bodies to civil society. That does not ensure participation on an equal footing. These new bodies also require a considerable extra outlay on the part of the Member States, which risks eventually proving too much for the smaller states.

These bodies would create a kind of shadow government of experts responsible for examining whether both existing and also future legal standards are compatible with the free trade agreement. In democratic terms, they are as problematic as the planned dispute settlement tribunals: competences that the national parliaments originally transferred to the EU will be shifted from there to bodies that function as a kind of force majeure or legal inspectorate. They are subject to very little public control but have a strong impact on the democratically elected institutions.

One of the dangers is that this change to the 'rules of play' will invalidate EU standards achieved after years of political wrangling. Looking to the future, society will certainly lose some of its political freedom of decision. Under these framework conditions, policy-makers will have no alternative but to follow the dictates of free trade.

It is also worth noting that even if the TTIP negotiations are not concluded, CETA may have a considerable impact on genetic engineering regulations in Europe since many interested US companies also operate through subsidiaries in the Canadian market and can therefore enjoy the advantages granted to 'Canadian' firms.

If environmental and consumer standards are to be maintained and improved, they should have been excluded explicitly from the scope of the CETA agreement. At the very least, important foundations of EU regulations such as the precautionary principle and consumer freedom of choice should have been mentioned explicitly as the basis of CETA. But that is not the case. For that reason alone, the CETA agreement that has already been fully negotiated should not be signed, at least from the perspective of environmental and consumer protection.

In the case of the TTIP negotiations, the mistakes made with CETA could, in theory at least, still be avoided. To this end, the agriculture and food production sector should be taken out of the negotiations to prevent any lowering of environmental and consumer protection standards. Patents on animal and plant breeding should also be excluded from the agreement. Unless this can be specified in the negotiating mandate, the only way to avoid the risk of a deterioration of the status quo will be to break off the talks.

