European Commission

Towards an EU-US trade deal
Making trade work for you

The Transatlantic Trade and Investment Partnership (TTIP) Regulatory Issues

EU position on chemicals

The purpose of this paper is to outline the main elements of a possible approach under TTIP to promote regulatory convergence and recognition in the chemicals sector.

1. Overall objectives

Industry associations, civil society and governments are aware that neither full harmonisation nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and EU: REACH (Regulation (EC) 1907/2006) and TSCA (Toxic Substances Control Act) are too different with regard to some fundamental principles.

The recently completed REACH Review concluded that REACH should not be amended, while in the US a bipartisan proposal to amend TSCA has been introduced into Congress in May 2013.

However, the draft TSCA reform legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation, while it would give the EPA (Environmental Protection Agency) new and easier possibilities to conduct chemical assessments and adopt risk management measures such as restrictions.

The objective of the negotiations, therefore, should be to find and agree on all possibilities for regulatory co-operation/ convergence within the limits of the existing basic legal frameworks – details are set out below. Some of these objectives could already be achieved at the time the negotiations are concluded, while for others only adherence to certain regulatory principles and mechanisms for further work might be feasible.

2. Main objectives

Four main areas have been identified in which a higher degree of convergence may be sought to increase efficiency and reduce costs for economic operators. These would 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 destined to better coordinate certain practices.

Both sides would also maintain intact their capacity to regulate and to take decisions in accordance with their respective regulatory framework, as the cooperation and actions envisaged would take place upstream in the preparatory activities of regulators.

They should also lead to greater rationalisation of the regulatory work of both sides and to greater acceptance of international disciplines,

resulting in the avoidance of unnecessary duplications or inconsistencies.

Being based also on an improvement in the exchange of information and experiences, it could also lead to efficiency gains in the regulatory activity of both sides and to a better understanding of the challenges raised by new technologies and issues.

2.1. Co-operation in prioritising chemicals for assessment and assessment methodologies

Prioritisation happens in the US in the framework of the so-called Chemicals Management Plans of the EPA as well as through the selection of chemicals for the so-called 'Reports on Carcinogens' by the National Toxicology Programme (NTP), and in the EU through:

a) the establishment of the Community Rolling Action Plan (CoRAP) for Evaluation under REACH drawn up by ECHA (to note though: evaluations under REACH are in general much more targeted and limited in scope than the full assessments made by the EPA under its Chemicals Management Plans), as well as

b) in a less formalised and voluntary risk management option analysis followed by proposals for restrictions, substances of very high concern (SVHC) identification (candidate list), and authorisation, as well as proposals for harmonised classification and labelling under Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP Regulation).

None of these processes in the EU and US, respectively, currently foresees the consultation or involvement of authorities of the other side, but TTIP could be an opportunity to develop relevant mechanisms.

Methods for assessment/evaluation are also an area where EPA and ECHA already co-operate and this can be intensified – in particular in the development/integration of new scientific developments. The already existing Statement of Intent[1] signed between EPA and ECHA could be a good basis for developing further co-operation activities.

US Agencies should also accept to monitor the activities of individual States in this regard and inform the EU about all draft measures envisaged at sub-federal level.

2.2. Promoting alignment in classification and labelling of chemicals

This is an area with great potential due to the fact that an international standard exists, which is essentially a 'fusion' of the earlier EU and US systems.

In the EU the CLP Regulation constitutes a comprehensive implementation of the UN GHS (Globally Harmonized System), whereas in the US only OSHA (Occupational Safety and Health Administration) has implemented the GHS for chemicals used at the workplace.

EPA (and possibly also the Consumer Product Safety Commission CPSC) would have to also implement the UN GHS for legislation under their responsibility if this objective were to be reached.

The EU and US authorities could also commit to implement the regular updates of the GHS and, in areas, where a certain flexibility is allowed, to work towards convergence. This would also fit with an initiative in the UN GHS promoted by the US for a global list of agreed GHS classifications.

The EU already maintains a list of binding harmonised classifications in Annex VI to the CLP Regulation, and an inventory of all existing industry self-classifications – which are not fully harmonised yet - has been established in the C&L Inventory maintained by ECHA. An enhanced EU-US co-operation on agreeing classifications for chemicals could become a good basis for a global list.

2.3. Co-operation on new and emerging issues

Co-operation on new and emerging issues in a forward-looking manner has the greatest potential to avoid trade irritants in the future.

Examples of current topics of interest are:

- endocrine disruptors (where contacts between the Commission and EPA are already well established),
- nanomaterials (contacts have also already been established) and
- mixture toxicity.

Mutual consultation at an early stage, whenever US agencies or the Commission start developing new criteria or new legislation, could relatively easily become part of the preparatory processes conducted by both.

2.4. Enhanced information sharing and protection of confidential business information (CBI)

The US EPA and OSHA (mainly to obtain full test study reports from the EU) as well as ECHA (mainly to receive full information about substance identities from the US authorities, e.g. in the Chemical Data Reporting scheme) have expressed interest to discuss these issues in the framework of the TTIP negotiations.

In addition, several animal welfare organisations have called on the authorities to increase data exchange between regulators to avoid duplication of tests involving animals.

While it is undoubtedly important that the EU and US authorities exchange information, both sides also make vast and increasing amounts of data publicly available.

Therefore, several elements would require additional consideration before deciding what further steps could be taken or what benefits an agreement on sharing CBI would bring. For example, the US EPA is content with working with robust summaries (and does not require full study reports) in the context of the OECD HPV (High Production Volume) Programme.

Also, neither ECHA nor the Member States authorities do normally receive full study reports as part of REACH Registration or even evaluation – these are owned by the industry and shared between the registrants via Substance Information Exchange Fora (SIEFs) which could be approached directly by the EPA.

It also has to be ascertained that information exchange would be mutual, which raises the question of the limits on US authorities to provide any confidential information to third-country authorities under Section 8 of TSCA.

Another issue to be clarified is to what extent the definitions of CBI is equivalent in the EU and in the US.

3. Concrete suggestions

Achieving the objectives set out in section 2, would require adequate coordination between the different agencies/authorities with regulatory responsibility. The following is proposed:

3.1. For co-operation in prioritising chemicals for assessment and assessment methodologies

A mechanism for mutual consultation on prioritisation of chemicals for assessment/risk management and for cooperation in the development of assessment methodologies would be set up.

Both sides would also inform each other about activities at sub-federal level in the US and Member State activities in the EU, respectively.

3.2. For promoting alignment in classification and labelling of chemicals

The UN GHS as well as its regular updates should be implemented for a broad range of chemicals by a certain date.

A mechanism for mutual consultation and involvement in processes for classification and labelling of substances (i.e. harmonised classification in the EU under CLP – NTP reports on cancer in the US) would be set up,

or other ways of establishing a common list of classifications for substances (e.g. reviewing existing lists and identifying commonalities).

3.3. For co-operation on new and emerging issues

A mechanism to regularly consult with each other on all new and emerging issues – in particular those of regulatory relevance would be established.

Both sides would consult and respond to comments/questions from the other side and undertake efforts to work towards common criteria/principles/measures on such new and emerging issues, where feasible.

3.4. For enhanced information sharing and protection of confidential business information (CBI)

Identification of possible obstacles to exchange (confidential) data and of possible benefits of such exchange and perspectives for reciprocity, including - if considered worthwhile - a mechanism to achieve this objective within a certain time period.

The TTIP could include a periodical review of the functioning of the mechanisms developed for each of the above objectives and their revision as appropriate.

Furthermore, both sides could periodically examine whether additional and new objectives could be covered; if so decided by each Party (NB: in accordance with their own internal decision-making procedures), the respective rules could be amended subsequently, under the institutional mechanisms that may be set up under TTIP.

4. Future convergence

The horizontal chapter of TTIP would have provisions concerning an effective bilateral cooperation and consultation mechanism and an improved feed-back mechanism, for both parties to have sufficient time to comment before a proposed regulation is adopted and to receive explanations as to how the comments have been taken into account.
For the chemical sector, this would include in particular risk management proposals for prioritised substances at federal/EU level and US State/Member State level.