KAREL DE GUCHT
MEMBER OF THE EUROPEAN COMMISSION

Brussels, 0 2 1 0 1 4
KDG/MVH/CBE/dcm/S(14)3254715

Dear Mr. Thornton and Mr. Muffett,

Thank you for your letter of 10 July 2014 signed by 111 NGOs opposing the inclusion of any provisions in the Transatlantic Trade and Investment Partnership (TTIP) that would concern the regulation of chemicals, notably in the areas of regulatory cooperation, investment, technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) and the sectoral annexes.

First of all, I would like to reassure you that we take very seriously the concerns expressed by civil society, and we are also convinced that there is an adequate response to address them satisfactorily. In particular, we strongly underline that the Commission will not even consider any measure under TTIP that may give priority to trade or economic efficiency concerns over the protection of the health of our citizens or of the environment - as provided for by the relevant EU legislation – or undermine such protection. The Commission has the duty under the Treaty to uphold and implement EU legislation, and will stick to it scrupulously. We do hope that this is not put any longer in question.

We also need to contest in the clearest possible terms the statement that under TTIP may be negotiated "fundamental changes to (...) policies and law-making processes": as far as the EU is concerned, the broad lines of EU policies and law-making procedures are defined in the EU Treaties and policies made operational in EU legislation, and no such fundamental changes to them are being considered under TTIP.

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I would like to emphasise an essential point: a possible TTIP agreement would under no circumstances result in the lowering of existing EU environmental and health standards with regard to chemicals. Over the last decades, the EU has seen its standards rise to a level of global excellence and leadership in the field of chemicals, notably since the adoption of REACH[1]. This will not change due to a possible TTIP Agreement. We have also made clear in the EU's TTIP position paper on chemicals published on 14 May 2014[2] that neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US (Toxic Substances Control Act, TSCA) and the EU (REACH).

In your letter you consider that the inclusion of chemicals in TTIP would threaten to chill or even freeze forward-looking chemicals regulations. This argument is also often invoked in the public debate on TTIP. It is nevertheless unfounded: TTIP will have no chilling effect on the implementation of existing EU chemicals regulations, such as the REACH and the CLP (Classification, Labelling and Packaging of Substances and Mixtures)[3] Regulations, which will continue to be implemented in full compliance with the existing rules and procedures and respecting the applicable deadlines as foreseen in the respective Regulations.

As outlined in the EU's TTIP position paper on chemicals, we are seeking opportunities for cooperation exclusively in specific areas which do not require or imply any change in the regulatory systems of each side, as they essentially concern actions of cooperation between the relevant chemicals regulators with the intention to better coordinate certain practices in order to increase efficiency and reduce costs for authorities and economic operators, but without lowering any existing standards. It goes without saying that both sides will maintain intact their capacity to regulate and to take decisions in accordance with their respective regulatory frameworks, as the cooperation and actions envisaged would take place upstream in the preparatory activities of regulators.

Enhanced regulatory cooperation between the EU and US should also lead to greater acceptance of international disciplines such as those flowing from the UN and OECD. TTIP could, therefore, offer the opportunity to strengthen global chemicals regulation leading to better health and environmental protection globally. Improvement in the exchange of information and experiences could also lead to efficiency gains in the regulatory activities of both sides and to a better understanding of the challenges raised by new technologies and issues.

While it is correct, as stated in your letter, that the US – actually along many other third countries - has in the past repeatedly commented on aspects of the EU chemicals regulations (namely REACH), including in the context of the WTO TBT Agreement, you will have noticed that no formal dispute settlement procedure contesting REACH has been triggered. Furthermore, the US has not made any proposals in the chemical area in TTIP to change or challenge REACH.

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[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, OJ L 396, 30.12.2006, p.1.

[2] http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152468.pdf

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, OJ L 353, 31.12.2008, p.1.

As regards the possible inclusion of investor-state dispute settlement (ISDS) provisions in TTIP, the Commission is doing its utmost to respond to all possible concerns. The online public consultation on ISDS in TTIP has been closed on 13 July 2014 and the Commission is now evaluating the large number of contributions received.

I do not share your view that the TTIP negotiations are not sufficiently transparent. By their very nature, trade negotiations require some degree of confidentiality, in particular with regard to the negotiating positions and texts which cannot always be published. However, the Commission has published numerous TTIP position papers (including on chemicals and various other sectors) online and will continue to do so. A comprehensive public stakeholder session is part of every TTIP negotiating round. The online public stakeholder consultation on ISDS in TTIP is another example of our ambition to listen to the concerns of all civil society stakeholders with the view to reach a well-balanced EU position that is mindful of as many views as possible. To further support this process, the Commission has established a TTIP Advisory Group which includes both industry and NGO representatives. In this respect, I would like to assure you that the position paper published by the Commission contains all the issues which are currently subject to discussions, and that before any position or text takes a defining shape the necessary consultation will be carried out in order to ensure that any emerging outcome receives broad support from within the EU.

Finally, it would be a mistake to presuppose that any regulatory cooperation with the US can only have a negative impact on EU regulation and standards of protection. Instead, closer regulatory cooperation and greater exchanges with US regulators (including at State level) and the scientific community on issues of common regulatory interest in the chemical sector could benefit both sides, as it would offer opportunities to learn from experiences, have the best available information to reach decisions, and develop ideas that could be helpful to improve the effectiveness and efficiency of our own regulations and of their implementation.

In the Annex to this letter, you will find detailed responses to the specific issues outlined in the Annex to your letter of 10 July 2014.

My services would appreciate the opportunity to further discuss these issues with you and we look forward to continuing our dialogue.

Yours sincerely,

Karel De Gucht

Encl.: Annex – Detailed response to Annex of letter of 10 July 2014

Annex – Detailed response to Annex of letter of 10 July 2014

In the annex to your letter of 10 July 2014 you claim that the inclusion of chemicals in TTIP would result in a variety of negative effects. In the following, please find responses to these claims that will hopefully dispel the concerns.

1. ***TTIP will freeze the development and implementation of stronger, more health-protective laws***

TTIP will in no way lead to a "regulatory freeze" as both the US and the EU will keep their full regulatory autonomy. Both sides will continue to develop the regulatory regimes they deem appropriate for the protection of the environment and the health of their citizens.

Existing regulatory procedures in the EU and US will not be slowed down. The EU's legal framework for chemicals – namely REACH and CLP – will continue to be implemented in line with the general objectives to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals and to enhance competitiveness and innovation. There is, by the way, no intention to strive for a 'common' prioritisation of chemicals of concern – the idea advanced in the EU's public position paper is rather to seek complementarity and avoid duplication of efforts.

Current EU impact assessment guidelines already require to examine the impacts of proposed legislation on trade (including of course transatlantic trade) and also mandate the Commission to examine the expected benefits and costs of action (and of inaction) in line with your request. This will continue.

The horizontal regulatory cooperation discussions of the TTIP negotiations are still at a relatively early stage. In any case, we intend to ensure that the institutional framework for regulatory cooperation between the EU and the US under TTIP will not create additional hurdles or increase possibilities for industry to interfere in processes going beyond what is already possible today. More in particular, the mooted "Regulatory Cooperation Council" should not have any regulatory competence or vetting powers over new regulatory measures: in our view, its main functions should be to provide a forum for regulatory exchanges, to discuss in a more structured way regulatory issues of concern, and monitor the implementation of the regulatory provisions of TTIP.

2. ***TTIP creates duplicative inefficiencies, providing no added value to the general public***

Both the EU and the US will continue to support the successful activities on chemicals in the OECD, and at UN level. However, this does not mean that bilateral cooperation between the US and the EU would a priori be inefficient of duplicative. To the contrary, bilateral and multilateral initiatives can complement each other; in the context of TTIP, the US and the EU could build upon existing work at OECD and UN level and, through joint initiatives or supportive actions, accelerate progress in international fora.

Increased regulator-to-regulator dialogue under TTIP, which is the EU's primary objective, could in fact enrich the risk management processes on both sides by promoting a broader perspective on regulatory actions, in particular by better taking into account

the activities at US State level. Experience with the existing Statement of Intent between the US EPA and ECHA has shown that there is clear scope for enhanced cooperation to achieve the full potential of what was envisaged. TTIP could be the right opportunity to create the formal context for such enhanced cooperation.

3. *TTIP favours chemical industry and other corporate rights over public health and the environment through ISDS*

The Commission's public online consultation on ISDS in TTIP has just been closed and a total of 149.399 contributions have been received (a statistical overview of the results is already available at http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152693.pdf). The Commission will use the coming months to carefully evaluate all contributions.

In due time, the Commission will inform stakeholders about possible next steps.

4. *TTIP derails European leadership on hormone (endocrine) disrupting chemicals, nanomaterials and other urgent and emerging issues*

TTIP will not put the EU's role as global regulatory leader in the field of chemicals into question. Possible future EU-US regulatory cooperation under TTIP on new and emerging scientific issues – such as endocrine disruptors and nanomaterials – will provide responsible regulators on both sides with the opportunity to share relevant scientific information and best practices, without in any way diminishing the regulatory autonomy of both sides.

As you know, the EU is in the process of preparing the adoption of criteria for the identification of endocrine disruptors which is particularly relevant in the context of the EU Plant Protection Products Regulation[4] and the EU Biocidal Products Regulation[5]. The Commission has recently published the Roadmap for the related Impact Assessment[6]. A public consultation is currently being prepared and will be launched very soon. An inclusive and open consultation process where all relevant aspects of the issue are examined and where any concerned stakeholders can present their views and any relevant evidence is likely to result in more informed – and therefore better – decisions. In view of the complexity of these issues, we do not think it would be the right policy to adopt decisions or policies without a thorough and transparent examination where all issues can be brought into the open.

As regards nanomaterials, the Commission will review the existing definition[7] by the end of 2014, and the Commission continues with its preparatory work for an amendment of the REACH Annexes to clarify information requirements for the registration of nanomaterials. Again, all such regulatory activity should be conducted in an open and transparent way where all relevant arguments and evidence can be put forward and considered.

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[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, OJ L 309, 24.11.2009, p.1.

[5] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, OJ L 167, 27.6.2012, p.1.

[6] http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

[7] Commission Recommendation 2011/696/EU, OJ L 275, 20.10.2011

While both actions are a priori independent of what is discussed in the TTIP negotiations, the EU and US authorities have amassed significant knowledge concerning endocrine disruptors and the properties of nanomaterials (including with regard to potential impacts on human health or the environment) and TTIP could well offer a possibility to advance work on both topics in a cooperative rather than confrontational manner. As indicated above, greater exchanges of scientific and technical information among the two most advanced scientific communities and regulators in the world is something from which both sides can only benefit: closing the door to such exchanges would be tantamount to pretending that one side is self-sufficient and cannot learn anything useful from the other.

5. TTIP blocks U.S. states and EU Member States from taking action in the face of inaction by the U.S. federal government and European Commission

TTIP will not block US States and EU Member States from taking action in compliance with the respective regulatory frameworks. TTIP could rather offer a kind of "early information" mechanism regarding US States' (and EU Member States') measures on chemicals. Currently, it is very difficult for the EU and European companies to follow the multitude of chemicals-related US States' measures. As you correctly note, some of the US States' activities are inspired by (or comparable) to regulatory action taken in the EU. A better and timelier overview of planned and ongoing initiatives would allow the EU and European companies to provide comments at an earlier stage and to contribute to the development of such measures so as to avoid unnecessary divergences. This will in no way undermine the US States' rights to regulate.

The implementation of the UN GHS would not restrict the ability of States to use restrictions to inform and protect the public – the GHS has been developed to inform accurately and in a detailed manner about the hazards of chemical substances and mixtures. As you know, the EU has broadly and comprehensively implemented the GHS including for chemicals sold to the general public with the objective to adequately inform and protect consumers when using chemicals.

As you point out, regulatory initiatives at sub-Federal or Member State level providing for a higher level of protection may sometimes be positive as they may trigger efforts to find safer alternative products. However, as indicated above, the differences we are aiming at do not concern different levels of protection – which, as stated in the High Level Working Group report, should not be affected – but those regulatory divergences arising from historical or other reasons that could be addressed without affecting the level of protection. Such divergences, whilst bringing no clear benefit, can lead to fragmentation of markets and inefficiencies and increase compliance costs thus absorbing resources that could otherwise be devoted to more useful purposes including investment in innovation.

6. TTIP limits public access to information on toxic chemicals, impeding innovation

TTIP will not affect the rules applicable in the EU or the US with regard to the public dissemination of information on chemicals, nor the rules on confidentiality. For the EU, these issues are clearly regulated in REACH and the respective rules will continue to apply.

In its earlier proposals for TTIP, the chemicals industry had proposed to examine possibilities for allowing the exchange of confidential information among authorities, while fully protecting of what is recognised as confidential on either side. Several animal welfare associations have also called on the EU and US authorities to increase their information exchange to avoid duplicative testing involving animals.

For the moment, the EPA and ECHA are actually prevented from exchanging confidential information that they hold, even though this might be of interest for assessing the risks from chemicals and deciding on appropriate risk management measures. REACH requires that before ECHA can exchange confidential information with a third country, the EU would have to conclude a formal agreement with that third country. TTIP could offer the opportunity to conclude such an agreement.

However, for the time being, there is no immediate interest to pursue the negotiations of such an agreement in the framework of TTIP, as both sides make vast and increasing amounts of data publicly available. By the same token, no action to limit the publication of data has been considered in the TTIP framework

7. TTIP will erase important differences between EU and U.S. laws

As stated before and confirmed in the EU TTIP position paper on chemicals, mutual recognition and harmonization of regulations are excluded for the area of chemicals, as the regulatory frameworks of both sides are too different. The EU constant position on mutual recognition is that it can take place exclusively when it can be concluded, after a thorough evaluation, that the regulations from both sides are equivalent.

This applies also to textiles and cosmetics. In the area of cosmetics, when mentioning mutual recognition of lists of substances, the EU position paper specifies that this refers to the exploration of possibilities for approximation of regulations, which would be a precondition for recognition of substances, or to the recognition of scientific findings once the safety assessment methods used are determined to be equivalent.

In the case of textiles, the only reference to the possibility of mutual recognition concerns the care instruction symbols – again after verification that this would not lead to lower protection. Any mutual recognition in the context of chemical substances would have to await any alignment on what substances are prohibited or restricted.