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Subject:	**G/TBT/N/USA/727 – DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS" – EU comments**		

Message:

Dear Sir or Madam

Please find attached the comments from the European Union on the above-mentioned notification.

Could you please acknowledge receipt of this e-mail? Thank you.

Yours faithfully

p.o.

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COMMENTS FROM THE EUROPEAN UNION CONCERNING NOTIFICATION G/TBT/N/USA/727

DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS"

The European Union (EU) would hereby like to submit comments on the draft Regulation of the California Department of Toxic Substances Control (hereinafter "DTSC") on Safer Consumer Products, which was notified on 8 August 2012.

The EU would like to thank the US authorities for the notification of the draft Regulation, as this allows the EU and other trade partners of the US to comment on it. This draft establishes a number of direct obligations for producers of chemical substances, mixtures and articles, as soon as the substance, mixture or article is listed as a so called "Priority Product" and contains a so-called "Chemical of Concern". Whilst the draft Regulation does not yet list specific products or specific substances, all the conditions and requirements that companies eventually have to comply with are already contained in the draft Regulation and cannot be changed at a later stage.

The EU will first provide general observations on the principles of the draft Regulation and then offer more detailed comments on the text itself.

General Comments

First of all, the EU would like to underline that it fully shares the objectives of the draft Regulation, namely to achieve a high level of protection of human health and the environment by substituting the most hazardous chemicals with safer alternatives and adequately informing users about the risks from chemicals. To this effect, the EU has put into place, among others, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as "REACH" and "CLP" Regulations).

The EU would, therefore, also like to share with the Californian authorities some of the experience gained with regard to the adoption and application of the above-mentioned Regulations.

With regard to the main principles of the draft Regulation, the EU is concerned about three issues, which will be explained in more detail below:

- potential for unequal treatment of economic operators,
- extreme complexity of the proposed alternative assessment procedure and high administrative burdens related to its implementation raising concerns about their compatibility with Article 5.1.2 of the TBT Agreement and

- creation of a highly specific accreditation and certification system which seems to be disproportionate in view of Article 5.1.2 of the TBT Agreement and moreover could potentially disadvantage manufacturers located in third countries (Article 5.1.1 of the TBT Agreement).

1. Several provisions of the draft Regulation have the potential of discriminatory effects among the so-called "responsible entities" (i.e. manufacturers, importers or retailers), both at the beginning and the end of the process.

   For example, under § 69501.4 (a) (3) and (4) of the draft Regulation, DTSC can request a responsible entity or a chemical manufacturer or importer to make existing information available to DTSC within a specified time frame, or even oblige an economic operator to generate new information and provide it to DTSC. Failure to do so results in the responsible entity being "black-listed" on the 'Response Status List' of DTSC in accordance with § 69501.4 (c). However, a responsible entity not known to DTSC or not having been asked to provide information will not appear on this list, without the stigma of having failed to respond to requests from DTSC. Hence, solely the fact of being known or not known to DTSC will potentially lead to discriminatory consequences for responsible entities.

   According to §69503.7 responsible entities must submit priority product notifications, following the listing of the priority products concerned by DTSC. However, if companies do not identify their products themselves, they will not be known to DTSC and will be spared the burdensome consequences of conducting an alternative analysis and of implementing regulatory response(s). The EU would like to ask how DTSC will ensure that all duty holders will be treated equally given that at the time of listing priority products, DTSC will not have a complete market overview.

   According to § 69505.1 (f), a responsible entity may fulfil its requirements to conduct an alternative analysis (hereinafter "AA") by submitting to DTSC a report for a previously completed AA for the priority product. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection). Consequently, the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

   After having conducted the alternative analysis, different responsible entities marketing the same (or very similar) priority product(s) with the same chemicals of concern, can come to very different results – some being able to replace the priority product or chemical of concern, while others might not and hence propose different 'regulatory responses'. Whilst DTSC will review the proposed regulatory responses, it is not clear from the draft Regulation that DTSC will actually require in such circumstances that all entities have to replace the product or chemical of concern, or whether DTSC will indeed impose one or several regulatory response(s), which could again be different for the responsible entities.

   Lastly, some of the regulatory responses that DTSC can impose also have the potential of having very different consequences for responsible entities, in particular when these are small or medium-sized enterprises (SME) or located

outside California. For example, an SME (or an importer on behalf of an SME manufacturer outside California) selling only relatively few priority products will never be able to set up the very demanding and costly End-of-Life Management Requirements described under § 69506.8; whilst this might well be feasible for a big company imposing this regulatory response it would, *de facto*, amount to a ban for the SME producer. Likewise, DTSC can impose the regulatory response to fund research and development projects for the advancement of Green Chemistry and Green Engineering (§ 69506.9), but there is no indication as to which amount(s) will be involved. In order to avoid disadvantages for SMEs, there should preferably be a link with a certain percentage of the turnover made with the priority product in question.

2. The EU would like to elaborate below on the provisions of the draft Regulation related to the alternative assessment procedure and the administrative burdens related to the implementation, with respect to which it has concerns about their compatibility with Article 5.1.2 of the TBT Agreement.

   First of all, the EU would like to note that the US Government is taking strong efforts in recent years to reduce and avoid administrative burdens for businesses. Accordingly, the Californian proposal seems to be at odds with the US 'smart regulation' policies and principles. In particular, the EU would like to refer to Executive Order 13563 of January 18, 2011 on Improving Regulation and Regulatory Review, which notably provides that the US regulatory system must: promote predictability and reduce uncertainty; identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends; take into account benefits and costs, both quantitative and qualitative; ensure that regulations are accessible, consistent, written in plain language, and easy to understand and measure, and seek to improve, the actual results of regulatory requirements.

   The alternative analysis (AA) as described in Article 5 is excessively complex as the range of factors to be analysed is extremely broad and will require huge amounts of data that might be very difficult to obtain. In particular, responsible entities that are SMEs might well not be able to find all relevant data, not even with the help of a certified assessor – or, if so, only at very high cost compared to the company's financial means. It is regrettable that in its analysis of economic impacts DTSC has not actually analysed a few case studies (e.g. a simple case of a chemical mixture and a more complex case of an article composed of many components) to actually demonstrate that the prescribed AA is feasible within the given amount of time and at what costs[1] (even leaving aside the actual costs for substituting the chemical of concern). This type of analysis for processes and procedures was conducted by the EU before REACH was adopted - in fact, this had been strongly called for by economic operators and third countries, including the US, and this has ultimately helped to modify a number of provisions in

[1] In fact, in the attachment to the Economic and Fiscal Impact Statement, DTSC merely states on pages 4 and 5 that costs could vary between a few thousand dollars and hundreds of thousands of dollars, which is not very informative. Analysis of a few real case studies as for example conducted in the electronics industry and/or the US EPA Design for the Environment Programme would probably have provided more concrete estimates, both for costs and the necessary time.

REACH in comparison to how they were originally envisaged[2]. The EU would therefore call on DTSC to reflect on ways that the AA can be simplified, for example in the guidance that is to be developed in accordance with § 69505, or by designating a more limited and specific range of parameters to be analysed when listing a priority product and chemical(s) of concern according to § 69503.4.

The numerous (and in themselves already rather complex) notifications and reports to be submitted by the responsible entities to DTSC, their evaluation by DTSC (within rather short periods of time), the various notices of approval or deficiencies, further submissions and updates of already submitted AA reports, as well as possibilities for administrative disputes etc. could often be duplicative and bear the risk that DTSC might quickly become overwhelmed by the programme. For example, if, as projected, the first list of priority products contains 5 products and each of these is marketed in California by 10 responsible entities, DTSC would have to deal with 50 product notifications (a certain % of which might require follow-up), up to 50 preliminary AA reports (again a certain % of which might require follow-up actions), and up to 50 final AA reports, each probably containing several hundred pages and complex information, many being different from each other in terms of content and quality, all to be analysed by DTSC within 60 days and, if necessary followed-up with complementary submissions by the responsible entities concerned. In parallel, DTSC will have to continue the (also rather demanding) work of identifying further priority products and chemicals of concern and many other activities.

The EU would like to ask whether DTSC has considered an alternative way of crafting the process, which would avoid duplicative work for both responsible entities and DTSC and correspond more to the Restrictions Title under REACH or the Canadian Chemicals Management Plan. For example, after designating a priority product and its chemical(s) of concern and thus requiring responsible entities to notify the priority products, DTSC could then call for submission of all relevant data by a certain date from these responsible entities and all other stakeholders (including the NGO Community) and itself conduct the alternative analysis (either in house, with the help of the Green Ribbon Science Panel, or an outside assessor – in the latter case, costs could be split among all responsible entities having been identified with the priority product notification process according to their turnover with the priority product), and then determine directly a regulatory response. This could well be more efficient in terms of resources required and the necessary time for implementation and would ensure equal treatment of all responsible entities. In fact, in order to be able to review AA prepared by responsible entities and decide on their being appropriate (as required by section § 69505.6) DTSC will in any case need the expertise required for conducting AA and by having to conduct and review multiple AA for the same (or similar) priority product(s) with potentially different outcomes for each of them, the overall workload is multiplied compared to one single analysis. Such an alternative has, unfortunately, not been evaluated under section D of the Economic and Fiscal Impact Statement, where the alternatives considered are all based on the concept that the AA has to be conducted by responsible entities, while nothing in Assembly Bill 1879 on which this draft Regulation is based actually so requires.

[2] Further information is available at: http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

3. Furthermore, the EU would like to elaborate below on the provisions of the draft Regulation related to the accreditation and certification system, with respect to which it has concerns about their compatibility with Article 5.1.1 and Article 5.1.2 of the TBT Agreement.

   Article 8 of the draft Regulation establishes a very specific and highly challenging system for the recognition of accreditation bodies who in turn can certify assessors according to very demanding criteria. This creates a serious risk of disadvantaging potential accreditation bodies and potential assessors not located in California. The required qualifications for accreditation bodies cover such a broad range of topics, while also being highly specific, that probably only a university can fulfil them (e.g. extensive experience in teaching and the need to present entire curricula when applying for accreditation combined with knowledge of Federal and State regulatory and statutory requirements for various areas etc.). In addition, the requirements for assessors to become (and remain) certified are very strict and the time frame for DTSC to designate accreditation bodies and for assessors to pass the necessary training and certification process is short. The EU would be interested to know on which basis DTSC has determined that there will be enough certified assessors to conduct all AA as of 2016 – the study underpinning the Economic and Fiscal Impact Statement mentions on page 15 that there could well be a shortage of certified assessors leading to high fees for responsible entities and then claims – albeit without much evidence – that in the long run, firms and individuals seeking profits will attain the accreditation necessary to perform alternative analysis. However, there is no information related to the costs that an interested assessor may face in order to obtain certification, which depending on the amount involved could be a strong deterrent to seek certification.

   In this context, the EU would also like to recall that the delegation of the United States to the WTO circulated on 12 March 2012 a Communication on the use of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) by Central Government Bodies, which stated that on 12 January 2012, three White House agencies – the Office of Information and Regulatory Affairs, the Office of Science and Technology Policy and the Office of the U.S. Trade Representative – issued a memorandum for the heads of Executive Departments and Agencies entitled "*Principles for Federal Engagement in Standards Activities to Address National Priorities*", which, among other things contained guidance aimed to strengthen implementation of Article 9 of the TBT Agreement:

   > "Agencies should evaluate whether their objectives necessitate creating government-unique conformity assessment schemes, which may be expensive to develop and maintain, may impose additional costs on the private sector, and may not be recognized beyond national boundaries. In doing so, agencies should use existing best practices and leverage available resources in the private sector as well as within the Federal Government[3]."

[3] http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf

Article 8 of the draft Regulation seems to run counter to this US Policy, by setting up a highly unique accreditation and certification scheme that is not recognised beyond State boundaries.

Specific comments:

In the following, the EU will comment on the various sections of the draft Regulation in their order of appearance in the draft text.

Article 1:

§ 69501.1. Definitions

Page 6, lines 10-16: It seems highly unlikely that a chemical substance could have the adverse impacts mentioned under points (A) or (B), and (D) could only materialise if the chemical was intentionally used for that purpose (e.g. asphalt or concrete).

Page 8, lines 10 to 17: The definition of "chemical" is rather specific and not in line with international standards such as "substance" and 'mixture' defined in the UN Globally Harmonised System (GHS). This can lead to confusion and clarity could be increased by specifying that a chemical is either a substance or a mixture and then using the definitions of the UN GHS for these two terms.

Page 8, lines 18 to 21: The definition for the term "molecular identity" is somewhat confusing and includes parameters that go well beyond molecular characteristics. It might be better to use the term 'substance identity'.

Page 10, lines 11 to 14: It is unclear why the term "import" also includes imports into the rest of the United States. It might well be that manufacturers in third countries do not import into California and the Regulation would, therefore, not be applicable to them (or their importers). It should be clarified that the Regulation only applies to products actually placed on the market in California.

Page 13, lines 9 to 10: The final part of the definition of a "retailer" is somewhat confusing. According to the Health and Safety Code in California, the term 'Consumer Product' includes also products sold to professional users. A retailer selling such a product to professionals would, therefore, also be covered by the rules of the Regulation, whilst this definition seems to suggest that this is not actually the case.

§ 69501.3. Information Submission and Retention Requirements

Page17, lines 5 to 6: When and where will the "manner and electronic format" for data submission be specified? Will DTSC consider using internationally recognised formats such as International Uniform Chemical Information Database (IUCLID)?

§ 69501.4. Chemical and Product Information

As already commented above, the provisions of this paragraph lead to potentially discriminatory treatment between responsible entities solely due to whether they are known to DTSC and receive requests for input or not. An arbitrary selection of

economic operators for soliciting information would create obligations for some but not for others. The EU would like to seek clarification on whether this provision includes also manufacturers in third countries and how DTSC will ensure that they have the same possibilities to act as manufacturers in the US, given that they might not be aware of the obligations under the Regulation and correspondence/communication might not be as easy as with manufacturers based in California (or in the US). In addition, the public listing of companies for having failed to respond to requests from DTSC for information even before a decision has been taken on whether or not a product and/or chemical of concern will be selected for prioritisation is not justified. Rather than contacting individual companies with information requests and denouncing companies for not having submitted information at this stage of the process, DTSC might wish to limit the information requests to general calls as specified in subsection (b)(2) and then publish the names of those companies that have co-operated and responded. This would then be a reward and incentive for companies to participate in line with what is already foreseen in section (d).

Page 18, lines 34 to 35: How will the quality and integrity of voluntary AA be evaluated? Whilst a detailed process is laid out in § 6505.2 to 5 for responsible entities to conduct a "mandatory" AA and in §69505.6 for DTSC to verify the results of a "mandatory" AA, there seems to be no such verification for voluntary AA.

§ 69501.5. Availability of Information on the Department's Website

This paragraph sets out a long list of information to be made available on DTSC's website, much of which will require almost constant updating. As this will be very resource-intensive and bears a high risk of displaying inaccurate information, DTSC might wish to consider prioritisation of a more selected list of information for publication. Has DTSC ensured that the publication of the names of individual persons (e.g. as required by subsection (b)(3)(D) the person that will fulfil the requirements of article 5) is compatible with rules on the protection of personal data?

§ 69502.2. Chemicals of Concern Identification

Page 21, lines 30 to 32. The EU supports that the draft Regulation refers to substances classified in the EU and also to other recognised classifications. As an editorial remark, the EU would suggest that the correct wording of the reference in point (B) should rather be as follows:

"(B) Chemicals classified as carcinogens, mutagens and/or reproductive toxicants Categories 1A or 1B in Annex VI to Regulation (EC) No 1272/2008"

The EU notes that the legal certainty for references to lists of endocrine disruptors and persistent, bioaccumulative and toxic substances as indicated in points (C) and (G) could be improved by reference to those that have been officially identified for these characteristics in accordance with the procedure outlined in Article 59 of REACH:

"(C) Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH as endocrine disruptors[4].

.....

[4] The list is available at: http://echa.europa.eu/candidate-list-table

(G) Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH for being persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative."

§ 69503.4. Priority Products List

Page 29, line 35: Why has a criterion of more than 100 manufactured components been selected to identify a 'highly durable product'? There can be many highly durable goods with less than 100 components, for example furniture, mattresses, carpets etc.

Page 30, lines 3 to 4: A reference to products that are *'dispersed as an aerosol or vapour, or applied to hard surfaces with the likelihood of runoff or volatilization'* in the context of highly durable goods seems misplaced. By their very nature, these products cannot be highly durable goods.

Page 30, lines 35 to 38: How will priority products be identified in the list? By (more) general descriptors of purpose and function, or by individual brand names? It could be very important for companies to know this in order to assess whether their products are concerned or not. Also, can DTSC provide an estimate of how many chemicals of concern will be identified in the initial list as the reason for listing the (up to five) priority products?

§ 69503.7. Priority Product Notifications

The EU would be interested to learn how DTSC will ensure that all responsible entities concerned will comply with their obligations under this paragraph, which is also the basis for all subsequent obligations. Point (b) sets out the consequences of a failure to comply, but does not describe any steps that DTSC will take in order to determine cases of non-compliance. This is not set out in the draft Regulation, nor in the Initial Statement of Reasons.

Article 5. Alternatives Analysis

As already pointed out above, the requirements in the draft Regulation for conducting alternatives analysis (AA) are highly complex, both technically/content-wise and administratively with multiple notifications and submissions of reports, each of which will require reactions by DTSC and the submitting entities. The time periods foreseen for completing the various steps seem short compared to the tasks to be accomplished, in particular for preparing a final AA report (12 months) and for DTSC to review and react to the final report (60 days). For reasons of comparison, the EU would like to inform the US authorities that under REACH the normal time frame for preparing a request for authorisation for continued use of a substance on Annex XIV of REACH (which includes an analysis to demonstrate that there is no suitable alternative for the substance concerned) is between 18 and 24 months (while the range of parameters to be analysed is substantially narrower than in the draft Regulation of California), whilst the European Chemicals Agency (ECHA) has then one year to provide the opinions of its Risk Assessment Committee and its Socio-Economic Analysis Committee, before the Commission takes a formal decision on whether or not an authorisation for continued use of a substance can be granted.

Page 36, lines 4-7: The EU observes that it will be absolutely indispensable that California develops guidance for the implementation of the very demanding obligations that companies have to comply with under the draft Regulation. In particular for small and medium size companies it will be extremely difficult to conduct the required alternative analyses – even with guidance. Third country authorities and trade associations should be involved in the process for the development of such guidance documents. The EU also offers to make available the very extensive guidance that has been developed for the purposes of REACH and CLP, which could be a good starting point for the authorities in California.

Page 37, line 39-40: This provision specifies that *'Failure of the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request'*. However, what does this mean for a responsible entity having submitted a request without response within 30 days? It would need to know according to which timeline it has to prepare the AA.

Page 37, line 42 to Page 38, line 1: The draft Regulation requires that all AA completed on and after the date that is two years after the date on which the Regulation takes effect have to be conducted by assessors certified for the appropriate product type and industry sector. However, against the background of the very demanding process for obtaining certification (see comments above on Article 8), what evidence does DTSC have that there will be enough certified assessors available by that date and that their services can be procured at reasonable costs?

Page 38, lines 6 to 10: As already commented above, the provision to allow a responsible entity to fulfil its requirements to conduct an alternative analysis (AA) by submitting to DTSC a report for a previously completed AA for the Priority Product is problematic. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection) as otherwise the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

Page 39, lines 4-5: it seems excessive to require that responsible entities must summarise in their AA reports how they have made use of information made available on DTSC's website.

Page 34, lines 6-10: as already commented before, and for reasons of legal certainty, the Regulation should specify the consequences of DTSC's failure to react within the required deadline rather than specifying what this failure does not mean.

Page 40, lines 25 to 32: The provisions in this subsection are somewhat confusing as they seem to allow the placing on the market in California of new priority product(s) containing chemical(s) of concern (subject to the conduct of an AA within a certain deadline), even after the products have been listed, all responsible entities having already conducted their AA and DTSC having already imposed a regulatory response (which might actually be a ban or an obligation to replace a chemical of concern). This provision should, therefore, be limited until such time that DTSC has imposed a regulatory response for a given priority product after which any entity wishing to

market a new product would have to comply with the regulatory response. It seems not efficient to require another AA to be conducted then.

Page 42, line 31 to page 45, line 15: The EU would comment that the range of factors to be analysed during the second step of the AA is extremely broad, which makes it very difficult to conduct the analyses within reasonable cost and time. For many parameters it will be virtually impossible to find (or just model) the required data, and this will be even more complicated if products are manufactured in third countries. The EU notes that in the framework of the Economic and Fiscal Impact Statement DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate. The EU would also like to recall that in the development of the REACH Regulation, the Commission, the Member States and industry conducted numerous feasibility experiments – the so called Strategic Partnership on Reach Testing (SPORT) and Piloting REACH for Downstream Use and Communication in Europe (PRODUCE)[5], the results of which led to significant changes between initial drafts and the final Regulation in the light of feasibility and proportionality considerations.

Page 46, lines 32 to 34: There is no particular reason to require this information as part of the AA as it does not bring any meaningful contribution to the analysis. In fact, the chemical industry and the broader manufacturing industries are operating globally. Even if a particular chemical is produced very close to a plant consuming this chemical in the manufacturing process of a product, that chemical (or an alternative) can easily be sourced from another country. It is also not clear what consequences this requirement would have for products manufactured in third countries.

Page 48, lines 10 to 11: It is unclear how a responsible entity could comply with this obligation. If certain information is not available, it is difficult to assess whether it would meet the criteria listed under points (A) to (C).

Page 48, line 34 to Page 49, line 22: This subsection establishes the obligation to determine the entire chemical composition of a selected alternative product. It will be extremely difficult in the case of complex products such as cars or household appliances to conduct an assessment of the entire chemical composition of each component in their product, as these are often assembled out of hundreds of different components, each containing potentially many different chemicals and provided by a variety of suppliers possibly in different countries. If DTSC maintains this requirement, it actually creates a strong incentive for responsible entities not to select an alternative and maintain the priority product as then they do not seem to have to comply with this obligation. A more feasible approach would be to limit the information requirement to whether the selected alternative contains other chemicals of concern.

Page 51, lines 1 to 10: as already commented before, the time frame for DTSC to review an AA report (60 days) and also the time frame for responsible entities to redress deficiencies (60 days) seem excessively short against the background of the complexity of the work required.

[5] Further information is available at:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

Article 6. Regulatory Responses

As a general question, what will DTSC do in the case of diverging or conflicting results of alternative assessment for the same/similar products and chemical(s) of concern? Given that many different actors will conduct AAs the risk that there will be diverging results with regard to regulatory responses will be quite high. Does § 69506.1 have to be understood in the sense that DTSC will ultimately impose the same regulatory response on all responsible entities or will there be different ones for different entities?

Page 53, lines 29 to 39: § 69506.2 entails again a significant risk of discriminatory treatment between responsible entities. If requests for additional information are made, they should concern all entities and not only individual ones. If one of them has already provided the information, DTSC could increase efficiency by using it and require all others to participate in the costs of the first one for generating the information, rather than requiring them to produce the same information again.

Page 54, lines 23 to 24: Is the intention really to require the listing of all chemicals of concern or rather the chemicals of concern due to which the product had been identified as a priority product? In fact, lines 34 – 35 specifically refer to the applicable alternatives analysis thresholds, which only exist for the chemicals of concern due to which the priority product had been selected.

Page 55, line 29 to page 57, line 5: It is not clear why DTSC wishes to operate with individual notifications to responsible entities to establish product sales prohibitions. Would it not be more efficient and less discriminatory, if, instead, DTSC established a horizontal rule prohibiting the product (or chemical of concern) in general and for all entities wishing to place it on the market in California?

Page 57, line 29 to page 59, line 17: The regulatory response to set up a comprehensive end-of-life management programme (including comprehensive financial guarantees and burdensome yearly reporting) seems impossible to meet for individual companies – in particular for manufacturers that are SMEs and/or located in third countries - and can probably only be achieved if the DTSC establishes a rule applicable to (a range of) products that would apply to all responsible entities to create this jointly. Again, the EU would like to know whether the DTSC has undertaken any feasibility studies with regard to this particular regulatory response, in particular for SMEs. In the light of the high costs involved, this regulatory response could amount to a disguised ban on marketing the product in California.

Page 59, lines 22 to 59: The EU would like to know according to which criteria the obligation to fund 'Green Chemistry' Research will be put into practice. How will the amounts be determined that a responsible entity will have to provide? As a share/percentage of overall sales? How will the DTSC avoid discriminatory treatment of different responsible entities?

Page 61, lines 18 to 24: Again, this subsection implies that different responsible entities will get different regulatory responses imposed for the same (or similar) priority product(s). It would seem more logical that DTSC informs all retailers and publishes general rules about one identical regulatory response applicable to all responsible entities in a non-discriminatory way.

Page 61, line 37 to page 62, line 22: these subsections establish burdensome reporting requirements for responsible entities and even more so for DTSC itself, as the number of products and regulatory responses concerned could easily run into the hundreds after a few years and would grow continuously over time.

Article 8: Accreditation Bodies and Certified Assessors

See comment number 3 in the section on general comments above.

The EU thanks the US authorities in advance for taking into account the above comments and looks forward receiving a reply.

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