

CETA, TTIP and the EU precautionary principle

Legal analysis of selected parts of the draft CETA agreement
and the EU TTIP proposals.

Study

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A. Executive summary

1. TTIP is a free trade agreement currently negotiated between the USA and the EU. CETA is a similar, but already finalized agreement between the EU and Canada, which now awaits signature, provisional application and ratification. In both cases, the reduction of non-tariff barriers to trade is an important objective. These non-tariff barriers to trade include regulation of sensitive areas such as health, environmental as well as consumer protection.
2. In the EU, the regulation of the activities and products covered by these legal branches can be based on the precautionary principle (scientific uncertainty), which is reflected in international law and is firmly established in the European Treaties, laws and jurisprudence.
3. The precautionary principle basically enshrines that in case of insufficient scientific evidence on the existence of a risk, for instance by a product, the decision-maker may nevertheless take action and, for instance, apply regulatory restrictions on the producer or the product. One of its main considerations is that science must and need not be the only factor to take into account when deciding on whether to take regulatory action against a potential risk. While generally also prescribing the conducting of research and application of scientific methods, it is this regulatory situation of scientific uncertainty which the precautionary principle treats differently from the regulatory approach in USA and Canada. There, regulation is pertinent only where there is proof of causation of a risk, and regulation is tested against cost/benefit analyses.
4. Because TTIP and CETA aim for regulatory branches in which the EU applies the precautionary principle, there is concern that these treaties would hinder and inhibit the EU to continue to regulate in accordance with this fundamental EU law principle in the future.
5. TTIP and CETA, as envisaged, would operate in the ambit of the WTO. The parties of TTIP and CETA would continue to be bound by WTO-law, which thus provides an important normative framework also for the application of the precautionary principle by the EU.
6. The WTO-SPS-Agreement, which covers sanitary and phytosanitary measures, entails an obligation that such measures must be based on a risk assessment (Art. 5.1). Where there is no sufficient scientific evidence available, only provisional measures are allowed (Art. 5.7), accompanied with an obligation to seek to obtain additional information necessary for a risk assessment, and to review the provisional measure within a reasonable period of time.
7. This obligation under the WTO-SPS-Agreement, which as it stands allows for precautionary measures only to a very limited extent, gave rise to two disputes before the WTO between the EU and the USA and Canada: on beef produced from hormone treated cattle, and on the European regulation on genetically modified organisms. In both disputes, the EU unsuccessfully tried to justify its measures with reference to the precautionary principle. Still, both and other WTO decisions include passages which imply some margin and flexibility for regulation based on the precautionary principle.
8. TTIP and CETA both encompass chapters on SPS-measures, which overall confine themselves to incorporate the WTO-SPS-Agreement. In the light of the WTO disputes and the EU's lack of success in invoking the precautionary principle, such reference to WTO-law must appear as if the EU conceded its position on the admissibility of the precautionary principle. The EU failed to add provisions and language that point to the EU's obligation to adhere to the precautionary principle, and make use of existing margins for the precautionary principle in WTO jurisprudence.

9. The same is true for the chapters on technical barriers to trade (TBT) in the CETA- and in the TTIP-drafts. These chapters likewise merely refer to the respective WTO Agreement on TBT-Measures. Neither does the WTO-TBT-Agreement contain any explicit provision on measures based on the precautionary principle, nor is there any WTO jurisprudence on this issue. The reference in the CETA- and TTIP-drafts to the WTO-TBT-Agreement thus transfers the existing legal uncertainty on this matter in WTO-law into CETA and TTIP, without clarifying the EU's position and making use of existing margins in WTO law for the application of the precautionary principle.

10. In the SPS- and TBT-chapters of the CETA- and TTIP-drafts, procedures of mutual recognition (TBT) and of equivalence of standards (SPS) play a key role. In both these cases, relevant provisions fail to adequately accommodate and respect the application of the precautionary principle with sufficient clarity. Accordingly, such procedures are allowing products produced and authorized under US and Canadian standards to be marketed in the EU without being previously authorized under an EU regime in accordance with the precautionary principle.

11. Both CETA- and TTIP-drafts cover chapters on regulatory cooperation. These chapters cover the full range of regulations that may have an impact on trade, and extend to the regulations' drafting stage. The CETA- and TTIP-drafts are formulated in a way that there is no direct and open contradiction to the precautionary principle. However, the methods and basic assumptions of regulatory cooperation do not sufficiently safeguard the precautionary principle as a regulatory approach either. Although the chapters acknowledge the parties' commitment to high standards of health and environmental protection, the focus lies on the reduction of trade barriers and efficiency, and the precautionary principle is not mentioned explicitly.

12. Both CETA and TTIP-drafts each cover chapters on "Trade and Labour" and on "Trade and Environment". These enshrine a right to regulate for the prospective treaty parties in the material scope of the respective chapter. Albeit not explicitly mentioning the precautionary principle, the right to regulate in these chapters take over Principle 15 of the Declaration of the UN Rio Conference on Environment and Development from 1992, which explicitly mentions the term "precaution".

13. However, the range of this reference to the precautionary principle is limited. The chapter on Trade and Labour addresses labour standards and thus only covers a limited part of health protection. The right to regulate in the chapter on Labour and Environment is guaranteed only to the extent that regulations conform to other provisions of the respective treaty, which importantly includes the far reaching and already criticized SPS-chapters. The chapters on regulatory cooperation refer to these two chapters, however without the needed precision so as to bring to bear the precautionary principle in regulatory cooperation on the areas of Trade and Labour as well as Trade and Environment. With a view to the EU precautionary principle, the named provisions in the chapters on Trade and Labour and Trade and Environment are welcomed. At the same time, they reflect a problematic normative imbalance, as the precautionary principle is partly and only anchored in norms on the protection of labour standards and environment, but not in the same manner for the highly sensitive regulatory area of protection of human health in general and for consumer protection.

14. European food law explicitly highlights the precautionary principle. Comparable to the WTO-SPS-Agreement, it encompasses an obligation to revise precautionary measures in a reasonable period of time. However, it concretizes the term “reasonable” by pointing to nature and intensity of the risk at stake, as well as the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment. This concretization increases the margin for regulatory action on the basis of the precautionary principle, albeit without being recognized under WTO-law yet. However, there is no clear reference to the precautionary principle. It is thus likely that existing and future EU food regulation may increasingly be challenged, questioned and delayed or even prevented from being enacted.

15. Regarding the regulation of maximum residue levels of pesticides, it is problematic that the CETA- and TTIP-drafts are orientated towards Codex-Alimentarius-Standards, which are lower than the EU’s. It is particularly surprising that the European Commission, apparently in anticipation of the conclusion of CETA- and TTIP, has offered to lower the stricter EU standards towards Codex-Alimentarius-Standards.

16. The dispute on beef produced from cattle treated with hormones is barely touched by the CETA- and TTIP-drafts. There are no indications that the EU is to deviate from its position which is based on the precautionary principle.

17. The EU’s position on GMO regulation based on the precautionary principle is not directly threatened by the CETA- and TTIP-drafts, but not safeguarded either. Legal risks arise in particular from the envisaged cooperation in the SPS-chapters of the treaty drafts. The CETA-draft in addition covers a dialogue on cooperation regarding GMO regulation without reference to the precautionary principle. Neither of the two drafts refer to the important Cartagena-Protocol on Biosafety and its far reaching safeguards for the precautionary principle.

18. EU regulation on chemicals – in particular the REACH-regulation – is likewise not directly and explicitly threatened by the CETA- and TTIP-drafts, but not safeguarded either. It is to be expected that the REACH-regulation, which is highly criticized by a number of states, including the USA and Canada, will get under further pressure when regulatory cooperation orientated towards efficiency and the reduction of trade barriers is intensified, because the precautionary principle is not even implicitly acknowledged in the relevant treaty provisions.

19. The regulation of endocrine disruptors is another field that could be affected by CETA and TTIP. Apparently at least partly in anticipation of the conclusion of CETA and TTIP, the European Commission postponed establishing criteria necessary to give effect to European laws on endocrine disruptors which are based on the precautionary principle. The General Court of the EU found in December 2015 this omission to be in violation of EU law (T-521/14). This reflects a possible pattern of how the precautionary principle might be undermined by CETA and TTIP.

20. Nanotechnology as a particularly dynamic field of research with a broad range of possible market uses is another important example for the application of the European precautionary principle, because its risks are still scientifically uncertain. Also in this field, a greater pressure to justify measures based on the precautionary principle is overall to be expected by CETA and TTIP.

21. Overall, it is likely that current and future EU regulation for the protection of health, the environment and consumers will be rendered more difficult by the CETA- and TTIP-drafts. The EU precautionary principle and its future application is not sufficiently anchored and safeguarded in the treaty texts. The chapters on SPS-, TBT-measures and regulatory measures as well as the chapters on Trade and Labour and Trade and Environment follow an approach that is not in line with the precautionary approach. Endocrine disruptors and residues of pesticides are cases in which such detrimental impact on the precautionary principle becomes apparent already at present. Apparently with a view to ongoing negotiations, the EU Commission has delayed establishing criteria concerned with endocrine disruptors. The EU Commission also offered to consider reducing maximum residue levels of pesticides. In both instances, the EU Commission departed from prior public announcements, according to which TTIP would not lead to a reduction of the EU level of protection.

22. It should be noted, that the present paper does not address the CETA and draft TTIP chapters on investment and investor-State dispute settlement. The possible additional impact of these provisions on EU regulatory change, the continued realization of the EU precautionary principle and the attainment of high levels of the protection of human health and the environment certainly merits a closer look in the near future.

B. Introduction

The currently negotiated TTIP and CETA represent two of the most ambitious free trade agreements ever drafted (so called “mega-regionals”). As tariffs between the EU, Canada and USA are already on a low level, both the CETA draft agreement and the TTIP negotiations focus on the reduction of non-tariff barriers to trade, which are caused by regulations and standards of the prospective treaty parties which may impede import and export of goods and services. This includes regulation of feed, foods, chemicals, drugs and cosmetics, which aim at protecting health and the environment. Concerns arise at this point, as EU regulatory policies are guided by the precautionary principle as laid down in the European treaties. This principle meets with stark criticism from the US and Canada, both countries buttressing quite different regulatory cultures.

The question therefore is, whether the continued implementation of the precautionary principle on the side of the EU is properly secured in view of the various rules, procedures and institutional arrangements contained in the CETA draft agreement text and the EU text proposals for TTIP which aim for reducing trade barriers in this very area of regulation.

The analysis will first revisit the European precautionary principle in its legal dimension (C.). In a second step, it is necessary to see, how the principle is reflected in the law of the World Trade Organization (WTO), in the ambit of which CETA and TTIP would operate (D.). Thirdly, some of the pertinent provisions of the proposed agreements will be analysed by focusing on the chapters on sanitary and phytosanitary measures (SPS), technical barriers to trade (TBT), regulatory cooperation and trade and labour and Trade and Environment (E.). In concluding, the potential implications of the agreements on a number of regulations of the EU and implicitly on the precautionary principle will be seen (F.).

It should be noted, that the CETA and draft TTIP chapters on investment and investor-State dispute settlement chapters are beyond the scope of the present paper. They might very likely have an impact on EU regulatory change, the continued realization of the EU precautionary principle and the attainment of high levels of the protection of human health and the environment. These questions certainly merit a closer examination in the near future.

C. The precautionary principle in EU-law

The precautionary principle is legally binding EU-law, enshrined in Art. 191 TFEU on the Union policy on the environment. Art. 191 para. 1 stipulates, that this policy inter alia aims at „preserving, protecting and improving the quality of the environment [and] protecting human health“. According to Art. 191 para. 2, „Union policy on the environment shall aim at a high level of protection ... [and] shall be based on the precautionary principle ...“

In the essence, the precautionary principle stipulates that the EU or its member states may take action against a risk, even though that risk is not or not yet scientifically proven or if there is lingering scientific uncertainty. In Principle 15 of the (legally not binding) Rio Declaration of 1992, it was for the first time internationally acknowledged, with the US and Canada being in consent. Against the background of this international development, the precautionary principle was firstly introduced to EU-law in the Treaty of Maastricht. It heavily influenced EU legislation and CJEU jurisprudence, and was expressly acknowledged by the European Commission to apply in the entire field of EU law, including human health, environmental protection and consumer protection.

The precautionary principle can be considered as a modern regulatory tool for the handling of risks for health and the environment. It is based on the fundamental idea that, in the interest of a high level of protection for health and the environment, risks should be addressed at an early stage, before they concretize and materialize or damage is caused. It thereby also aims at preventing the possible high cost and losses caused by inaction in the case of hazards potentially materializing. The precautionary approach is to be realized in three different steps: Risk assessment, risk management and risk communication.

Risk assessment involves hazard identification and characterization as well as appraisal of exposure and risk characterization by continuously considering available scientific data. Crucially, scientific uncertainty in the sense of a lack of knowledge is to be taken into consideration and weighed at every stage of this process. On the basis of this scientific evaluation, risk management is conducted, which

calls for deciding if and how measures should be taken to reach a certain level of protection. As the EU Commission's Communication on the precautionary principle from 2000 stipulates, recourse to the precautionary principle is to be taken if “a scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.”

It follows that also in situations of scientific uncertainty, measures can and should be taken, if certain conditions are met as prescribed by precautionary principle. These are inter alia the principles of proportionality, of non-discrimination and of coherence. Furthermore, as confirmed by the same Communication, “a comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of the overall cost to the Community”, without however reducing this task to an economic cost-benefit analysis. “It is wider in scope and includes non-economic considerations.” Most importantly, according to the 2000 Communication of the Commission, “[i]n the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations.”

Moreover, scientific developments are to be taken into account: Scientific research should continue to be carried out while precautionary measures are in effect, which should be re-evaluated in the light of new scientific information. The precautionary principle forms the basis of a series of important EU legislative acts, such as the EU regulation of food, chemicals, biocides and pesticides, in which the precautionary principle is often explicitly mentioned. In its Communication from 2000, the EU Commission points out that the requirement of “prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives”, is one way of applying the precautionary principle. Shifting the burden of proof for producing scientific evidence to companies in EU legislation, assuming that a product is hazardous until proven otherwise, may thus be seen as an expression of the precautionary principle. Even before the principle was covered by the EU treaties, its underlying ideas had already formed part of the CJEU's reasoning in its jurisprudence since the early 1980s. The CJEU from thereon onwards frequently referred to the precautionary principle in its judgments,

which often played a decisive role in the outcome of the respective case. Not only did it serve to justify measures directed against member states, such as the export ban issued on British beef in 1998. The precautionary principle inter alia also obliged the European Commission to take certain protective measures against uncertain risks, and operated as a limitation to EU fundamental rights. Only recently, on 4 May 2016, the CJEU has found valid a EU regulation which restricted the marketing of electronic cigarettes referring to the precautionary principle.

Overall, the precautionary principle is nowadays deeply anchored in the EU legal system, in its treaties as well as in its legislative acts and jurisprudence. Importantly, it is of high relevance for continuously and dynamically safeguarding a high level of protection of health and environment in light of new scientific insights, technological and scientific developments in the future. It is a firm basis and a core of the *acquis communautaire* in the protection of health, the environment and consumers.

D. WTO-law and international regulatory cooperation: Challenges to the European precautionary principle

The critical relevance of the precautionary principle in the context of CETA and TTIP is owed to the fact that the principle is differently conceptualized in Canadian and absent in US legal systems and has not been endorsed by their regulators in the policy areas as discussed here. Both countries hold the view that an activity or a product can be regulated in as much as the link of causation between the event and the damage is manifestly proven. This contradicts the EU precautionary principle, which also takes into account scientific uncertainty. The precautionary principle allows for and even demands to take into account other than scientific criteria when confronted with scientific uncertainty (implementation, social uncertainties, etc.). Furthermore, according to their understanding, a regulation is justified where it benefits society more than it costs in the sense of a cost-benefit analysis. While the EU precautionary principle is open to such method, it is used as only one option. Furthermore, it is firmly established in the 2000 Communication of the Commission, “that the protection of health takes precedence over economic considerations”. Countries as the USA and Canada often criticize EU regulation based on the precautionary principle as unnecessary trade barriers in international fora.

In order to minimize these barriers, the rules of world trade as enshrined in the WTO and in free trade agreements set limits to national regulatory discretion and provide for means to harmonize or otherwise to provide for coherence.

The 1947 General Agreement on Tariffs and Trade inter alia allows for the adoption and enforcement of measures which are “necessary to protect human, animal and plant life and health” (Art. XX lit. b). The agreement was incorporated in the body of rules of the WTO as established in 1995 and therefore is still applicable. However, not least because of the 1947 GATT agreement, the reduction of tariffs has been progressed quite far in those days and accordingly, a need was felt to address non-tariff barriers as well. Two specific WTO-agreements were concluded to complement Art. XX GATT.

The WTO Agreement for Technical Barriers to Trade (WTO-TBT-Agreement) contains rules and procedures for technical regulations and standards in general. Moreover, a specific agreement was added to govern sanitary and phytosanitary measures (WTO-SPS-Agreement). It was particularly aimed to meet concerns of agricultural export nations about a potential use of such measures for protectionist intentions after the liberalization of trade in agricultural products. Under the WTO-SPS-Agreement, Members shall ensure that their measures are based on scientific principles and are not maintained without sufficient scientific evidence. To this end, their measures shall be based on a risk assessment. Art. 5.7 of the WTO-SPS-Agreement allows for the adoption of provisional measures in cases where relevant scientific evidence is insufficient, but requires Members in turn to seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

These rules under the WTO-SPS-Agreement as they stand substantially restrict the scope of admissible regulation in this field, leaving only very narrow room for the EU precautionary principle. Hence, a series of important disputes involving the EU, Canada and the USA arose out of these provisions and were brought before the WTO Dispute Settlement Body, which is mainly comprised by Panels and the Appellate Body. In the EC – Hormones decision, an EU import ban on US and Canadian beef produced out of cattle raised with growth hormones was found to violate the WTO-SPS-Agreement. Likewise, in the EC – Biotech judgment, the EU's postponement of admitting genetically modified organisms for market purposes was declared to violate the WTO-SPS-Agreement. In both cases, the EU was unsuccessful in justifying the respective measure by referring to the precautionary principle in more general terms as a norm of international law.

However, some passages of the above mentioned decisions seem to imply some margin for the application of the precautionary principle, albeit they are phrased in soft language and contrasted with the highlighted obligation to follow a risk assessment approach restricted to scientific criteria. Overall, WTO practice has so far proven to provide only for a rather small room for SPS-measures based on the precautionary principle and go along with considerable legal uncertainty.

Importantly, apart from SPS-measures, due to the absence of explicit provisions on regulatory methodology in other WTO-agreements, including the WTO-TBT-Agreement and the GATT, it is unclear whether other EU-measures could validly be based on the precautionary principle in the areas of regulatory policies outside the realm of sanitary and phytosanitary protection.

However, the EU precautionary principle and its implementation is not only challenged by rules of the WTO. The principle and more concrete EU positions and proposals based on it have been contested more than once, for instance by the Codex Alimentarius Commission, a body instituted jointly by FAO and WHO to elaborate international food standards.

E. General implications of the CETA- and TTIP-drafts for the the EU precautionary principle

Against this background, the potential impact of the CETA- and TTIP-drafts on the future application and implementation of the precautionary principle in the EU has to be assessed. In doing so, it should be kept in mind that free trade agreements, while being concluded outside the WTO, by no means signify a departure of its parties from the WTO and its rules. In particular, the WTO allows for Members to engage in such agreements by Art. XXIV GATT / Art. V GATS. As a result, the agreements can be seen as defining additional obligations on top of WTO rules and obligations, which remain the basis of trade relations. As a consequence, trade relations of WTO members which are parties to a free trade agreement have a somewhat hybrid structure, where both WTO obligations and the agreement's additional rules are applicable and can be enforced by WTO dispute settlement or the free trade agreement's own proper dispute settlement mechanisms respectively.

I. The SPS chapters of the CETA- and TTIP-drafts

Both CETA- and TTIP-drafts largely incorporate the text of the aforementioned WTO-SPS-Agreement and thus make it an integral part of both freetrade agreements. Such incorporation of WTO rules is a legal technique applied quite frequently in free trade agreements in order to foster a closer cooperation among parties on the basis of additional rules, institutions and procedures. In this way, CETA- and TTIP-drafts additionally incorporate earlier agreements on mutual recognition. As a consequence, parties are subject to obligations both under the WTO and the free trade agreement and enforcement by respective dispute settlement mechanisms, including eventually the adoption of trade sanctions.

At first glance, the intensification of commitment and cooperation in the area of SPS-measures might have been seen as a means to overcome the long-standing controversies between the parties in this area. However, that would have had required the parties to acknowledge the fact that the European Union is bound by the precautionary principle and that there is room for a better accommodation of

this principle in the future. Neither the CETA- nor the TTIP-draft's texts give any hint in this direction, but confine themselves to refer to the relevant rules as they stand. This is remarkable, as particularly the CETA-draft is quite elusive in incorporating wording of a Canadian-European understanding to settle the beef hormones dispute, which, however, mainly refers to Canadian positions (see for details *infra* at E.VII). The pure reinstatement of rules in the agreements under which the EU has lost two disputes brought by Canada and the US, the intensification of commitment achieved by incorporation and even more so the cooperation envisaged in the texts must appear as full EU endorsement of the state of affairs as they stand. It appears that the EU did not see the need or did not succeed in inserting some language in the draft, be it some acknowledgement of the precautionary principle or a hint in the context of the mandate of the respective institutions and processes. Lacking any textual reference in the draft, it is difficult to see how the EU could effectively table its position in the later activities of the respective institutions in CETA and TTIP.

This lack of any reference to the EU's precautionary principle is also relevant in view of the recognition of equivalence of measures as envisaged in the SPS chapters of the CETA- and TTIP-drafts and Art. 4 of the WTO SPS agreement. Procedures for the recognition of equivalence require one party to explain the reasons for a particular regulation as well as its objectives and its basis in order for the other party to be able to show that its standards and regulations meet the same objective. In this process, however, the European Union is very likely to come under pressure, as it is required to justify its regulations in accordance with the WTO-SPS agreement and its underlying values and purposes, which do not comprehensively and clearly reflect the EU precautionary principle. Although recognition of equivalence does not directly change European standards of protection, the precautionary principle and its implementation are constrained, as US and Canadian standards could be recognized as equivalent and products complying to such standards could be marketed in the EU, without being previously authorized under an EU regime in accordance with the precautionary principle.

In summary, both the CETA- and TTIP-drafts' chapters on SPS measures are in urgent need for language suitable for comforting the position of the European Union, which is bound by the precautionary principle.

II. The TBT chapters of the CETA- and TTIP-drafts

The CETA- and TTIP-drafts' TBT chapters generally follow the approach taken in the SPS chapters and refer as well as reaffirm the parties' obligations under the WTO-TBT-Agreement. Again, this approach does not serve the EU's interest in clearly safeguarding the precautionary principle. To the contrary, the extent to which measures based on the precautionary principle are admissible under the WTO-TBT-Agreement remains unclear, as there is neither any jurisprudence nor any explicit provision on this issue. By way of reference, this legal uncertainty is brought and transferred into the CETA- and TTIP-drafts. The CETA- and TTIP drafts in the TBT-chapters foresee provisions on mutual recognition of standards, which must be criticized for the same reasons. Thus, also regarding the TBT chapters, the current CETA and TTIP-drafts missed the chance to safeguard the EU precautionary principle and to avail of WTO-law's margins for its consideration.

III. Regulatory cooperation

Beyond the scope of the SPS and TBT chapters, the CETA- and TTIP-drafts aim at the reduction of non-tariff barriers to trade more generally by way of regulatory cooperation. Building on existing informal structures, the respective chapters in both draft agreements envisage a cooperation in the whole range of regulations, which can potentially impact trade. This includes issues in the range of application of the SPS and TBT agreements, but goes far beyond. Furthermore, the chapters do not only address existing regulations, but are also concerned with future policies and rules. Regulatory cooperation includes information on existing and future regulations, their objectives and their methodology and related discussions which aim at promoting coherence and may entail the harmonization, but also the mutual recognition of equivalence of regulations. Both chapters address the main objectives and orientation of such regulatory cooperation by highlighting the protection of human health and the environment, the reduction of barriers to trade and the effectiveness of regulations. Furthermore, the chapters envisage that international

standards, such as the standards of the Codex Alimentarius Commission, should be the starting point of such cooperation and the parties will furthermore work together in such international bodies for standard-setting. The two chapters heavily rely on modern concepts of procedures and methodologies for risk management and regulation. In sum, both chapters lay ground for intensive and far reaching work on regulations.

The challenge for the precautionary principle is that regulatory cooperation might bring up a clash of opposed basic regulatory methodologies in the handling of risks that are not scientifically proven. In this regard, it is worth noting that the precautionary principle, which does so importantly underpins and guides European regulatory policies, is not mentioned in this context. Similar to what has been said already in context of the SPS-chapter, it will be again difficult to see how the European Union could mainstream the precautionary principle in the important and far-reaching work done in this area without any textual basis. Importantly, the language used in the chapters on regulatory cooperation roots in modern regulatory methodology and culture of the USA and Canada, and generally favours an approach that calls for proving causation of a risk for measures to be taken against it. Notwithstanding that scientific foundation of regulation forms an important part of the EU precautionary principle as well, such language will make it hard for the EU to introduce other regulatory criteria than science in case there is no available scientific proof for a certain risk, which is central to the EU precautionary principle.

It should be noted, however, that both chapters on regulatory cooperation explicitly state, that parties are not prevented from adopting different legislative approaches. Especially the newest TTIP-draft expressly acknowledges both parties' right to pursue their regulatory principles with regard to risk assessment and risk management and referring to the principles laid down in the Treaty on the Functioning of the European Union. Without mentioning the precautionary principle explicitly, this provision could thus warrant its use in regulatory practice. In addition, participation in regulatory cooperation is explicitly characterized as voluntary in the CETA-draft, albeit the party at hand is required to be prepared to state the reasons for its withdrawal in such case. Notwithstanding that the TTIP-draft's text does not lay down that regulatory cooperation

is voluntary, the whole TTIP-chapter on regulatory cooperation is exempted from the application of the agreement's dispute settlement. These provisions may eventually allow a party to escape from being subjected to legally enforceable obligations in view of its regulations as a result of regulatory cooperation procedures. For the sake of clarity, however, it should be added, that neither these specific provisions nor the rules on regulatory cooperation altogether relieve a party from fully respecting obligations regarding regulations under the GATT, the WTO SPS and TBT agreements and under related chapters of CETA or TTIP and to face complaints brought by the other party in this regard in CETA, TTIP or WTO dispute settlement.

Notwithstanding the absence of a direct and straight legal conflict of the relatively vague regulatory cooperation chapters with the EU precautionary principle, it must be stressed that the precautionary principle is not considered in the chapters' underlying rationale and content. In a future, progressively closer cooperation, regulatory decisions and positions based on the precautionary principle are very likely to be forced onto the defensive. The more concrete the regulatory program developed by regulatory cooperation, the more important it becomes to secure and bring to bear the precautionary principle. This cannot be guaranteed without explicitly anchoring the precautionary principle in the texts of TTIP and CETA.

IV. Chapters on labour and the environment in the CETA- and TTIP-drafts

In line with a number of recent free trade and investment protection agreements, both the CETA- and TTIP-drafts include chapters on Labour and Trade as well as the Environment and Trade. While, again, the chapters avoid to explicitly mention the term "precaution", they encompass provisions on a right to regulate, which in both cases paraphrase the wording of principle 15 of the UN-Rio-Declaration. This wording endorses the precautionary principle. It has to be highlighted that the wording directed to both parties. Even more, the text comes very close to an obligation of Parties to take precautionary action, when the conditions are met.

However, regulations as adopted and applied under those conditions will in many cases also represent SPS or TBT measures or at least fall in the ambit of regulatory cooperation. The significance of the provisions therefore heavily depends on the way they are related to the SPS-, TBT- and regulatory cooperation-chapters of the CETA- and TTIP-drafts, which, as has been shown, are much less responsive to the precautionary principle. The CETA-draft's provisions on Labour and Trade do not explicitly address the issue, thus leaving room for treaty interpreters to consider the call for precautionary action in labour issues in parallel and on an equal footing with other provisions of the agreement. However, as regards the Trade and Environment provision, the exercise of the right to regulate with its mentioning of the precautionary principle is explicitly required to conform to other provisions of the agreement. This way, the precautionary principle in a way is subordinated to other provisions of the agreement, including those on SPS measures. Although the CETA-draft's regulatory cooperation chapter refers to the Trade and Labour as well as the Trade and Environment chapters, this rather general linkage does not serve as a proper incorporation of the precautionary principle into the rules on regulatory cooperation.

While in the view of the precautionary principle both these provisions can be welcomed as a certain achievement, it should nevertheless be noted that they do not address the full range of policy areas and objectives which the precautionary principle aims to serve according to the law and policies of the European Union. Certainly, environmental protection is fully covered. Under the EU's concept, the precautionary principle is applicable also in other highly important and sensitive areas such as human health and consumer protection. It must be highlighted that in the particularly sensitive regulatory area of the protection of human health, the precautionary principle is covered only to a very limited extent, where it coincides with labour protection and indirectly with environmental protection.

Overall, the CETA- and TTIP-drafts do not sufficiently safeguard the EU precautionary principle. The observed possible consequences on the EU precautionary principle by the CETA- and TTIP-drafts can be traced to concrete European branches of law which rely on the principle.

V. Food

1. General food regulation

EU food law, which inter alia is concerned with preventing health dangers from food, is based on the precautionary principle, as prominently articulated by the General Food Law Regulation 178/2002. It enacts a rather strict standard in international comparison, notwithstanding existing deficiencies in fulfilling the precautionary principle. One implication of the precautionary principle worth highlighting is the obligation to receive authorization for the production and marketing of novel food by the European Food Agency under EU law, in the process of which the onus is placed on companies to prove the absence of health risks. Such a far reaching obligation is generally unfamiliar to US and Canadian food law.

The European Food Agency has the competence to step in already in case of potential, albeit scientifically unproven risks under Art. 7 of the General Food Law Regulation, the wording of which closely follows the WTO-SPS-Agreement and corresponding jurisprudence. Notably, however, it goes beyond existing WTO provisions and jurisprudence by including an additional sentence. This phrase concretizes the criteria to take into account when determining the reasonable time period in which a measure taken based on the precautionary principle should be reassessed as to the risks emanating. When determining that period, the EU and its member states should consider the nature of the risk for life or health identified as well as the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment. This addition in the provision is favourable to the precautionary principle, as it increases the leeway for the EU and its member states to take measures against potential risks. It can be seen as an attempt to make use of statements in WTO jurisprudence which indicate a certain margin for applying the precautionary principle. In light of this regulatory approach, it is unfortunate that the EU abstained from including comparable passages and provisions in the SPS- and TBT-chapters of the CETA- and TTIP-drafts so far.

2. Pesticides

Residues of pesticides in food are a particularly controversial subject, as the EU under its two-fold regulatory approach covered by Regulation 1107/2009 and 396/2005 regulates pesticides significantly more restrictively than international standards as proclaimed by the Codex-Alimentarius-Commission, or as generally applied in the US and Canada. However, this international standard shall form the basis of cooperation in food security matters under the current TTIP-draft. Although no obligation is supposed to trigger under the TTIP-draft when a reservation is stipulated in the Codex-Alimentarius-Commission by the EU for certain substances, the provision still reflects a general preponderance of international standards, methods and regulatory culture that do not sufficiently safeguard the European precautionary principle. This holds the risk that the strict maximum residue levels of pesticides in the EU will be undermined and eventually lowered in the future. In fact, apparently in anticipation of the envisaged conclusion of TTIP and CETA, the EU Commission has already offered to consider to replace the strict European maximum residue levels for pesticides by the far less ambitious standards of the Codex Alimentarius.

3. Hormone beef

Another food regulation controversy is beef produced from cattle treated with hormones, which has been a long-standing trade dispute between the US, Canada and the EU, including before WTO tribunals, as described above. The dispute led to follow-up compliance proceedings before the WTO, and eventually, to a mutual understanding between the parties that was communicated to the WTO, which envisages different stages for resolving of the dispute. This understanding is reflected in CETA and TTIP.

In the aftermath of the WTO dispute, the EU was proven right to prohibit beef produced from hormone treated cattle on the basis of the precautionary principle at least with regard to one hormone (oestradiol-17 β). A couple of years after the European ban, scientific studies commissioned by the EU have proven its health risks, although this assessment is still contested by the USA and Canada.

VI. Chemicals

The EU regulation of chemicals under the REACH-directive, which is expressly based on the precautionary principle, could be another regulatory area impacted by CETA and TTIP. REACH represents one of the strictest regulations of chemical substances worldwide, with authorization required for chemical substances to be marketed. Proof is to be shown by the respective companies that there is no risk for health or environment, with restrictions and prohibitions available already in case of a potential risk without scientific certainty. Although some deficiencies in realizing the precautionary principle to its fullest extent may be observed, EU law goes substantially beyond rules in other jurisdictions, such as in the USA, where the Toxic Substances Act generally assumes the safety of chemical substances unless the US Environmental Protection Agency proves otherwise. Regulatory cooperation with a lack of safeguards for the precautionary principle will most likely at least delay and/or impede respective regulation of chemicals.

VII. Endocrine disruptors

Endocrine disruptors are substances in food that may cause detrimental hormone reactions in the human body. Again, under EU law in accordance with its precautionary principle, endocrine disruptors are generally banned from production and marketing, although health risks are not scientifically proven yet for the relevant suspicious substances. However, arguably in connection with the pursued conclusion of TTIP and CETA, the European Commission has postponed to adopt scientific criteria for the determination of endocrine disrupting properties of active substances, which are necessary to give effect to the EU law. This failure to act was found to be in violation with EU-law by the General Court of the EU (case T-521/14). Only in June 2016, the EU Commission belatedly put forward respective proposals. Similar patterns of action or inaction could follow from regulatory cooperation within TTIP and CETA.

VIII. Genetically modified organisms

The EU is internationally known for its restrictive approach towards the production and commercial use of genetically modified organisms, and indeed often criticized for it. Although there has been a recent alleviation concerning

genetically modified organisms in seeds which may in the future in general be regulated autonomously by the EU member states, EU law continues to impose strict standards on admission and marketing even in light of scientific uncertainty. GMO regulation thus roots in the precautionary principle, notwithstanding some gaps and enforcement problems in practice.

Significantly less demanding requirements can be found in many other jurisdictions, such as in the USA and Canada. Apart from the already raised concerns emanating from the CETA- and TTIP-drafts' general regulatory cooperation, the current CETA-draft specifically covers provisions on a dialogue on genetically modified organisms, stemming from a mutually agreed solution on the GMO WTO dispute between Canada and the EU described above. They impose a legal obligation on the parties to cooperate and exchange information in this matter, highlighting the importance of promoting efficient, science-based admission procedures for genetically modified organisms. A lack of consideration of the precautionary principle in the norms governing future cooperation is particularly clear in this passage. This is all the more notable in light of the fact that the Cartagena Protocol on Biosafety is not taken into account or referenced by the CETA-draft at all. The Protocol is ratified by 170 states, including the EU and its member states, but not by the USA and Canada, and contains an explicit safeguard for the precautionary principle. The EU itself unsuccessfully invoked the Cartagena Protocol in the WTO litigation with Canada and the USA. It is hard to understand why the provisions on a dialogue on GMOs in the CETA-draft, which is supposed to further a mutual understanding of the parties on the matter, only reflect the Canadian position without even implicitly referring to the Cartagena Protocol.

Thus, it is not unreasonable to expect an even aggravated pressure against a precautionary approach in the EU with regard to GMOs, especially due to the obligations to provide information and to cooperate already in an early regulatory stage. Such concerns could for instance materialize in case of proposals to extend labelling of GMO products. It is to be expected that CETA and TTIP will substantially hinder future regulation which aims for realizing and bringing to bear the precautionary principle, such as the originally envisaged extension of labelling requirements for genetically modified food in Germany.

IX. Nanotechnology

Nanotechnology is a new technological field which makes use of specific physical and chemical effects and properties of substances with a scale between 1nm and 100nm, which are substantially different from the properties of their macroscale counterparts. Nanomaterials' risks to health and the environment continue to be scientifically uncertain. Nanotechnology is covered by a variety of different EU laws, including the Basic Food Law-, the REACH- and the Seveso III-regulation. The EU regulation is criticized for not sufficiently enforcing the precautionary principle. In the last years, the EU started to modify its legislation, successively addressing nanotechnology's potential risks with specific provisions based on the precautionary principle. Such more tailored action is not taken by many other jurisdictions, including the USA and Canada, which generally opt to wait for a scientific proof of risk. In this open and highly innovative technological field, significant developments are to be expected, with a particular need for future regulatory action and reaction. Thus, nanotechnology could be a particularly sensitive field of EU law in which regulatory cooperation has a significant potential of impairing the continuation and strengthening of the precautionary principle.

F. Conclusion

This survey of particular areas of EU regulation makes it clear, that European regulatory policy for the protection of health and the environment is decisively characterized by the precautionary principle. The precautionary principle is of high relevance for attaining the overarching objective of securing a high level of protection for human health and the environment as envisaged by Art. 191 para. 2 TFEU in view of technological change and scientific developments.

The EU Commission itself explicitly names endocrine disruptors and nanomaterials as areas which call for new regulatory action. Current and future EU protection of health and environment by implementation of the EU precautionary principle through adapting existing and developing new regulation is likely to be impeded by the current CETA- and TTIP-drafts.

In both treaty drafts, the precautionary principle is not sufficiently anchored in the texts. The chapters on SPS- and TBT-measures and on regulatory cooperation follow an approach which does not conform with the precautionary principle. The chapters on labour and environment allude to the principle of precaution by textual reference without explicitly using the term. However, their range of application is far too limited to really make a difference.

Endocrine disruptors and residues of pesticides are cases in which such detrimental impact on the precautionary principle becomes apparent already at present. Apparently with a view to ongoing negotiations, the EU Commission has delayed adopting criteria concerned with endocrine disruptors. The EU Commission also offered to consider reducing maximum residue levels of pesticides. In both instances, the EU Commission departed from prior public announcements, according to which TTIP would not lead to a reduction of the EU level of protection.

Note on the citation of CETA and TTIP

In this study, “CETA-draft” refers to the consolidated text negotiated by EU and Canada, published on the 29.2.2016, available online:

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

(last access on 2.4.2016).

“TTIP-draft” refers to the EU’s negotiation proposals on TTIP, available online:

<http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230>

(last access on 2.4.2016):

- on the SPS-chapter, published on 7.1.2015,
 - on the TBT-chapter, published on 7.1.2015,
 - on the chapter on regulatory cooperation, published on 21.3.2016,
 - on the chapter on dispute settlement, published on 7.1.2015.
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References

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2226 U.N.T.S. 208 (concluded 29.12.2000, entry into force 11.9.2003).
- Convention on Biological Diversity, 1760 U.N.T.S. 79 (concluded 5.6.1992, entry into force 29.12.1993).
- Douma, Wybe Th., *The Precautionary Principle*, 2003.
- EU Commission, *Communication from the Commission on the Precautionary Principle*, COM(2000) 1 final, 2000.
- EU Commission, *The Transatlantic Trade and Investment Partnership (TTIP), Regulatory Issues*, EU position on chemicals, 2014.
- EU Commission, *Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products*, COM(2016) 350 final, 2016.
- EU Court of First Instance, Case T-13/99, 2002 E.C.R. II-3305 – Pfizer Animal Health/Commission.
- EU Court of First Instance, Case T-70/99, 2002 E.C.R. II-3495 – Alpharma/Commission.
- EU Court of First Instance, Case T-229/04, 2007 E.C.R. II-2437 – Sweden/Commission.
- EU General Court, Case T-521/14 (16.12.2015) – Sweden/Commission.
- EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.
- EU Directive 2009/41/EC on the contained use of genetically modified microorganisms.
- EU Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances.
- EU Directive 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.
- EU Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- EU Regulation 1829/2003 on genetically modified food and feed.
- EU Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.
- EU Regulation 2065/2003 on smoke flavourings used or intended for use in or on foods.
- EU Regulation 1935/2004 on materials and articles intended to come into contact with food.
- EU Regulation 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.
- EU Regulation 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH).
- EU Regulation 1333/2008 on food additives.
- EU Regulation 1107/2009 concerning the placing of plant protection products on the market.
- EU Regulation 1223/2009 on cosmetic products.
- EU Regulation 1169/2011 on the provision of food information to consumers.
- EU Regulation 528/2012 concerning the making available on the market and use of biocidal products.
- EU Regulation 2015/2283 on novel foods.
- European Commission, *Opinion of the SCVPH on Review of Previous SCVPH Opinions of 30 April 1999 and 3 May 2000 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products*, 2002.
- European Court of Justice, Case C-157/96, 1998 E.C.R. I-2211 – National Farmers' Union and Others; Case C-180/96, 1998 E.C.R. I-2265 – UK/Commission.
- European Court of Justice, Case C-236/01, 2003 E.C.R. I-8166 – Monsanto Agricoltura Italia SpA and Others/Presidenza del Consiglio dei Ministri and Others.
- European Court of Justice, Case C-442/09, 2011 E.C.R. I-7419 – Karl Heinz Bablok and Others/Freistaat Bayern.
- European Court of Justice, Case C-356/12, ECLI:EU:C:2014:350 – Wolfgang Glatzel/Freistaat Bayern.
- European Court of Justice, Case C-477/14 (4.5.2016) – Pillbox 38 (UK) Ltd/Secretary of State for Health.
- European Food Safety Authority, *Opinion of the Scientific Panel on Contaminants in the Food Chain on a Request from the European Commission related to Hormone Residues in Bovine Meat and Meat Products*, 2007.
- European Parliament, *Directorate-General for Internal Policies, Legal Implications of TTIP for the Acquis Communautaire in ENVI Relevant Sectors*, 2013.
- European Parliament, *Report containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP)*, A8-0175/2015, 2015.
- de Sadeleer, Nicolas, *Les principes du pollueur-payeur, de prévention et de précaution*, 1999.
- de Sadeleer, Nicolas, *Le principe de précaution*, 2008.
- Stoll, Peter-Tobias, *Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement*, in: *Yearbook of International Environmental Law* 1999, S. 82.
- Stoll, Peter-Tobias, *Sicherheit als Aufgabe von Staat und Gesellschaft*, 2003.
- UN Framework Convention on Climate Change, 1771 U.N.T.S. 107 (concluded 9.5.1992, entry into force 21.3.1994).
- UN Rio Declaration on Environment and Development, 31 I.L.M. 874 (1992), 1992.
- Wolfrum, Rüdiger/Stoll, Peter-Tobias/Seibert-Fohr, Anja (eds.), *Max Planck Commentaries on World Trade Law, Vol. III Technical Barriers and SPS Measures*, 2007.
- WTO Panel Report, EC – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R.
- WTO Panel Report, EC – Measures Affecting the Approval and Marketing of Biotech Products, Notification of a Mutually Agreed Solution, WT/DS292/40.
- WTO Panel Report, EC – Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R/USA.
- WTO Panel Report, US – Continued Suspension of Obligations in the EC (Hormones), WT/DS320/R.
- WTO Appellate Body Report, EC – Measures Concerning Meat and Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R.
- WTO Appellate Body Report, Japan – Measures Affecting Agricultural Products, WT/DS76/AB/R.
- WTO Appellate Body Report, Japan – Agricultural Products II, WT/DS76/AB/R.
- WTO Appellate Body Report, United States – Continued Suspension of Obligations in the EC – Hormones Dispute, WT/DS320/AB/R.
- WTO, EC – Measures Concerning Meat and Meat Products (Hormones), Joint Communication from the European Union and the United States, WTDS26/28 und WT/DS26/29.
- WTO, EC – Measures Concerning Meat and Meat Products (Hormones), Joint Communication from the European Union and Canada, WT/DS48/26.
- WTO, *Agreement on Technical Barriers to Trade* (concluded 15.4.1994, entry into force 1.1.1995, part of the Marrakesh Agreement establishing the World Trade Organization, 1867 U.N.T.S. 3).
- WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures* (concluded 15.4.1994, entry into force 1.1.1995, part of the Marrakesh Agreement establishing the World Trade Organization, 1867 U.N.T.S. 3).
- WTO, *General Agreement on Tariffs and Trade 1994 with reference to General Agreement on Tariffs and Trade 1947* (concluded 15.4.1994, entry into force 1.1.1995, part of the Marrakesh Agreement establishing the World Trade Organization, 1867 U.N.T.S. 3).