

WORLD TRADE ORGANIZATION

TN/MA/W/137
19 March 2010

(10-1482)

Negotiating Group on Market Access

Original: English

MARKET ACCESS FOR NON-AGRICULTURAL PRODUCTS

Negotiating Text

Understanding on Non-Tariff Barriers Pertaining to Standards, Technical Regulations and Conformity Assessment Procedures for Chemical Products

Communication from the European Union

The following communication, dated 17 March 2010, is being circulated at the request of the delegation of the European Union.

Understanding on Non-Tariff Barriers Pertaining to Standards, Technical Regulations, and
Conformity Assessment Procedures for Chemicals

Members,

Recalling that pursuant to paragraph 16 of the Doha Ministerial Declaration, Members agreed to negotiations aimed at reducing or as appropriate eliminating tariffs and non-tariff barriers on non-agricultural products,

Recognizing the important contribution of chemicals to global economic growth, trade and sustainable development, in particular its significance for the economies of developing countries,

Renewing their commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment, inter alia, aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment,

Acknowledging that the chemical industry is essential for a wide variety of manufacturing and agricultural industries and bearing in mind its contribution to the transfer of advanced technology, whilst noting that parts of these chemical industries are composed of small and medium-sized enterprises,

Affirming their existing rights and obligations under the WTO Agreement, including the Agreement on Technical Barriers to Trade (TBT Agreement),

Recognizing that no Member should be prevented from taking measures that are necessary for the protection of human, animal or plant life or health, for the protection of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Understanding;

Desiring to ensure that technical regulations, standards, and conformity assessment procedures are not designed, neither adopted, nor applied so as to create unnecessary obstacles to international trade in chemicals;

Reaffirming the commitment to the conclusions of the World Summit on Sustainable Development in Johannesburg of 2002 encouraging Members to implement the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as soon as possible,

Confirming their shared objectives and principles of:

- establishing competitive market conditions based on principles of openness, non-discrimination, and transparency;
- ensuring a high level of protection of human health and the environment;
- enhancing international cooperation to foster continued beneficial development in trade;
- promoting alternative methods for assessment of hazards of substances and reducing animal testing;
- implementing appropriate regulatory mechanisms and protecting confidential information;

- contributing to the fulfillment of the Strategic Approach to International Chemicals Management (SAICM), and
- developing and promoting best practices on chemicals assessment and management globally,
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Recognizing, based on the objectives and principles above and with a view to facilitating and promoting trade, the importance of:

- ensuring transparency regarding the content of their laws, regulations and other measures of general application in the area of chemicals,
- providing transparency and due process when regulating and operating their chemical management regimes,
- applying, whenever possible, best practices with respect to the adoption and implementation of regulations concerning management of chemicals, and
- cooperating in the development of international standards on good laboratory practice and testing, in order to seek more harmonized approach to chemical assessment and management,
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Recognizing that no country should be prevented from taking measures necessary to fulfill its legitimate objectives in accordance with the provisions of Article 2.2 of the Agreement on Technical Barriers to Trade, and in particular the protection of human health or safety, animal or plant life or health, the environment, or for the protection of its essential security interests,

The Members,

Agree as follows:

1. SCOPE AND COVERAGE

1.1 This Understanding shall apply with respect to chemicals.

1.2 Members assume obligations under this Agreement only with respect to standards, technical regulations and conformity assessment procedures.

1.3 This Understanding shall not apply to purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies.

1.4 Any reference in this Understanding to standards, technical regulations or conformity assessment procedures shall be construed to include any amendment thereto and any additions to product coverage or other provisions thereof, except amendments and additions of an insignificant nature, to the extent such amendment or addition pertains to chemicals.

STANDARDS, TECHNICAL REGULATIONS, AND CONFORMITY ASSESSMENT PROCEDURES

2. INTERNATIONAL STANDARDISATION AND REGULATORY HARMONISATION

2.1 *International Standard-Setting Bodies*

For the purpose of applying Articles 2.4, 5.4 and point F of Annex 3 of the Agreement on Technical Barriers to Trade, with regard to the areas of testing, data acceptance and good laboratory practice the Organisation for Economic Co-operation and Development (OECD), in relation to the classification and labeling of chemicals the United Nations Subcommittee of Experts on GHS (UNSCE GHS) under the auspices of UN Economic and Social Council, and otherwise the International Organization for Standardization (ISO) shall be considered the main relevant international standard-setting bodies for the purposes of this Understanding.

2.2 *Regulatory Harmonisation*

2.2.1 With a view to harmonizing technical regulations and conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards, guides and recommendations pertaining to chemicals.

2.2.2 Members commit to participate actively in the development of international standards, guides and recommendations, in particular in the international standard-setting bodies identified in paragraph 2.1, and shall cooperate for the adoption, without undue delay, of new international standards, guides and recommendations by these bodies.

2.3 *Development of International Standards, Guides and Recommendations*

For international standards to make a maximum contribution to the achievement of trade facilitation for the chemicals under this Understanding, Members confirm the importance they attach to the principles announced in the Decision of the WTO Committee on Technical Barriers to Trade *on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement*.¹

3. CLASSIFICATION AND LABELLING OF CHEMICALS

3.1 Members recognise the importance of achieving global harmonisation of the classification and labelling of chemicals and the progress achieved with the establishment of the Global Harmonized System of Classification and Labelling of Chemicals.

3.2 Members shall gradually align their technical regulations to the Globally Harmonized System of Classification and Labeling of Chemicals with a view to having substantially aligned their domestic legislation by the end of [2015].

3.3 Any Member's classification and labelling requirements for chemicals under the coverage of this Understanding shall be in conformity with Article 2.2 and 2.4 and 2.5 of the Agreement on Technical Barriers to Trade.

¹ Annex B of the Document G/TBT/1/Rev. 9 dated 8 September 2008.

4. TECHNICAL REGULATIONS AND CONFORMITY ASSESSMENT PROCEDURES

4.1 *Management of Chemicals*

4.1.1 Members recognise the importance of achieving global harmonisation of the management of chemicals.

4.1.2 Members shall ensure that in respect to regulations and conformity assessment procedures relating to management of chemicals, chemicals imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like chemicals of national origin and to like chemicals originating in any other country.

4.1.3 Any Member shall endeavour to provide in its regulations and conformity assessment procedures relating to chemicals for special and differentiated treatment with regard to small and medium enterprises with a view to reducing the administrative burden for them.

4.1.4 Any Member shall ensure that its regulations and conformity assessment procedures ensure full and comprehensive protection of confidential business information.

4.1.5 In accordance with Article 2.2 of the Agreement on Technical Barriers to Trade, any Member that is planning to establish regulations relating to chemicals, shall ensure that the information required cannot be obtained by other means that would be less trade-restrictive to fulfil the legitimate public policy objective.

4.2 *Registration of Data*

4.2.1 Members recognise that the current knowledge of hazards deriving from chemicals for safety, health and the environment requires the collection of data and scientific evidence of their hazardous effects to allow a proper assessment of the risks associated with their handling and management. For this purpose, requirements on collection and registration of data may be set up by any Member in view of pursuing their legitimate public policy objectives.

4.2.2 Members shall ensure that in respect to registration of data,² chemicals under the coverage of this Understanding imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like chemicals of national origin and to like chemicals originating in any other country.

4.2.3 When a Member designs, adopts or applies a technical regulation requiring collection or registration of data for chemicals covered by this Understanding, it shall ensure that costs and procedures associated with registration of data are proportionate with regard to the legitimate objectives pursued according to Article 2.2 of the TBT Agreement. In particular, the impact of such costs for small and medium companies shall be taken into account.

4.2.4 Members should, when determining the appropriate level of data collection, take into account the objective of minimizing negative trade effects whilst meeting the objectives of the measure.

4.2.5 When data and scientific information and evidence of their hazardous effects become available through the data collection process itself, the Member shall periodically review the scope of the data collection and registration obligations on the basis of this new information.

² Registration of data means any submission of information concerning chemicals to a national or regional authority as part of a regulatory and non-regulatory scheme. It therefore covers, for example, notification schemes for new substances and chemical registration schemes.

4.2.6 Members may require registration of data for chemicals contained in imported articles³ when the chemicals are intended to be released.

4.2.7 Members may require registration of data for chemicals contained in imported articles⁴ when the chemicals are not intended to be released, if there is sufficient scientific evidence that, because of their intrinsic properties, the chemicals in those articles pose a risk for human, animal, plant health and life, or the environment.

4.3 *Testing and Sampling of Chemicals*

4.3.1 If a Member requires a positive assurance of conformity for a chemical, in accordance with Article 5.4 of the Agreement on Technical Barriers to Trade, any government body of this Member shall use, require or accept the use of test methods for conformity assessment conforming with technical regulations or standards, and relevant guides or recommendations issued by international standardising bodies or conforming with the principles of Good Laboratory Practice (GLP) and the Guidelines for the testing of chemicals as established by the Council of the Organisation for Economic Co-operation and Development on 12.05.1981 (C(81)30/Final) and with the principles of Good Laboratory Practice as adopted by the Council of the Organisation for Economic Co-operation and Development on 02.10.1989 (C(89)87/Final), respectively.

4.3.2 In accordance with Article 5.1.2 of the Agreement on Technical Barriers to Trade, any procedure to assess the conformity of a chemical shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that such chemicals conform with the applicable technical regulations or standards.

4.3.3 Members shall neither require any re-certification, nor any re-declaration for chemical substances which have not changed from the moment of their first certification or declaration.

4.3.4 In accordance with Article 5.1.2 of the Agreement on Technical Barriers to Trade, any sampling required by a Member to establish a positive assurance of conformity shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that the chemicals conform with the certificates or declarations provided by the manufacturer or supplier. The sampling methods shall be proportionate to the risks non-conformity would create.

5. MUTUAL ACCEPTANCE OF DATA

5.1 Any Member shall give positive consideration to accept registrations of data that originate from any other Member when:

- (a) it has an equivalent level of requirements; and
- (b) it fulfils the same legitimate objectives; and
- (c) it uses the internationally agreed data reporting format.

With this purpose, Members shall also participate in international initiatives aimed at harmonizing registration of data requirements.

5.2 Whenever possible, Members shall strive to adhere to the plurilateral system of mutual acceptance of data in the assessment of chemicals as established by the Council of the Organisation

³ As defined in "Guidance on definitions of key terms for new chemical notification", OECD ENV/JM/MONO(2007)13 of 20.06.2007.

⁴ As defined in "Guidance on definitions of key terms for new chemical notification", OECD ENV/JM/MONO(2007)13 of 20.06.2007.

for Economic Co-operation and Development on 12.05.1981 (C(81)30/Final) according to the rules and procedures thereof.

5.3 Members that are not yet members of the Organisation for Economic Co-operation and Development shall endeavour to adhere to the Council acts related to the mutual acceptance of data in the assessment of chemicals according to the procedure established by the Council decision of the Organisation for Economic Co-operation and Development of 26.11.1997 (C(97)114/Final).

5.4 Members that are part of the plurilateral system of mutual acceptance of data in the assessment of chemicals as referred to in paragraph 5.1 shall accept test data generated by an accredited laboratory of another Member in accordance with the Good Laboratory Practice (GLP) principles as soon as that Member has adhered to the system in accordance with its rules and procedures and has issued the assurance of GLP Compliance according to the Council decision on compliance with principles of Good Laboratory Practice as adopted by the Council of the Organisation for Economic Co-operation and Development on 02.10.1989 (C(89)87/Final).

TRANSPARENCY, PROCEDURES FOR JUDICIAL REVIEW, AND CONFIDENTIAL INFORMATION

6. TRANSPARENCY

{Disciplines as resulting from the horizontal discussions on transparency.}

7. GOOD REGULATORY PRACTICE

7.1 Where a Member prepares or proposes to adopt a technical regulation or conformity assessment procedure covering registration of data and a relevant international standard or a relevant guide or recommendation issued by an international standardizing body does not exist, it shall:

- (a) consider, *inter alia*, the commitment to achieve the 2020 goal articulated in paragraph 23 of the Johannesburg Plan of Implementation
- (b) assess the available regulatory and non-regulatory alternatives to the proposed technical regulation or conformity assessment procedure that may fulfill the Member's legitimate objective in accordance with Article 2.2 of the TBT Agreement, and
- (c) consider, *inter alia*, the impact of the proposed technical regulation or conformity assessment procedure on interested parties as well as its impact on international trade; and

7.2 The requirements in paragraph 7.1 do not imply any determination on the way or format this consideration shall take.

7.3 Each Member shall establish or maintain procedures for it to review, at regularly-scheduled intervals, its technical regulations and conformity assessment procedures to determine whether such measures should be modified or eliminated so as to make the Member's regulatory program more effective in achieving the legitimate objective(s) pursued.

8. REGULATORY COOPERATION

8.1 Members agree to discuss in good faith any issues arising from the application of any Member's regulation on chemicals that have a substantial effect on the trade of another Member.

8.2 The authorities of Members responsible for regulating chemicals shall endeavour to enhance their regulatory cooperation on a multilateral level to share experiences, inter alia, in the application of regulatory matters under this Understanding with a view to facilitating trade whilst enhancing regulatory practices. Participating Members shall report on the outcome of their cooperation to the Subcommittee established under Article 12.

9. PROCEDURES FOR JUDICIAL REVIEW

Each Member shall establish or maintain judicial, quasi-judicial, or administrative tribunals and procedures for the purpose of the prompt review and, where warranted, correction of its final administrative actions relating to technical regulations and conformity assessment procedures. Each Member shall ensure that such tribunals are impartial and independent of the office or authority entrusted with administrative enforcement and do not have any substantial interest in the outcome of the matter, and that proceedings before such tribunals are transparent and comply with due process of law.

10. CONFIDENTIAL INFORMATION

Nothing in this Understanding shall be construed to require a Member to furnish or allow access to confidential information or business secrets, the disclosure of which would impede law enforcement or otherwise be contrary to the public interest or which would prejudice the legitimate commercial interests of particular economic operators, public or private.

11. TECHNICAL ASSISTANCE

11.1 As provided for by Article 11 of the TBT Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions with developing and least-developed country Members, technical cooperation in the implementation of the commitments under this Understanding.

11.2 Members shall endeavour to take effective actions in order to promote the exchange of technical expertise, experience and information within the context of the technical regulations, standards and conformity assessment procedures applicable to chemicals covered by this Understanding.

11.3 Developed Member countries shall provide, upon request and under terms and conditions mutually agreed with developing countries and less developed countries, technical cooperation to assist compliance with registration of data requirements and with mutual acceptance of data agreements.

ADMINISTRATION, DISPUTE SETTLEMENT AND FINAL PROVISIONS

12. MONITORING AND OVERSIGHT

12.1 A Subcommittee on Chemicals (Subcommittee) is hereby established as a subcommittee to the TBT Committee to oversee the operation and implementation of this Understanding and further its objectives and to provide a forum for discussions on any matter related to this Understanding.

The Subcommittee shall:

- (1) comprise representatives of each Member, including from its regulatory authorities;
- (2) elect its own Chairman and apply the TBT Committee working procedures;
- (3) meet, at least every [five] years, to review the implementation and operation of this Understanding (a) and share experiences, inter alia, in the application of regulatory matters under this Understanding with a view to facilitating trade whilst enhancing regulatory practices;
- (4) report to the TBT Committee with a view to complementing and not duplicating the work of that Committee and, to this end, communicate to the TBT Committee the results of its review conducted pursuant to subparagraph (3); and
- (5) update Annex 1 in accordance with the provisions in paragraph 4.3.1.

13. DISPUTE SETTLEMENT

Article 14 of the TBT Agreement shall apply *mutatis mutandis* to this Understanding.

[Note: Need to further consider relationship with Dispute Settlement Understanding]

14. FINAL PROVISIONS

[Note: Need to consider final provisions to be included in this Understanding, such as entry into force, withdrawal, amendment, WTO Secretariat to service Understanding, deposit etc.]
