24 April 2013

Cefic Comments on
Draft Technical Regulation of the Customs Union
"On Safety of Chemical Products"
(Version received on 24 January 2013 (in Russian) – translation received on 12 March 2013)

General Comments:

Cefic appreciates that the Russian Federation has provided a latest version of the draft Regulation. Cefic would be interested to receive information about the further adoption process of the draft Regulation, in particular the envisaged timing, as well as the schedule for adoption of more detailed implementing measures that will be necessary for the Regulation to become operational, for example the procedure for establishing and keeping of the Register of Chemical Substances and Chemical Products of the Customs Union as referred to in Article 3, paragraph 2.

Detailed comments:

Scope (Article 1)

Cefic welcomes the clarification concerning the scope of products covered by the draft CU Regulation (or excluded from it) as set out in paragraph 3 and Appendix 1. However we suggest to further complete the Appendix 1 (see our comments in Appendix 1)

As the CU Technical Regulation "On Safety of Synthetic Detergents and Household Chemical products (TP 201/00/TC) already covers classification, labelling (i.e warning marking) , Safety Data Sheet and Conformity Assessment for those products, we suggest to indicate in paragraph 4 that fertilizers, synthetic detergents and household chemical goods as well as paint-and-lacquer materials, should be exempted from this Technical Regulation on "Safety of chemical products" as equivalent requirements are already requested under another specific sector legislation on those products.

Definitions (Article 2)

Cefic notes that the definitions for '***chemical substance'*** and '***mixture***' are now rather well aligned with those of the UN GHS and also the EU CLP Regulation (Regulation (EC) No 1272/2008).
It is also good to see that *"**Information-analytical subsystem "Safety of Chemical Products"*** has been removed and the definition of "**Notification**"has been further clarified

The definition of ***Circulation of chemical products*** – need to clarify if it excludes any complicated downstream users steps.
*The term "***Chemicals product***;"***remains unclear as to whether it refers to a mixture or a substance or both in the Technical Regulation. We would suggest that the draft CU Regulation only uses the terms 'substance' and 'mixture' similarly to the UN-GHS, EU CLP Regulation and the REACH Regulation in the EU. However, if the terms 'chemical product" is maintained, the

CU Technical Regulation should clearly specify when it applies to 'chemical substances', or 'mixtures' or both.

*The definition of "***chemical substance**" indicates that:; "…*product, in which a chemical substance is present at a concentration of 80% (by weight) or more, refers to chemical products while the remaining 20% (by weight) or less are considered impurities and (or) additions*…" This part should be removed from the legal text and eventually be put in guidance. Indeed many exemptions to this rule exist (see REACH ECHA Guidance on "Substance Identification*"; therefore it would be dangerous to have it in the legal text".
* http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

*We suggest to change "**Chemical products of variable composition**" by "Chemical substance of variable composition" to be consistent with EU REACH regulation. Indeed, REACH recognizes 3 types of substance i.e. a) mono-constituent (>80% pure) which is already provided in your definition b) multi-constituents and c) UVCB (Substances of Unknown or Variable composition) . These definitions should preferably be given in a guidance document.

Lack of clarity on chemical products of variable composition being a multicomponent chemical product (page 6 etc…): is it a UVCB substance, is a multi -constituent substance or is it a mixture?

*Similarly we suggest to change "***new chemical product of variable composition"** by "*new chemical ~~product~~ substance of variable composition"*

* As the term "***applicant***" is frequently used in the text, its definition should be provided in this Article. We suggest to define it as follows: *"Applicant is a manufacturer, importer , supplier, or an Only Representative .Applicants are legal persons and individual entrepreneurs registered within the CU common customs territory and bearing responsibility for compliance of chemicals released into free circulation with requirements of the present Technical Regulations. "*

Definition of a **manufacture** is not clear

*The term of "***Only Representative**" should also be added in this Article 2 (see a proposal below) and should be in line with REACH Art 8 i.e the only Representative should have the same rights than an importer or manufacture. In this case the non-Customs Union manufacturer shall inform the importer (s) within the same supply chain of this appointment. Indeed it is critical for non-Customs Union manufacturers to have the possibility to fulfill their duties through an "Only Representative" (as under REACH), i.e. a legal entity who would represent the non-Customs Union manufacturer in the Customs Union. This will also significantly relieve local importers from their notification duties if they can pass over this responsibility to non-Customs –Union manufacturers. It is also critical to have this "only Representative" like in REACH for confidentiality reason. Indeed, if non-CU supplier do not have this possibility, it will force them

to disclose the full composition of their mixtures to their importer to perform the substance notification.
Only Representative*: Any natural or legal person established outside the Community who manufactures a substance on its own, or in mixtures or formulates a mixture that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Customs Union to fulfil, as his only representative, the obligations on importers under this Technical regulation* . i.e. *an Only Representative is a legal entity who would represent the non-Customs Union manufacturer in the Customs Union.*

*Moreover, we suggest to add the following definitions of items we proposed to add in Appendix 1 (list of items exempted to this Technical Regulation:

Polymer (OECD definition): A substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least 1 other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein the differences in the molecular weight are primarily attributable to differences in the number of monomer units.

Article (OECD definition) means a manufactured object formed to a specific shape or design relevant to its function.
An article undergoes no change of chemical composition or form during its use, other than that which is incidental to its use, that which is an intrinsic part of its use, or that which has no commercial purpose separate from that of the article.

Intermediates*(OECD definition)*
Intermediate is a substance produced and consumed in the course of the manufacture of another substance.
Consumed means the substance has chemically reacted to form a different chemical substance, although some of the substance may remain as an impurity in the final product.
Non-isolated intermediate is an intermediate that is not intentionally removed (other than sampling or disposal), from the equipment in which it is produced. The equipment includes the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, any equipment through which the chemical substance passes during a continuous flow or batch process, and vessels in which the substance is transiently held.
Site-limited Intermediate is an intermediate that is manufactured and consumed at the site of manufacture.
Transported Intermediate is an intermediate that is manufactured at one site and transported to a second site where it is consumed.
Imported Intermediate is an intermediate that is imported and transported directly to the site where it is consumed.

Substances occurring in nature (OECD and REACH definitions) are substances that are unprocessed, processed only by manual,
gravitational, or mechanical means, or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means, without chemical change in the

substance.

Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water".

Alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

An **impurity** (OECD definition) is an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it was not intentionally added, nor does it enhance the commercial value of that substance.

Incidental reaction products (OECD definition) are substances produced when a substance undergoes a chemical reaction that is consequent to the use to which the substance is put or that results from storage or from environmental factors.

'**Medical device'** (from EU Medical Device Regulation) means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturerto be used for human beings for the purpose of: ◄
— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

waste' (based on EU Waste Directive) means any substance or object which the holder discards or intends or is required to discard;

"Research and Development substance" (R&D) (OECD definition) means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objective of which is:
(a) to create or improve a product or process, or
(b) to determine the technical viability or performance characteristics of a product or process, or
(c) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials or panelist tests under supervision, other than test marketing, in order to modify the technical specifications in response to the performance requirements of potential customers."

Definition of **SDS** – no seller responsibility or involvement?

<u>Rules for Circulation in the Market (Article 3)</u>

We recommend that clear threshold needs to be defined when Registration is required. Indeed it is impossible for companies to work without threshold. Similarly it would be unmanageable for

Authorities to handle huge amount of Registration of products put on Customs Union market in tiny amount (e.g. R&D materials). We recommend that substances should only be registered or put in the information system when they are put on the Customs Union market at more than 1 metric tonne per year per legal entity. This threshold is broadly used worldwide i.e in the EU-REACH, Turkey, Japan, Malaysia etc….

If a substance is not included in the Register, it must be notified as a 'new substance' in accordance with Article 11. How will this be applied in the period after the adoption of the Regulation and the establishment of the Register? All substances would then be 'new' – or does the initial version of the Register start with an existing inventory of substances? If so, how will this inventory be established?

If all substances under the scope of the Technical regulation would be treated as "new", how could industry manage the requirements of technical regulation which states that all data outlined in article 11 should be provided before marketing i.e "release for circulation" ? It will be impossible for industry to stop their chemical business in Customs Union until notification is generated and submitted to Authorities. All countries with existing chemical evaluation (like EU, Canada and Japan) allow to notify existing substances in parallel of the manufacturing of the product and placing it on the market. If some rules are needed, we could suggest e.g. that notification should be done within 6-12 months of the first manuf./import.

We have the following suggestion: to streamline the work of both Authorities and industry, there should be no need to notify chemical substances already subject to harmonized classification or REACH Registration in the EU (there is currently ~10,000 substances with harmonized Classification and labeling ; see CLP Regulation:
http://echa.europa.eu/web/guest/regulations/clp/legislation; see Annex VI, Table 3.1.).
We suggest that reference to CLP Regulation Annex VI Table 3.1. is made in the CU Technical Regulation

* In addition, could the notification be submitted in English (as most of the data used under REACH will be available in English)?

Classification of Chemical Products for Hazardous Properties (Article 5)

Cefic notes that the draft CU Regulation includes all hazard classes of the UN GHS, while not being specific about the categories from the UN GHS. Paragraph 11 refers to the obligation to indicate hazard categories (i.e. '*subclass/type'*) in the safety data sheets without indication of further details. Where these details would be specified? The CLP Regulation in the EU also includes all hazard classes, but not all hazard categories. The EU considers that inclusion of all categories will lead to over-classification in certain cases. The draft CU Regulation may therefore diverge from the EU CLP, which will complicate trade between the EU and the customs union (and hence the Russian Federation). If differences between both systems are maintained, this would mean a lot of additional classification assessment and generation of different labelling for CU companies supplying to the EU (and for EU companies supplying to CU).

If classification is taken over directly from CLP, it is critical that it is only done as a minimum classification, with the freedom to self-classify at a higher level, or for other non-harmonized endpoints.

Paragraph 5 lists the hazard classes *'capable to bioaccumulation'*, '*resistant to decomposition and transformation processes (persistent)*' and *'being toxic to soil'*, which do not exist in the GHS. As commented for paragraph 4, it might, therefore, be more appropriate to create a separate article with rules for substances that are persistent and bioaccumulating.

The entire class *'hazardous for soil'* (paragraph 8) does not exist in GHS, nor in the EU CLP Regulation. Although the GHS allows including hazards in national systems that are not yet covered by GHS when they are part of existing systems, keeping this specific class "hazardous for soil" will diverge significantly from the CLP Regulation and will thus complicate trade between the EU and the customs union.

According to paragraph 12, test data are to be generated in laboratories selected by a manufacturer, his representative, or an importer. However, there are no requirements with regard to the quality certification of the laboratory (i.e. GLP or accreditation). This seems to contradict the definition of 'notification' in Article 2, and also the provisions of Article 11, according to which data for the purpose of notification to the Register have to be generated in laboratories that are GLP compliant (the EU supports this requirement). In order to guarantee the quality of the data used for classification purposes, the same requirement should be included in this paragraph.

Related to paragraphs 13 and 14:

Neither the UN GHS, nor the EU CLP Regulation foresee an obligation for testing of chemicals for purposes of classification. Classification should be based on available existing data, or bridging principles or based on calculation methods in order to minimise testing on animals. This seems to be the intention also of paragraphs 9 and 13 of Article 5, but the principle could be made clearer – in the current draft CU Regulation, paragraph 12 could be interpreted as a requirement for testing for classification purposes. Instead any relevant and reliable existing data should be used including QSAR, in vitro testing, read-across as also stated in UN-GHS and CLP Regulation. It would also be essential that data provided in REACH registration dossiers in the EU would also be recognised for purposes of classifying and notifying substances in the Custom Union. This will benefit also those companies in the Customs Union that have successfully participated in the REACH Registration process. Classification of substances in other countries/regions should be recognised if it is done in conformity with the GHS criteria. In particular, if classification of substances under the EU CLP Regulation is recognised in the Customs Union, this would help companies from the Customs Union having registered under REACH or exporting chemicals to the EU while classifying and labelling them in accordance with CLP. Many substances (>10,000) have already been officially classified in the EU (see CLP Regulation: http://echa.europa.eu/web/guest/regulations/clp/legislation; see Annex VI, Table 3.1.)..
We strongly suggest that these data are re-used by Customs Union in their Technical Regulation e.g. reference to CLP Annex VI Table 3.1. could be made in CU Technical Regulation
*There should also be the possibility to use "weight of evidence" and "expert judgement" when classifying a substance or a mixture, to be in line with UN-GHS and EU CLP (Art 9 (3 & 4) which give both this possibility.

*To be consistent with UN-GHS and EU-CLP (Art 12), this Technical Regulation should also recognize special cases to perform classification i.e : "*The following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification:*
(a) adequate and reliable information demonstrates that in practice the physical hazards of a substance or a mixture differ from those shown by tests;
(b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable;
(c) adequate and reliable scientific information demonstrates the potential occurrence of synergistic or antagonistic effects among the substances in a mixture for which the evaluation was decided on the basis of the information for the substances in the mixture."

* Finally the draft Regulation should add a new statement to be aligned with UN-GHS and CLP Regulation. This statement is the same as the one provided in CLP Regulation Art 15 (3): "*A new evaluation in accordance with the above shall not be required if there is valid scientific justification that this will not result in a change of classification."*

Article 5.7 chemical mixture should be classified for "ozone depleting" if it contains at least one substance classified for "ozone-depletion" at>0,1% (this is according to both CLP Regulation and UN-GHS).

Labelling of Chemical Products (Article 7)

*In Paragraph 1, it is indicated that "*the name of chemical substances and/or chemical products of variable composition classified as hazardous and contained in chemical products in concentrations above those specified in interstate standards for classification and labeling of chemical products developed according to GHS recommendations*". To be consistent with EU CLP (art 18 (3)), we suggest that only substances which contributed to the following classification of the mixture should appear on the label i.e acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

*Regarding "Storage conditions"; this should not be a general requirement, but only provided "if applicable", and then the pertinent Precautionary phrase will be used.

Label should include the storage conditions (so what is the expected size of the label) which should rather be an information in the SDS and "the name of the document in accordance with which chemical products have been manufactured (when available)". What does it mean?

It is not clear that the labelling requirements concur fully with the GHS rules, in particular the various elements such as pictograms, signal word, hazard and precautionary statements – or are these all contained in GOST standard 31340 which is referred to in paragraph 5 of Article 7 and in Article 8?

Safety Requirements for Marketing of Chemical Products (Article 9)

Paragraphs 1 and 2 require that a safety data sheet is to be drawn up for all products and has to accompany all products supplied. This is not in line with the GHS (nor the EU REACH

Regulation), which require the establishment of an SDS only for hazardous substances and mixtures, and SDS have to be provided on a systematic basis only to professional users. If a mixture as such is not hazardous but does contain hazardous ingredients, and if it is intended for consumer use, an SDS is to be made available on request only. In fact, it is very doubtful that all consumers would fully understand the information provided in a SDS and logistically it seems difficult to ensure that all products sold to consumers (via retailers) would be accompanied by a SDS. Also, the requirement in paragraph 2 that all products must be accompanied by a SDS is conflicting with paragraph 8, which establishes that a SDS is to be provided on request of a user (buyer) or any legal or physical person concerned.

It is unclear what is meant with the *'original SDS'* in paragraph 5. Paragraph 6 establishes that the validity period of a safety data sheet is unrestricted (i.e. unlimited), which seems to contradict Paragraph 7, which (correctly) requires that SDS have to be updated under certain conditions.

It is suggested to modify the text as follows to be in line with CLP Regulation Art 31 (9 a): "*4) when additional or new information which may affect the risk management measures, or when new information on the hazards becomes available*

How long is a manufacture entitled to keep copy of all original SDS?

Requirement to provide an updated SDS to those who received the previous SDS within the last 12 months (which was contained in paragraph 8 of the version of the draft CU Regulation from December 2011) has been deleted. In fact, a requirement for updating SDS and informing all downstream users should be included; when the additional/new information may affect the risk management measures or when new information on the hazards becomes available (this is contained in Article 31(9) of the EU REACH Regulation).

Notification of New Chemical Substances (Article 11)

The first paragraph should clearly specified that manufacturer, importer but also Only Representation have the possibility to submit this notification i.e. " *Notification of new chemical substances and/or new chemical products of variable composition submitted by the manufacturer, importer or Only representative , is carried out in order to enter data in the Register of Chemical Substances and Chemical Products of the Customs Union*"

New notification – is it related to a brand new substance for the area, or per manufacturer?

To be in line with Article 3, we suggest that only new substances manufactured /imported at >1t/y/manuf (importer) and present at >0.1% (if present in mixtures) should be notified.

Noted that Appendix 5 "Chemical Safety Report" form includes exposure assessment, exposure scenarios and risk characterization; these are terms that are associated with the EU REACH regulation. Under the Explanatory Note, there is reference to the EU REACH regulation and the comment that unlike the Regulation 1907/2006 (REACH), there is no need under the draft CU Technical Regulation to study every substance studied previously. Does this mean that the Chemical Safety Report is only for new substances – substances not notified in the Register of Chemical Substances and Chemical Products of the Customs Union?

Paragraph 2 is unclear: How can a manufacturer determine whether a substance (or product of variable composition) is new? The paragraph refers to the '*new chemical substances …which are released for circulation after coming into effect of the Regulation'* – however there is no

reference to a list of substances already released into circulation at that moment in time which would be necessary to determine if a substance is new. Otherwise, all substances would actually be new. Will the first version of the Register contain such a list of substances already notified? If so, how will this initial list be established? Who are the '*Authorised Bodies of the Customs Union*' for notification and when will they be made known?
There are no provisions on confidentiality (i.e. information on the exact composition of substances or products of variable composition), and it is unclear whether public commenting or disclosure of 'non-confidential' information so that stakeholders could comment is foreseen.

The Technical Regulation should clarify which information will be make publicly available from the Information System. In any case, we suggest that appropriate and meaningful information should be placed in the public domain, taking due account of the need to safeguard the commercial interests of companies.

Conformity Assessment (Article 12)

As already commented earlier, we see no need for 'conformity assessment procedures' for each chemical product placed on the market in the Customs Union – in particular not for non-hazardous chemical products. It should be the responsibility of the manufacturers/importers to comply with the legal requirements (which can be subject to enforcement by Authorities) without having an approval process conducted by the authorities for every individual product. Registration/notification could be limited to substances (as in REACH) – and not be required for each mixture many of which will contain the same substances, which have already been notified. Number of mixtures placed on the market can be very high (several millions in the EU) compared to the number of substances contained therein.

The authorities will enter information on the composition of all products into the Register of Chemical Substances and Chemical Products. This is, in fact, very sensitive information that should be kept confidential. Other provisions of the Regulation seem to suggest that the Register will be available for consultation by companies and the general public. How will the protection of confidential information be assured and which information will be recognised as confidential?

Again, none of the procedures foresees public commenting or disclosure of 'non-confidential' information so that stakeholders could comment before the authorities take a decision.

Appendix 1

Appendix 1 is unclear and incomplete. It is about the "list of products to which this Technical Regulation is not applicable". It mixes exemptions and exclusions.

- Exclusions are related to the scope of the regulation and generally refers to wastes covered by waste legislation, transportation, radioactive substances, substances under customs supervision, food, feeding stuffs etc…. i.e. because they are otherwise regulated.
- Exemptions seem to copy & paste REACH exemptions but they are not complete

The list of exemptions should be further extended and also includes the following:

- Medical Devices
- Naturally occurring substances
- Hydrates (if the anhydrous form is listed)
- Alloys
- Impurities
- By-products
- Non-isolated chemical intermediates (formed in-situ
- Site-limited intermediates
- Transported intermediates
- Imported intermediates
- Substances formed inadvertently upon exposure to environmental factors or upon storage
- Substances formed during the intended end use of a substance or mixture
- Substances formed unintentionally during the blending of a mixture or formulation
- Substances in Articles
- Polymers
- The carriage of substances and mixtures by rail, road, inland waterway, sea or air;

Does the exemption in Appendix 1 "**perfumes and cosmetics**", refer to the finished products?

Exemptions should also be aligned with those given in single list of goods subject to sanitary and epidemiologic supervision (control) at the customs border and on the customs territory of the Customs Union, part II, list of goods subject to state registration:
Raw material, active ingredients, intended by the manufacturer (producer) only for the production of perfumery and cosmetic products, household chemical products, plant-protecting, fumigation, pest control and extermination products, as well as pharmaceutical products, are not subject to state registration. (as amended by Decision of the Customs Union Commission N 456 of 18.11.2010)

Other more general questions:

According to which criteria are substances restricted for use or banned? There are multiple references to such chemicals in the draft CU Regulation, but neither the process nor criteria for deciding that a chemical will be restricted or banned are specified.

The format for submission of applications and for notifications is not specified. Will this be done all on paper or in electronic form? If so, would data in IUCLID be accepted?

The transitional period (5 years – in the earlier draft of the Regulation from December 2011) has disappeared. How will all the necessary implementing measures be developed in time? When will the competent authorities designated? How the first version of the Register populated: who will enter the data and how?

Several articles make reference to other standards which are not accessible such as interstate standards for classification and labelling of chemicals developed according to GHS recommendations (Article 7.1 para 3), GOST 31340 for labelling (Article 7.5, Article 8), GOST 30333 (Article 9 on SDS) etc.....What are they?

This Technical regulation should ensure conformity with international rules, and in particular the WTO Technical Barrier to Trade policy.