

*This document is the European Union's proposal for an annex or a chapter on chemicals. It was tabled for discussion with the US in the negotiating round of 11-15 July 2016 and made public on 14 July 2016. The actual text in the final agreement will be a result of talks between the EU and US.*

*NOTE: The EU reserves the right to make subsequent modifications to this text and to complement it at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time.*

*The relationship between sectorial annexes and the architecture of TTIP, including the applicability or not of general exceptions and dispute settlement, will be considered at a later stage.*

## **TTIP- EU proposal for:**

### **ANNEX/CHAPTER<sup>1</sup> ON CHEMICALS**

#### *Article 1*

#### **General principles and objectives**

1. Co-operation activities between the Parties shall aim at improving, and not reduce, undermine or otherwise compromise, the level of protection in public policy areas such as the protection of workers' and consumers' health, public health, and the protection of the environment, as considered appropriate by either Party. The Parties share the intention of achieving a high level of protection in these areas.
2. Nothing in this Annex shall oblige the Parties to achieve any particular regulatory outcome, or to advance, suspend, delay, or stop their regulatory activities, or shall affect the ability of each Party to conclude its respective regulatory procedures within the applicable deadlines as provided under the respective procedures. Wherever possible, co-operation activities between the Parties shall be part of the regular consultation procedures as provided for in the existing procedures of the Parties.
3. Nothing in this Annex shall require changes to the laws and regulations of either Party, including their implementing measures and procedures, and affect the ability of each Party to apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management<sup>2</sup>.

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<sup>1</sup> *As already noted in footnote 7 in the EU's proposal for a chapter on Regulatory Cooperation, it remains open at this stage, whether and to what extent the provisions of this Annex/Chapter will be considered to regulate this sector exhaustively. If the latter was the case, Article 1 would have to be modified.*

<sup>2</sup> *For the EU, such principles include those established in the Treaty on the Functioning of the European Union as well as in Regulations and Directives adopted pursuant to Article 289 of the Treaty on the Functioning of the European Union.*

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4. Nothing in this Annex shall affect the ability of each Party take appropriate and immediate measures when it determines that a chemical substance or mixture is not safe for consumers or the environment or does not comply with its regulatory framework.
5. In case of any inconsistency between this Annex and other provisions of the Agreement, this Annex shall prevail.
6. The objectives of this Annex are to:
  - a) Enhance cooperation on the review and assessment of chemicals of common priority to enable governments and stakeholders, including in particular small and medium-sized enterprises, to better use their limited resources;
  - b) Enhance scientific cooperation related to hazard identification and risk assessment methodologies;
  - c) Improve the exchange and/or availability of information and data generated on chemicals for regulatory purposes, while ensuring the protection of confidential business information;
  - d) Promote alignment in classification and labelling of chemicals based on the UN GHS including *inter alia*:
    - i. classification and labelling of individual chemicals;
    - ii. identification of differences in the Parties' respective requirements for Safety Data Sheets (SDS), including for providing information on classification of chemicals, and consideration on how to implement those requirements in a way that could make the SDS compliant in both Parties, where feasible;
  - e) Enhance cooperation on new and emerging issues of common interest;
  - f) Strengthen cooperation in relevant international organisations and bodies;
  - g) Promote regulatory cooperation with a view to (i) facilitate the coordination of regulatory initiatives on chemicals; (ii) avoid unnecessary duplicative requirements; (iii) if possible and compatible with the regulatory framework and the intended level of protection defined by each Party, identify and implement actions that can lead to reduction of unnecessary costs to bilateral trade in chemicals.

## *Article 2*

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## **Definitions**

For the purposes of this Annex:

- a. "responsible authorities" means:
  - For the EU: the European Commission, the European Chemicals Agency (ECHA), or the competent authority of a Member State where it has lead responsibility for activities related to the work areas provided for in Articles 6 to 11.
  - For the US: the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Consumer Protection Safety Commission (CPSC), or any other Federal Agency as well as State authority or Agency that is responsible for activities related to the work areas provided for in Articles 6 to 11.
- b. "contact point" means: the authority nominated by each Party to ensure coordination among its responsible authorities and to facilitate contacts between the responsible authorities from both Parties that are relevant for cooperation activities related to the work areas provided for in Articles 6 to 11.
- c. "UN GHS" means: the United Nations Globally Harmonized System of Classification and Labelling of Chemicals<sup>3</sup>.
- d. "substance" means: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
- e. "mixture" means: a mixture or solution composed of two or more substances.

### *Article 3*

#### **Scope**

This Annex applies to chemical substances and mixtures intended for general industrial, professional or consumer use except for those specific uses that fall under other provisions of the Agreement.

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<sup>3</sup> Available at: [http://www.unece.org/trans/danger/publi/ghs/ghs\\_welcome\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html)

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#### *Article 4*

### **Relevant international organisations and bodies**

The Parties recognise that international organisations and bodies, in particular the Organisation for Economic Cooperation and Development (OECD) and the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (SCEGHS) of the United Nations Economic and Social Council (ECOSOC) are relevant for developing scientific and technical guidelines with respect to chemicals.

#### *Article 5*

### **Participation in relevant international organisations and bodies and regulatory convergence**

1. The Parties shall actively contribute to the development of scientific or technical guidelines with respect to the assessment of hazards and risks of chemicals and the formats for documenting the results of such assessments.
2. The Parties shall cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines, including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies in particular those referred to in Article 4.
3. The Parties shall implement the guidelines from the international organisations indicated in Article 4 unless those guidelines would be ineffective or inappropriate for the achievement of each Party's public policy objectives. In any case, each Party shall recognise data generated in the other Party in accordance with such guidelines.

#### *Article 6*

### **Assessment of Priority Substances**

1. The Parties shall inform each other promptly when updating the lists of priority substances foreseen in their respective legislations with a view to allowing the responsible authorities of the other Party to comment on the selection of such priority substances and on the planned timing of their assessments. The Parties may identify substances that are of their common priority and shall cooperate with respect to the assessments of such substances.
2. The Parties shall inform each other promptly when updating their respective criteria for the selection of priority substances referred to in paragraph 1 in order to allow for bilateral consultations.

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3. The responsible authorities of each Party shall conduct assessments of priority substances in line with their respective rules and procedures. For substances identified as being of common priority for both Parties, the responsible authority of each Party shall accept requests for information exchange made by the responsible authority of the other Party. Such information exchange may take place via meetings, telephone or video conferences, exchanges by e-mail, or in any other mutually agreed form.
4. The responsible authorities of the Parties shall not be required, as a result of requests for information exchange in accordance with paragraph 3, to advance, suspend or delay their activities related to the assessment of substances of common priority for both Parties, including the completion of assessments within the deadlines provided in their respective rules and procedures.
5. This Article shall not oblige the Parties to achieve any particular outcome regarding the assessment of a given priority substance.

#### *Article 7*

#### **Assessment Methodologies**

1. The responsible authorities of the Parties shall inform each other promptly when reviewing their respective methodologies for the assessment of priority chemicals and related scientific issues, in particular those related to hazard and risk assessment.
2. Upon request of a Party, the Parties shall enter into discussions when assessment methodologies are reviewed or technical guidance documents are developed or reviewed by either Party, with a view to avoid divergences, where feasible, while aiming at a high level of protection.
3. When updating or reviewing assessment methodologies, each Party shall take into account the work done in the international fora provided for in Article 4, where relevant.
4. No Party is required to advance, suspend or delay its activities related to the assessment methodologies as a result of requests for consultation in accordance with paragraph 2.

#### *Article 8*

#### **Classification and Labelling of Chemicals**

1. Each Party shall implement the UN GHS as comprehensively as considered feasible within its respective systems, including for chemicals that are not within the scope of this Annex unless there are specific reasons to apply a different labelling system for particular

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chemical products in the finished state. Each Party shall periodically update its implementation based on the regular revisions of the UN GHS.

2. The Parties commit to periodically examine cases in which the building block approach and in-built flexibilities of the UN GHS have led to divergent implementation in the Parties, including the rules concerning the calculation of the classification of mixtures and how these classifications are reflected on labels and in Safety Data Sheets (SDS). The responsible authorities of each Party will consult with their respective stakeholders on whether such identified divergences lead to actual problems in the practical application of the classification and labelling rules and the compilation of SDS. The Parties commit to discuss possibilities for finding solutions on how to overcome such problems in a way that could make the SDS compliant in both Parties, where feasible.
3. When the responsible authorities of each Party consider to classify individual substances, either in a binding or non-binding way, in accordance with its respective procedures, they shall give the responsible authorities of the other Party, upon their request, the possibility to express their views within those respective procedures. This may include bilateral exchanges via meetings, telephone or video conferences, e-mail, or participation in the consultation processes, expert meetings or otherwise as provided for in the respective procedures.

In order to give the other Party the possibility to request such participation, the responsible authorities of the Parties shall inform each other promptly when launching procedures related to the classification of substances, including for the assessment of scientific evidence. Before taking a final decision on the classification of substances, each Party shall respond to comments received from the other Party during such procedures.

4. Nothing in this Article shall oblige the Parties to achieve any particular outcome regarding the implementation of the UN GHS in their territories, nor regarding the classification of a given substance, nor shall the Parties be required to advance, suspend or delay their respective procedures and processes.

#### *Article 9*

#### **Facilitation of exchange of information**

1. The Parties agree to cooperate on the dissemination of data related to chemicals safety which shall be made available to the public with the objective to foster easy access and comprehensibility of the information by different target groups. Upon request of either Party, the other Party shall provide available non-confidential information on chemicals to the requesting Party.

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2. The Parties commit to undertake efforts to facilitate the exchange of non-confidential information among their relevant responsible authorities, including through cooperation on electronic formats and tools used to store data.
3. If considered beneficial by both Parties, the Parties shall consider to work towards the establishment of the necessary agreements to allow exchange and adequate protection of confidential business information related to chemicals.

#### *Article 10*

### **Regulatory Initiatives on Individual Chemicals**

1. Each Party shall make publicly available, in accordance with its rules and procedures, information about planned regulatory initiatives concerning individual chemicals, and shall endeavour to keep such information up-to-date. This information shall cover planned initiatives of responsible authorities at EU and US Federal level, and, to the extent possible, at the level of EU Member States and US States.
2. The Parties shall inform each other at an early stage of their respective procedures to allow for consultation on planned regulatory initiatives affecting individual substances. The Parties shall enter into discussions when so requested by either Party. Such consultation may be held through bilateral exchanges via meetings, telephone or video conferences, e-mail, or via participation in the consultation processes, expert meetings or otherwise as provided for in the procedures established in the respective Party.
3. Each Party shall consider comments provided by the other Party and shall respond to them.

#### *Article 11*

### **New and Emerging Issues of common interest**

1. The Parties shall enter into consultations, if so requested by either Party, on scientific information and data in the context of new and emerging issues related to the hazards or risks posed by chemicals to human health or the environment with a view to creating a common pool of knowledge and promoting, if feasible and to the extent possible, a common understanding of the science related to such issues.
2. The Parties shall inform each other when they consider to adopt regulatory measures with regard to such new and emerging issues. If both Parties consider regulatory measures, consultations shall be organised in order to avoid, if feasible and being mindful of the principles in Article 1, paragraphs 1, 2 and 3, divergent regulatory approaches that create unnecessary barriers to trade.

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#### *Article 12*

### **Communication between the Parties**

The contact point for the EU shall be the European Commission. The contact point for the US shall be the Environmental Protection Agency (EPA). The contact points shall act as the primary points of communication and shall ensure the involvement of the appropriate responsible authority(ies) in the Parties, which then conduct the respective cooperation activities directly.

#### *Article 13*

### **Regulatory cooperation**

*[NB: this Article may need to be adjusted as discussions on the Institutional, General and Final Provisions Chapter and on the Regulatory Cooperation Chapter proceed. This Article is to be read in conjunction with the functions and roles of the Joint Committee, the Transatlantic Regulators' Forum and the Working Group on sectors as defined in the Chapter on Institutional, General and Final Provisions]*

1. The regulatory cooperation between the responsible authorities of the Parties shall be guided by a joint regulatory cooperation work plan which sets out short and medium term priorities for regulatory cooperation under this Annex.
2. The joint regulatory cooperation work plan shall be endorsed by the responsible authorities of the Parties at political level.
3. The responsible authorities of the Parties shall transmit the joint regulatory cooperation work plan to the Transatlantic Regulators' Forum [established under the Institutional, General and Final Provisions Chapter] and publish it on their respective websites.
4. The responsible authorities of the Parties shall regularly review the joint regulatory cooperation work plan. In this review, the responsible authorities of the Parties shall take into account, *inter alia*, progress achieved [during the preceding years] and consider new areas that would benefit from regulatory cooperation. For the review of the joint regulatory cooperation work plan, the responsible authorities of each Party shall consult stakeholders including small and medium size enterprises, employers and workers representatives and public interest groups.