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AUPRÈS DE L'UNION EUROPÉENNE

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The Japanese Mission to the European Union presents its compliments to the European Commission and has the honour to inform the latter of the comments of the Japanese Government on the Internet Consultation on the Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization of Chemicals (REACH) as detailed in the attachment to this Note Verbale .

The Japanese Mission to the European Union avails itself of this opportunity to renew to the European Commission the assurances of its highest consideration.

Brussels , 10 July 2003

MISSION DU JAPON AUPRÈS DE L'UNION EUROPÉENNE 在欧州連合日本政府代表部

EUROPEAN COMMISSION
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Comment by the Government of Japan on the draft consultation document concerning The New Chemical legislation- the REACH system

July 10, 2003

I. General Issues

[Topic: Duty of Care, Chemical safety assessment, Data sharing/consortia formation, Procedures for downstream users, Others]

1. The government of Japan (GOJ) recognizes the importance of the objective of protecting human health and the environment that the European Union (EU) intends to achieve, and appreciates the attitude of the EU in tackling this issue.

2. However, measures written in the draft of the REACH system should be in conformity with the idea of "sustainable development" that EU reiterates as a principle of its environmental policy. Therefore, EU should ensure a sound balance between the purpose of the REACH system and the scope and contents of the regulation lest the existence of the REACH system should unnecessarily impede economic activities, innovation of chemical products by companies, and international trade and investment. From this point of view, the GOJ has concerns particularly about the following points regarding the REACH system's impacts not only on chemical industries and downstream users in the EU Member Sates but also on international trade and investments toward the EU from abroad including Japan.

3. First, the GOJ considers that the REACH system has a possibility to impose excessive and unnecessary burdens on companies to comply with the new legislation. As companies including small and medium-sized ones manufacturing, importing or using many kinds of chemical substances are numerous and diversified, the whole system proposed by the European Commission (the Commission) could not be implemented smoothly if the criteria which requires the extent of data for registration and the scope of the duties of mandatory initial risk assessment are not established at rational level. Accordingly the future legislation of the REACH system should be required to avoid redundancy of duties already imposed by existing regulations such as Council Directive 67/548/EEC in which companies are obliged to provide the Safety Data Sheet (SDS). In addition, the Commission should pay attention to the need to protect confidential business information.

4. Second, the REACH system should not create unnecessary obstacles to international trade. In particular, general and abstract provisions stipulated in the draft text of Point 63 and 64 might have trade restrictive effects, since they would create excessive barrier against exports toward EU, if such provisions were not appropriately implemented. They could be inconsistent with the principles stipulated in WTO

agreements.

5. Third, the REACH system should be consistent with the international activities that aim to harmonize each country's regulatory schemes. OECD and other international institutions have been working on harmonization of rules and procedures related to chemical management. Especially, studies of chemical substances which have been suspected to have endocrine disrupting effects have been in progress and still collecting scientific knowledge including on evaluation methods, therefore, it is premature to introduce the restriction on manufacturing and using of such substances based solely on a doubt that they have endocrine disrupting effects. Furthermore, the Commission should continue to accept the data acquired through non-EU GLP facilities for the REACH system.

6. Forth, the GOJ notes that each Member States should ensure REACH-system' s proportionality, transparency and fairness. No discriminatory practice of the REACH system should be conducted by the competent authorities of Member States, although the Draft gives them considerable discretion to carry out the system, such as evaluation of chemical substances. In addition, there are many ambiguous provisions in the Draft. Especially, many important definitions are not sufficiently nor precisely explained. The GOJ requests the Commission to specify the content of ambiguous definitions in the provisions of the Draft and show their scope by issuing guidelines with examples, in order to avoid different interpretations resulting from discretion of each Member States.

7. To ensure the workability of REACH system, the GOJ considers it is important for the Commission and each Member State to enhance the system to implement the REACH system by providing appropriate number of persons and those with expertise before its introduction.

8. The GOJ expects the Commission to consider and reflect every comment submitted through internet consultation, and continue further consideration to make the REACH system workable. The GOJ also expects receiving the Commission's reply to the comments and questionnaires, and would like to consult with the European Commission about the detail of the REACH system continuously. The GOJ would submit additional comments or questions, as necessary.

II. Specific Issues

1. Avoidance of an excessive burden to companies

[Topic: Chemical safety assessment, Information flow, Registration procedure, Intermediates, Data sharing/consortia formation]

- **Duty to prepare Chemical Safety Report (CSR)**

Since CSR stipulated in Point 4 of the Draft requires all actors in the supply chain to prepare detailed and broad information, it may impose excessive burden on companies, compared with the existing duty regarding the Safety Data Sheet (SDS). Current SDS formats contains information that overlap with that of CSR, such as hazard assessment data and instruction of treatment. Therefore, the Commission should reconsider the necessity of the duty to prepare CSR provided in Point 4, and consider and accept the SDS, by revising information required in the SDS, if necessary, as a substitute for CSR, because it is currently disseminated in the EU for sharing information among companies. Moreover, the Commission should take into consideration international efforts for sharing information about chemical substances. For instance, the United Nation are going to adopt the recommendation on Global Harmonized System (GHS) for Classification and Labeling of Chemicals that integrate a form for SDS system and other related factors in July 2003. Although the Commission has not clearly explained what kind of additional information should be submitted as a CSR, it should avoid imposing unnecessary paperwork due to the duplication of obligations concerning SDS and CSR, through revising the items of SDS formats, if necessary.

In addition, if companies were required to prepare information of every chemical substance in a preparation (eg. ink), it would not be practical for companies to execute its burden.

- **The definition of intermediate subject to REACH**

"Isolated intermediate transported" provided in Point 2-14 (iii) should not be defined by the number of sites in which they are used. There is no rational reason to limit the number of sites for to two to define "Isolated intermediate transported", since intermediates do not adversely affect human health or the environment as long as they are properly controlled.

- **Treatment of chemical substances listed in EINECS**

The Commission does not clearly explained why "phase in substance" should be manufactured or imported over the 10 years, while Point 2-20-(a) in the Draft defines "phase in substances" as ones which was manufactured or imported more than 1 tonne or more and listed in EINECS. The Commission should treat all substances listed in EINECS as "phase in substance" regardless of their past records.

- **Treatment of 90% provision and Confidential Business Information (CBI)**

The provision of Point 11-1-(a)-(iii) requires manufacturer or importer to grasp at least 90% of

intended uses by downstream user. The Commission should explain how manufactures or importers execute the requirement, since the procedures to grasp uses or prove duties have not clearly been stated. In particular, manufactures or importers might give up registration because it is quite difficult for them to obtain downstream user's information recognized as a confidential business information (CBI). Due allowance should be made if they would not be able to fulfill their duty provided in Point 11-1-(a)-(iii).

- **"Sole representative" system**

The "Sole Representative" system which is recognized as the method of notification under the present EU Directive 67/548/EEC (The 7th Amendment) should remain in the regulation. "Sole representative" system has been established to avoid the duplicate registrations and wasting the resources for exactly identical chemical substance in the case that a manufacturer outside EU Member States imports the chemical substances through plural number of importers within the EU area. The system similar to "Sole representative" system should be introduced under REACH system.

- **Languages used for Information to be submitted for registration**

According to the Draft, the registrant, the European Chemical Agency (the Agency) and the competent authority of the Member State are related to registration procedures. What language is supposed to be adopted in the registration procedures? If the registrant were required to submit more than two kinds of documents written in different languages, the registrant would have to bear a considerable burden, and therefore this kind of requirement should be avoided.

2. *Ensuring equal treatment for non-EU companies*

[Topic: Registration procedure, Procedures for downstream users, Data sharing/consortia formation]

- **Registration of chemical substances contained in articles**

Since the scope of article provided in the provision of Point 64-2 ("if during normal and reasonably foreseeable conditions of use and disposal the substance may be released in sufficiently high amounts and in such a way as to adversely affect human health or the environment") is not clarified, it is difficult to define what industry and manufactures are the subject of registration unless the Commission issues an adequate and precise guideline to interpret the provision. Without such a precise guideline with examples, importers could not decide whether the registration is necessary, and may not be able to gain benefits derived from their exports toward EU because of the burden of spending much time to register all substances contained in an article to be imported. Therefore, the GOJ requests the Commission to continue discussions regarding the provision of Point 64 including its necessity and the content of the guideline for implementation after the internet consultation and give further opportunities to make comments for foreign governments and people in the industries. The GOJ also requests that before deciding contents of the Draft, the Commission define the terms indicated in provisions stipulated in Point

64. For instance, a numerical threshold of "sufficiently high amounts", an exact meaning of "adversely affect human health or the environment", the factors which consist of adverse effect on human health or the environment, and an exact meaning of "quantities totalling over 1t per year" stipulated in Point 64-1 should be clearly explained. Moreover, the Commission should prepare a positive list that specifies targeted articles, required volume, the type of model that should be accumulated, and so forth. The Commission should propose the positive list to interested parties, seek comments again, and reconsider the contents of the list based on comments submitted. The GOJ has an intention to submit again its comment on the detailed guideline issued by the Commission in the near future.

The Point 63 and 64 should be deleted if the European Commission did not clarify points that the GOJ mentioned above. According to the 1st clause of Point 64, almost all articles will be subjects to the provision because most chemical substances contained in articles would leak out to the environment during disposal process. In addition, the terms, such as "be released in sufficiently high amount" or "adversely affect human health and the environment" stipulated in 1st clause of Point 64 are not defined clearly. If producers or importers have to judge the meanings of ambiguous terms in Point 64, the provision would place a heavy burden of assessing the risk of all chemical substances contained in articles. It would not be feasible for producers or importers to grasp all chemical substances contained in articles which they produce or import to comply with the duty of Point 64. In particular, it would not be possible for importers to obtain necessary information to execute the obligation to prepare registration regarding chemicals exported by non-EU suppliers to identify whether the article they are going to import are subject to Point 64. These importers may face adverse conditions than their competitor within the European Union because of the provision. The provisions of Point 64 would not be workable if it required producers or importers to confirm whether chemical substances they would use are registered or not, because such a process requires considerable labor from not only producers or importers but also subcontractors. Additionally, with respect to the provision of Point 64-2 which stipulates the exemption to "an actor up the supply chain", the GOJ have a concern that the provision could require producers or importers of articles to choose a chemical substance supplier within the EU Member States who has already registered the substance.

- **General issues regarding cost sharing, administration of consortium**

It is very difficult for producers or importers to share the cost for registration according to the volume of product or import in primary base in light of the principle of competition law or the protection of confidential business information, while sharing the cost according to the degree of benefit is the most useful way to realize "fair cost sharing". This is why the public authority, such as European Chemical Agency, should be involved in the process that allocate the ratio of cost sharing among the members of consortia.

The Commission should clarify the rule regarding establishing and conducting consortium, and observe each consortium properly in order to ensure fairness and transparency of information sharing,

administration and so forth.

3. Ensuring REACH's consistency with international arrangements

[Topic: Authorisation procedure, Data sharing/consortia formation]

- **The scope of chemical substances for authorizations**

According to the explanation by the Commission, chemical substances which are suspected to have endocrine disrupting effects should be treated as a substance subject to authorizations, which are identified on a case by case basis, while OECD is still conducting Task Force on Endocrine Disrupters Testing and Assessment (EDTA) to develop the method of evaluation of endocrine disrupters. The GOJ considers that inclusion of chemical substances which have been suspected to have endocrine disrupting chemicals in the subjects of authorizations seems to be premature and scientifically not appropriate at this stage.

- **Ensuring consistency between REACH's criteria and those of other international arrangements**

The Commission should ensure consistency between the criteria stipulated in the REACH and those of existing international treaties or arrangements, such as Annex D of Stockholm Convention on Persistent Organic Pollutant

- **Acceptance of data obtained by non-EU GLP faciliteis**

The Commission should ensure that high quality and reliable test data related to the safety of industrial chemical substances and preparations acquired through non-EU facilities which is certified according to the OECD Good Laboratory Practice (GLP) will be accepted for REACH's registration procedure.

4. Ensuring transparency and equality in the REACH and its application

[Topic: Evaluation procedure, Data sharing/consortia formation]

- **REACH's proportionality**

The GOJ have a concern that each Member State would not be able to conduct REACH's evaluation procedures equally because of the difference of each State's capability for the evaluation. According to the Draft, authorities of each Member State will conduct REACH's evaluation procedure, but several gaps have been recognized among each authority's capability of evaluation for conducting the current Council Directive 67/548/EEC.

REACH's evaluation procedure is one of the most important steps of the system to judge a risk of chemical substances. If there were differences among the result of the evaluation of the same chemical substance conducted by authorities of Member States, it would prove that REACH would not be a workable system. The Commission should establish a standardized evaluation system through showing

clear criteria lest an authority of each Member State should not continuously ask companies to conduct additional test.

- **Clarification of methods to judge the identity of a substance (isomer, impurity, structure, etc.)**

It is not clear in the Draft how substances (such as isomer) are identified as the same one, (by the volume of isomer, degree of impurity, etc.) and therefore the Commission should issue a guideline on the criteria of judgment. The Commission should regard substances whose volume of impurities or constituents are different as same substances, while Point 26-a requires the evidences including the degree of purity and the nature of impurities to identify the substance.

III. Questionnaire on technical issues

Questionnaire on technical issues are attached as annex. The GOJ appreciate receiving the Commission's reply.

Additional Questionarie for European Commission

1. Is it possible to regard the materials showing below as exemptions stipulated in Annex III?
(1) Iron, copper, zinc, beryllium or other metals which has changed chemically, or has gone through the process of manufacturing
(2) Silica or other industrial minerals which has changed chemically, or has gone through the process of manufacturing
2. With respect to the meaning of "be released sufficiently high amounts" stipulated in Point 64, is a clear numerical threshold going to be stipulated in a guidance for application of Point 64?
Likewise, with respect to the meaning of " to adversely affect human health or the environment", are evaluation methods to decide hazards and risks specifically stipulated by a guidline for application of Point 64?

3. When a company imports articles shown in thecolumn I, is it necessary to register the chemical substances contained in those articles (examples of major chemical substances are shown in Column II) based on the provision of Point 64, if the volume of those substances exceeding 1 tonne per year? This question is based on the premise that the 2nd clause of Point 64 is not applied.

Column I	Column II (typical chemical substances contained)
automobile	engine parts (aluminum alloy) radiator (lead or its substitution) solder on electronic boad (lead or its substitution) electric heater (lead or its substitution) battery (lead or its substitution) fuel tank (aluminium alloy) under coat for body (lead or its substitution) thin coating for bolt (hexavalent chromium or its substitution) brake (hexavalent chromium or its substitution) Fail lamp (hexavalent chromium or its substitution) Headlights (mercury) meters (mercury) liquid crystal display for car navigation system (liquid crystal substance) indoor fluorescent light (mercury) integrated circuit chip (cadmium) lubricant (paraffins) tyre (rubber, sulpher, antioxidant)
auto parts	In case when the above componets are imported as parts themselves.
game machine /personal computer /cellular phone	frame (fire retardant, polymer) semiconductor (silicon, germanium, indium, printing ink) solder (lead or their substitution) battery (nickel, cadmium, lithium) liquid crystal
television	cathoderay tube
refrigerator	refrigerant (CFC, HCFC)
phtografic cameras	lens frame (polymer, metal)
analysis instruments /measure instruments	frame (polymer, metal)
machine tool	frame (metal) lubricant (paraffins)

film (photographic or cinematographic	photosensitizer (silver (I) nitrate)
seat, film /pipe, tube, hose /plastic bag	Polyethylene(PE), Polypropylene(PP), Polyvinyl chloride(PVC), plasticizer (phthalate ester)
pet bottle	Polyethylene terephthalate(PET)
vinyl doll	Polyvinyl chloride(PVC), plastizer (phthalate ester)
kitchen equipment /table ware	Polyethylene(PE), Polypropylene(PP), Polyvinyl chloride(PVC), Polycarbonate
detergent	surface-active agent (Alkylbenzenesulhonate(LAS), Polyoxyethylene nonylphenyl ether)
wallpaper for building materials/flooring	Polyvinyl chloride(PVC)
putty in building material/seling	chloroprene rubber
adhesive packaged for consumer use	urea resin, chloroprene rubber, toluene
pigment, dye	Lead chromate, Zinc phosphate, Alkyd resin
prepared waxes	paraffin, stearic acid, hydrogenated oil
adhesive plaster	medicine containing poultice etc.
clinical thermometer	mercury
matches	ignition part
cosmetics	1,3-Butylene glycol, Propylene glycol, Polyvinyl pyrrolidone
carbonless paper /themal paper	organic solvent, dye, developer, coler fixing agent
cardboard	water repellent agent (paraffin, fatty acid derivative, PE), printing ink (complex chromium
ballpoint pen	ethylene glycol, pigment, dye
chemical fiber product	polyester, nylon, heavy metals(antimony etc.), dye, surface-active agent
shose, sandals	Polyvinyl chloride(PVC), polyurethane
blood bag for medical use, injector for medical use	plasticizer for vinyl chloride (phthalate ester)
thermographic ribbons, magnetic tapes	PET film, ink, magnetic materials
leather product (leather, tanned or finished fur skin, fur product, bag, shose)	tan (chlorinated paraffins)