

Outline for provisions on chemicals

Introduction

The outline below suggests provisions that could be appropriate for the chemicals sector. They are based on maximising the scope for interaction between regulators within each side's regulatory system in a way that preserves the respective levels of protection of the health of workers and consumers, as well as the environment, and is consistent with the mechanisms under which they function. As these provisions are intended to respond to the specific needs of a sector characterised by substantially different approaches in the Parties, it is important to ensure that the approaches and solutions outlined here are not counteracted by other parts of TTIP. These specific provisions intend to give a comprehensive view of an approach that would be suitable for chemicals and would prevail, in case of conflict, over the provisions in other parts of TTIP. The relationship of the provisions for chemicals and the other parts of TTIP will be kept under review as both sets of provisions start taking shape.

1. Objectives

- Recall principle of high level of environmental, worker and consumer protection as objective of chemicals regulations including their implementing measures and procedures in accordance with the systems of each Party, and that accordingly nothing in these provisions is to be understood as requiring changes in the legislative framework of either side, which are considered to be consistent with respective WTO obligations.
- To promote regulatory cooperation with a view to: (a) facilitate the coordination of regulatory actions, including for new technologies or issues, on the basis of the best available scientific information and knowledge; (b) avoid unnecessary duplicative requirements; (c) enhance exchanges on scientific issues including on risk assessment and other methodological issues; (d) if possible and compatible with the regulatory framework of each side and their destined level of protection, to identify and implement actions that can lead to reduction of unnecessary costs to transatlantic trade
- To promote alignment in classification and labelling of chemicals in accordance with the UN Global Harmonised System (GHS) of classification of substances
- To cooperate on the development and implementation of international disciplines and in work on international regulatory fora relevant for chemicals, notably at UN and OECD level

2. Fields of cooperation

Principles:

- Parties to commit to alert each other at relevant stages of their processes in order to give the other Party the opportunity to comment/engage.
- Parties to commit to respond to comments/requests for consultation – but no obligation to stop or suspend a process, including where timelines apply.

- Parties are not obliged to participate in the other one's procedures if they choose not to do so.
- Parties to commit to co-operate in international fora for topics covered by this Annex

Topics

- a) Cooperation on **prioritisation of substances for assessment**, in particular informing the other Party to allow for mutual consultation upon request when:
- setting or reviewing criteria for defining priority substances
 - updating priority lists.

Cooperation during the actual assessment that is being conducted in line with each Parties' rules and procedures, including in particular alerts to the other Party when occasions for commenting arise.

- b) Cooperation and exchanges on **assessment methodologies**, in particular informing the other Party to allow for mutual consultation upon request when assessment methodologies are reviewed and/or technical guidance documents are developed or reviewed, taking into account, where relevant, the work done in international fora.
- c) **Alignment in classification and labelling** of chemical products – Commitment to apply GHS across all chemicals within X years, and to implement the periodic amendments subsequently. Cooperation in GHS matters both towards greater alignment of building blocks actually implemented in the Parties, and for further development of GHS at UN level.

Mutual consultation and where feasible agreement on classifications for individual substances through participation in each other's existing processes. Parties to inform each other when processes to classify substances start to allow for submission of comments. Parties to commit to respond to the other's comments before taking decisions. Possibility to participate in expert meetings reviewing data for determining classifications.

- d) **Information on regulatory plans** (concerning general regulations as well as plans for regulating individual substances). Each side to publish their regulatory plans when available (and if possible periodically, e.g. every six/other months, or as matters arise (e.g. when substances are selected for priority assessment, risk management option analysis, when the Registry of Intent of ECHA is updated (which contains intentions for classification and labelling, restrictions, etc.)). Regulatory activities concerned covered at both EU and MS, Federal and State level under defined mechanisms, except for matters requiring urgency. [NB: tentative, for discussion]
- e) Parties to alert each other to allow for **consultation on regulatory processes affecting individual substances and on new draft regulations** upon request, commitment to consider comments expressed by the other Party and to respond to them. Where considered appropriate, Parties to offer each other the possibility to participate as observers in expert meetings reviewing data in view of proposed regulatory action.
- f) **Cooperation on new and emerging issues of common interest** and in particular to exchange scientific and other information and data on these issues and to promote insofar as possible a common understanding of the science underpinning regulatory decisions

3. Exchange of information

Cooperate in the publication of chemicals related data which are made available to the public. Provisions to facilitate the exchange of non-confidential information among regulators - this

includes cooperation on electronic formats and tools used to store data. If considered necessary, establish agreement to exchange and protect CBI: Principles and practical modalities, as necessary to be developed at a later stage

4. Chemicals working group *[NB: tentative illustration for discussion of what could be elements of such a group if it were to be established - subject to changes during the negotiations]*

- In charge of overseeing the application of the provisions of this annex. To this effect it will establish periodically a work plan with priorities for cooperation in each of the areas covered by the sector-specific provisions on chemicals
- In charge of organising the cooperation among regulators and of facilitating the exchanges of scientific information relevant for regulatory purposes while avoiding duplication of case-specific cooperation activities
- To exchange information on regulatory issues raised by either side
- To examine and make recommendations concerning areas for future cooperation and for new actions concerning the chemical sector under TTIP
- WG to be composed of the relevant regulators and officials from each side. Possibility to invite stakeholder organisations as observers on an ad-hoc basis. *[NB: membership/participation issues to be examined at a later stage]*
- To meet at least once a year unless otherwise decided, alternatingly at locations in the Parties.
- Can establish ad-hoc expert or scientific groups to discuss particular issues
- In charge of liaising with relevant stakeholders in a way that their input on chemical regulatory issues can be provided and taken into account in regulatory cooperation as appropriate
- Work to be conducted in a transparent way – Will publish in advance agendas of meetings and summary reports of its conclusions. Questions addressed by stakeholders that require the launch of internal procedures to be replied by each side in accordance with their own procedures.

5. Revision of sectoral provisions

- These provisions can be amended in accordance with [provisions on amendments to be developed].