REACH and 'Proportionality' under WTO rules

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This briefing was prepared for WWF by FIELD, a non-governmental organisation bringing together public international lawyers committed to the promotion of environmental protection and sustainable development through law.

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In WWF's view, the European Commission's proposal for new legislation regulating industrial chemicals in the European Union ('REACH') would contribute to better health and environmental protection. WWF is nevertheless calling for amendments to REACH in order to achieve the EU's objective of a *high level* of health and environmental protection.

It could be argued that, in its current form and with WWF's amendments, REACH would be consistent with the rules of the World Trade Organisation (WTO). In particular, it could be argued that REACH is 'no more trade-restrictive than necessary' to fulfil its legitimate objective of a high level of health and environmental protection within the meaning of the WTO's General Agreement on Tariffs and Trade and the Agreement on Technical Barriers to Trade.

What would REACH require?

One of REACH's paramount objectives is to ensure a high level of health and environmental protection through the application of the precautionary principle.

If adopted, REACH would require the registration of industrial chemicals produced or imported into the EU in volumes over one tonne each year, including certain chemicals contained in articles (such as finished products). The registration requirement would generate data on the hazardous properties of industrial chemicals, and the means by which people and the environment are exposed to them, in order to assess and manage the risks that chemicals pose to health and the environment. REACH would also require specific authorisation to use chemicals of 'very high concern'.

The production or import into the EU of unregistered chemicals and the unauthorised use of chemicals of 'very high concern' after a specified date would be prohibited.

What are WWF's proposed amendments to REACH?

WWF is calling for REACH to be amended in at least four respects:

1. WWF wants to see a registration system that requires more information on environmental hazards, and chemical safety reports, for chemicals produced in quantities between one to ten tonnes.

2. WWF is also calling for a registration system that applies to all chemicals contained in articles in quantities over one tonne each year, where: (1) total volume of a given chemical contained in all articles of a producer or importer is calculated on a cumulative basis; and (2) registration is required regardless of whether the chemicals are (a) known to be dangerous, or (b) intended or likely to be released.

3. WWF wants to see all chemicals with intrinsically hazardous characteristics of very high concern – such as those with endocrine disrupting properties or otherwise similar to chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR), persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) – subject to REACH's authorisation requirements.

4. WWF believes that authorisation of registered chemicals that have intrinsically hazardous properties of very high concern should be limited to circumstances in which: (1) safer alternatives are not available; (2) it is shown that the economic benefits to society outweigh the risk to human health or the environment; and (3) measures to minimise exposure are put in place.

Which WTO Agreements would apply to REACH?

The WTO Agreements most likely to apply to REACH are the General Agreement on Tariffs and Trade 1994 (GATT) and the more specific Agreement on Technical Barriers to Trade (TBT Agreement). The GATT applies to several types of measures relevant to international trade in products, while the TBT Agreement applies only to 'technical regulations', 'voluntary standards' and 'conformity assessment procedures' relevant to products. REACH contains provisions likely to fall within the definition of 'technical regulation' and 'conformity assessment procedures'.

Technical regulations can identify products by reference to their characteristics, such as containing a chemical, and do not need to specify a particular product (WTO *Asbestos* case). Accordingly, even with WWF's amendment to the calculation of volume of chemicals in articles on a cumulative basis, REACH is likely to come within the meaning of a 'technical regulation' under the TBT Agreement.

Can REACH aim for a high level of health and environmental protection?

Under WTO rules, the EU is entitled to have chosen a high level of protection for its people and the environment from harm caused by industrial chemicals. The EU's chosen level of protection cannot be challenged under the TBT Agreement or the GATT (WTO *Gasoline*, *Hormones*, *Salmon* and *Asbestos* cases).

Accordingly, REACH may aim for a high level of protection of people and the environment from exposure to chemicals of 'very high concern'. 'Controlled use' or 'adequate control' of chemicals of very high concern where safer alternatives exist would not, in WWF's view, achieve a high level of protection.

Is REACH 'proportionate' to its aims for the purposes of WTO rules?

Many WTO Members support REACH's objective of protecting health and the environment, however, some consider that REACH would violate WTO rules because it is not 'proportionate' to its aims. In particular, some WTO Members have criticised REACH as being 'more trade-restrictive than necessary' to fulfil its objective of a high level of health and environmental protection (TBT Article 2.2 and GATT Article XX).

Under the TBT Agreement and the GATT, whether REACH's requirements are 'more trade-restrictive than necessary' to achieve their objective is likely to depend on whether there is an alternative measure reasonably available to the EU which would be less restrictive of trade but which would still achieve the objective of a high level of health and environmental protection (WTO *Korea-Beef* and *Asbestos* cases).

In WWF's view, requirements that might be less restrictive of trade – such as registration requirements limited to high-volume chemicals or a narrower category of chemicals (e.g. those chemicals known to be dangerous, or intended or likely to be released) – would not achieve REACH's objective of a high level of health and environmental protection.

Can WTO Members take a precautionary approach to the regulation of risk?

Some WTO Members have described REACH as taking a 'hazard-based', rather than a 'risk management', approach to chemicals regulation. A 'hazard-based' approach, they argue, violates WTO rules. However, there is no express distinction between 'hazard-based' and 'risk management' regulatory approaches under WTO rules. Neither term is used in the TBT Agreement or the GATT.

'Risk' is nevertheless relevant to an assessment of proportionality under TBT Article 2.2 and GATT Article XX. An assessment of whether a measure is 'more trade-restrictive than necessary' to fulfil a legitimate objective under Article 2.2 of the TBT Agreement must take account of 'the risks non-fulfilment of the legitimate objective would create'. Adjudicators of past WTO and GATT disputes have considered 'risk' of harm relevant to their assessment of the least trade-restrictive measure under GATT Article XX.

Whether there is in fact a risk of harm might be the subject of debate among scientific experts. However, a WTO Member may rely on minority scientific opinion and still justify a measure as being 'necessary' to fulfil its objective under the WTO rules. In assessing whether an alternative measure would fulfil REACH's objective, the WTO's Appellate Body has acknowledged that it is appropriate to bear in mind 'that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.' (WTO *Hormones* case). Based on past disputes in the WTO, it is reasonable to conclude that it is 'the actual potential for adverse effects on human health in the real world where people live and work and die' that should be taken into account in assessing the risk addressed by REACH (WTO *Hormones* case).

Is REACH pursuing a common interest or value?

In past WTO disputes, it has been found that the more 'vital and important' the 'common interests or values' represented by a measure's objective, the easier it will be to accept the measure as 'necessary'. Some WTO Members have noted that they share REACH's objective of ensuring a high level of health and environmental protection from the harm caused by industrial chemicals. As such, REACH is pursuing a vital and important objective which is a common interest and value of all WTO Members.

1. Background

On 29 October 2003, the European Commission issued its proposal for new legislation regulating chemicals in the European Union (known as 'REACH').[1] Underpinned by the precautionary principle, the proposed regulation requires chemicals to undergo a process of registration in the European Union which is to be administered by a newly created European Chemicals Agency. REACH will amend elements of the existing European Union laws regulating industrial chemicals.[2]

The REACH proposal is the result of a review of the existing EU laws and procedures governing chemicals which was initiated in 1998.[3] A milestone in the review process included the Commission's 2001 White Paper on a Strategy for a future Chemicals Policy.[4] The White Paper identified several objectives necessary to achieve sustainable development in the chemicals industry within the EU which are reflected in REACH, including: the protection of human health and the environment; and conformity with EU international obligations under the World Trade Organisation (WTO).[5]

In May 2003, the European Commission launched an eight-week public consultation process inviting comments on a draft REACH proposal.[6] The EU informed WTO Members of the public consultation through the WTO's Committee on Technical Barriers to Trade (TBT Committee),[7] where REACH has been the subject of ongoing discussion among WTO Members.[8] The REACH proposal was subsequently notified by the EU to the TBT

[1] Proposal for a *Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}* and Proposal for a *Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals* (COM(2003) 644 final), 29 October 2003 ('REACH').
[2] REACH amends Council Directive 67/548/EEC of 27 June 1967 (as amended) on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L196, 16 August 1967 ('Dangerous Substances Directive'). Other EC laws regulating industrial chemicals include: Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations OJ L187, 16 July 1988, replaced by Directive 1999/45/EC of 31 May 1999, OJ L200, 30 July 1999 ('Dangerous Preparations Directive'); Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations OJ L262, 27 September 1976 ('Marketing and Use Directive'); Council Regulation 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L84, 4 April 1993 ('Existing Substances Regulation').
[3] Council of Environment Ministers, informal meeting in Chester in April 1998.
[4] White Paper on a Strategy for a future Chemicals Policy, (COM (2001) 88 final) http://europa.eu.int/eur-lex/en/com/wpr/2001/com2001_0088en01.pdf ('White Paper').
[5] *Ibid*, p. 7. Other objectives are: maintenance and enhancement of the competitiveness of the EU chemical industry; prevent fragmentation of the internal market; increased transparency; integration with international efforts; promotion of non-animal testing.
[6] Consultation draft of REACH, http://europa.eu.int/comm/enterprise/chemicals/chempol/reach/volume1.pdf
[7] WTO Committee on Technical Barriers to Trade, 'Registration, Evaluation, Authorisation of Chemicals under Article 2.9.1 of the Agreement' Communication of the European Communities G/TBT/W/208, 22 May 2003.
[8] WTO Committee on Technical Barriers to Trade, 'Minutes of the Meeting Held on 2 July 2003' G/TBT/M/30, 19 August 2003, paras 49-62 ('TBT July Minutes'); 'Minutes of the Meeting Held on 7 November 2003' G/TBT/M/31, 9 December 2003, paras 23-33 ('TBT November Minutes'); WTO Committee on Technical

Committee, inviting comments on the REACH proposal from WTO Members by 21 June 2004.[9]

Under WTO rules, WTO Members may take measures to protect human health and the environment and they are entitled to determine the level of protection.[10] Although they support REACH's objective of protecting human health and the environment, some WTO Members and chemical industry representatives claim that REACH would nonetheless violate provisions of the WTO Agreements that require REACH to be proportionate to its aims.[11] In particular, they argue that REACH is more trade-restrictive than necessary to achieve its objective under the General Agreement on Tariffs and Trade 1994 (GATT) and the more specific Agreement on Technical Barriers to Trade (TBT Agreement).[12]

In contrast, the European Commission maintains that REACH is consistent with the international trade rules of the WTO.[13] This paper sets out the basis upon which it could be argued that REACH – even if amended in accordance with proposals put forward by WWF to better protect human health and the environment – would be consistent with WTO rules requiring regulatory measures to be no more trade-restrictive than necessary to ensure a high level of health and environmental protection.

Barriers to Trade, 'Minutes of the Meeting Held on 23 March 2004', G/TBT/M/32, paras 29ff ('TBT March Minutes').

[9] Notification to WTO Committee on Technical Barriers to Trade G/TBT/N/EEC/52, 21 January 2004.

[10] *See* e.g. *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Panel Report and Appellate Body Report, adopted on 5 April 2001, WT/DS135/AB/R ('*Asbestos*'), para 168. *See* also *United States – Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body adopted 20 May 1996, WT/DS2/AB/R ('*Gasoline*') p 15, *Australia - Measures Affecting the Importation of Salmon* WT/DS18/AB/R, Panel Report and Appellate Body Report adopted on 6 November 1998 ('*Salmon*') para 199. *See* also SPS Article 2.1 referring to the 'right' of WTO Members to take SPS measures, and discussion in *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998 ('*Hormones*') para 172.

[11] *See* e.g. comments on the draft REACH proposal in the TBT Minutes G/TBT/M/30 and select contributions to the public consultation at http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/contributions.htm. *See* also comments made in TBT meetings after REACH was issued: TBT November and March Minutes.

[12] *See* representative of Japan, TBT November Minutes, para 23 and TBT March Minutes para 31. *See also* TBT July Minutes para 53, and representative of Mexico TBT July Minutes para 52, and representative of Chile TBT March Minutes para 39.

[13] Explanatory note to REACH, http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/03/213|0|RAPID&lg=EN&display=; *see* also REACH recitals. One recital to the proposed regulation states that it 'should be applied in a non-discriminatory manner whether chemical substances are traded on the internal market or internationally' (Recital 3). A further recital states that REACH 'does not go beyond what is necessary in order to achieve the objectives pursued' (Recital 103).

2. Chemicals and REACH

2.1 Chemical hazards, exposure and risk of harm

Industrial chemicals can have novel molecular compositions and structures that can make them hazardous to people and the environment. Some can accumulate in living organisms, causing damage to nervous systems, reproductive capacity and hormone systems. Some can also have significant adverse impacts on the natural environment.[14]

Many industrial chemicals once thought to be safe are now known to cause serious harm to human health and the environment.[15] For example, polychlorinated biphenyls (PCBs) were once considered harmless and inert, and were extensively used in electrical products. However, we now know that they have contaminated people and wildlife across the world, and affect intellectual development in children.[16]

The intrinsic hazard of a given chemical is a function of its molecular structure. When exposed to people and the environment in a given quantity, hazardous chemicals might cause harm. In contrast to naturally-occurring chemicals, large-scale production and use of industrial chemicals means that people and the environment can be exposed to vast quantities of industrial chemicals through direct and diffuse pathways.

Workers involved in manufacturing chemicals, or products containing chemicals, can be exposed to chemicals in large volumes. Consumers of commercial products containing chemicals – such as toys or clothing – can also be exposed to a wide range of chemicals over time. Some products emit chemicals into the environment during use – such as tyres – while some chemicals and products containing chemicals are released into the environment through their disposal in, for example, landfill.[17]

Despite our knowledge about the risks associated with some industrial chemicals, relatively little is known about the hazardous properties of many widely-used industrial chemicals, and how they interact with the natural environment.[18] We know even less about the risks posed by exposure to multiple chemicals. Given the absence of knowledge, REACH aims to generate data on the hazardous properties of industrial chemicals, and the means by which people and the environment are exposed to them. Armed with this information, the EU considers that it will be possible to better assess and manage the risks that chemicals pose to people and the environment.[19]

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[14] *See* Extended Impact Assessment of the economic, social, and environmental impacts of the New Chemicals Policy proposals; http://europa.eu.int/comm/enterprise/chemicals/chempol/bia/eia.pdf, section 6. *See* also: Royal Commission on Environmental Pollution, The Twenty-fourth Report, *Chemicals in Products - Safeguarding the Environment and Human Health, June 2003*, http://www.rcep.org.uk/chreport.htm (RCEP Report), Chapter 2; International Programme on Chemical Safety, Re-designing IPCS: Current Situation June 2003, http://www.who.int/pcs/docs/Current%20Situation%20Rev%205%20June.pdf

[15] *See* European Environment Agency, *Late lessons from early warnings: the precautionary principle 1896-2000*. *See* also RCEP Report.

[16] European Environment Agency, *Late lessons from early warnings: the precautionary principle 1896-2000.*

[17] EEA and UNEP, Chemicals in the European Environment: Low Doses, High Stakes?

[18] RCEP Report, Chapter 1. *See* also EEA and UNEP, *Chemicals in the European Environment: Low Doses, High Stakes?*

[19] Risk assessment has been described as 'the process of identifying and quantifying hazards and exposure', RCEP Report para 2.6.

2.2 REACH requirements

Among a number of objectives, REACH aims to ensure a high level of health and environmental protection through the application of the precautionary principle.[20] The proposed regulation explains that it is up to manufacturers, importers and downstream users of industrial chemicals 'to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment.'[21]

To this end, REACH sets out a range of procedures and requirements for the registration, notification, evaluation, authorisation and restriction of industrial chemicals manufactured or sold in the EU. In particular, REACH provides that:

- The manufacture or import of **unregistered** chemicals in quantities over one tonne each year is prohibited.[22]
- **Registration** requirements apply to the manufacture or import of chemicals in quantities over one tonne each year, whether they are manufactured or imported on their **own or in preparations**.[23]
- **Registration** requirements also apply to 'dangerous chemicals'[24] in quantities over one tonne contained in, and intended to be released from, **articles** (such as finished products) produced or imported in the EU.[25]
- Dangerous chemicals contained in articles which are likely to be released in quantities that may adversely affect human health or the environment must be **notified** to the newly created European Chemicals Agency, which may then require that they be registered.[26]
- Different information requirements apply for registration **depending on the volume** of chemicals produced each year, commencing with one tonne and increasing to 10, 100 and 1000 tonnes each year.[27]
- Manufacturers or importers submitting chemicals produced in quantities over ten tonnes each year for registration must **assess** the safety of their use in terms of human health and environmental hazards, and document the assessment in a chemical safety report.[28]

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[20] REACH recitals, such as recital (3), (4), (52), (61) and (104), together with Article 1, which refers to the Communication from the Commission on the precautionary principle, COM(2000) 1 final, 2 February 2000. Rio Principle 15 provides: 'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.' RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972.

[21] REACH Article 1. Chemicals are referred to in REACH as 'substances'. A 'substance' means 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.

[22] REACH Article 19.

[23] REACH Article 5.

[24] 'Dangerous chemicals' are those substances assessed and classified as 'dangerous' under the Dangerous Substances Directive.

[25] REACH Article 6. 'Articles' are defined to mean 'an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does'.

[26] REACH Article 6.

[27] REACH Article 11.

[28] REACH Article 9, together with Article 13. It is not clear whether chemicals in 'articles' are covered by this requirement, as Article 13 makes express mention only of chemicals on their own, in a preparation or a group of chemicals.

- Registration documentation, and chemicals submitted for registration that are suspected of presenting a health or environment risk, may be **evaluated** by Member States.[29]
- Chemicals of '**very high concern**' – such as those that cause cancer or accumulate in living bodies or equivalent chemicals 'identified as causing serious and irreversible effects to humans or the environment' – may be included by the Commission and the Member States in an annex to REACH (Annex XIII).[30]
- The decision to include chemicals of very high concern in Annex XIII shall specify a date after which those chemicals cannot be sold in the EU ('sunset date'),[31] unless they have been **authorised** or exempted from authorisation in accordance with REACH.[32]
- Manufacturers, importers or downstream users applying for authorisation of uses of chemicals of 'very high concern' must **assess** the safety of those uses in terms of risks to human health and the environment.[33]
- Authorisations shall be granted where the risks to human health and the environment of the use are '**adequately controlled**'.[34]
- **Restrictions** (such as sale bans or conditions) may be placed on the manufacture, sale or use of dangerous chemicals.[35]
- EU Member States may impose temporary measures (such as sale bans) on certain chemicals in order to **safeguard** human health or the environment.[36]

REACH also contains provisions concerning the sharing of data, animal-testing, information in the supply chain, downstream users, access to information and sanctions for non-compliance. Certain categories of chemicals are excluded from REACH as a whole,[37] and from particular REACH requirements.[38] The REACH requirements will be phased-in over time, commencing with chemicals of highest production volume and those of highest concern.[39]

2.3 WWF proposed amendments to the scope of REACH in order to fulfil its objective

In WWF's view, REACH would contribute to better health and environmental protection. However, WWF considers that REACH's registration and authorisation provisions fall short

[29] REACH Title VI.
[30] REACH Articles 54 and 56. Substances eligible for inclusion in Annex XIII are: specific categories of chemicals classified as (a) carcinogenic, (b) mutagenic or (c) toxic for reproduction under the Dangerous Substances Directive; chemicals that are (d) persistent, bioaccumulative and toxic, or (e) very persistent and very bioaccumulative, in accordance with Annex XII of REACH; and (f) chemicals, such as those having endocrine disprupting properties or PBTs, or vPvBs, which are 'identified as causing serious and irreversible effects to humans or the environment which are equivalent to those' chemicals listed in (a) to (e), assessed in accordance with Article 56.
[31] REACH Article 55.
[32] REACH Article 53.
[33] REACH Article 59.
[34] REACH Article 57.
[35] REACH Article 64.
[36] REACH Article 126.
[37] For example, non-isolated intermediates are excluded (Article 2). 'Intermediates' are defined to mean ' a substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.' There are three subcategories: (a) non-isolated intermediate; (b) on-site isolated intermediate (c) transported isolated intermediate.
[38] For example, medicines, food and feed additives (REACH Article 4) and polymers (REACH Article 14) are excluded from the registration requirements.
[39] *See* e.g. REACH Article 21.

of the stated objective of a *high level* of health and environmental protection for (1) chemicals between one to ten tonnes, (2) chemicals contained in articles, and (3) chemicals of 'very high concern'. WWF is calling for more robust registration and authorisation requirements to fulfil REACH's objective of ensuring a high level of health and environmental protection. In particular, WWF has proposed:[40]

1. **Amending the registration provisions to require more information on environmental hazards, and to require chemical safety reports, for chemicals produced in quantities between one to ten tonnes.**

The registration requirements currently contemplated in REACH for chemicals between one to ten tonnes require only limited information on environmental hazards, and contain no requirement to submit a chemical safety report.[41] WWF's demand for more information on environmental hazards would require additional ecotoxicological information, such as information on biodegradation. A requirement for a chemical safety report would be the same as the report required for chemicals in quantities over ten tonnes, documenting the safety assessment of the uses of chemicals in terms of human health and environmental hazards.[42]

Even in small amounts, hazardous chemicals are capable of causing serious harm to people and the environment. WWF maintains that, without basic information about the range of toxic effects on the environment of all chemicals produced in quantities between one to ten tonnes each year, it will be impossible to understand how widely-used chemicals interact with the environment. Moreover, they say that chemical safety reports are necessary to ensure timely and comprehensive assessments of the risks posed by those chemicals to human health and the environment. As it stands, REACH would not generate the data needed to fulfil classification and labelling requirements, without which users of a chemical cannot properly manage its risks.[43]

2. **Amending the registration provisions to apply them to all chemicals contained in articles in quantities over one tonne each year, where: (1) total volume of a given chemical contained in all articles of a producer or importer is calculated on a cumulative basis; and (2) registration is required regardless of whether the chemicals are (a) known to be dangerous, or (b) intended or likely to be released.**

The registration requirements currently contemplated in REACH for chemicals in articles are limited to chemicals that are known to be dangerous, or which are intended or likely to be released.[44] WWF believes that registration requirements for chemicals in articles should not be limited as to their hazard and exposure.[45] As is the case for chemicals on their own or in preparations, WWF maintains that *all* chemicals in articles should be subject to registration requirements where they exceed one tonne.

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[40] For more information about these and other amendments proposed by WWF, *see* 'WWF Response to the Science and Technology Committee Inquiry into EU chemicals legislation' December 2003.
[41] REACH Article 9, together with Article 13.
[42] REACH Article 13.
[43] Hannsson, S.O. and C. Rudén, *What REACH does and does not*, in *Better Chemicals Control Within REACH*, (S.O. Hannsson and C. Rudén, Editors, 2004), NewS project: Stockholm, Sweden: "Our comparison of the data requirements in REACH to the classification and labelling criteria shows that for substances produced in less than 10 tonnes, there will not be enough information to apply any of the classification or authorisation criteria under consideration here (i.e. acute mammalian toxicity, acute aquatic toxicity, skin irritation, eye irritation, skin sensitisation, carcinogenicity, mutagenicity, reproductive toxicity, PBT or vPvB)".
[44] REACH Article 6.
[45] REACH Article 6(1)(b) and (c).

The reasons for requiring registration of chemicals on their own or in preparations apply equally to chemicals contained in articles. Basic information on the health and environmental hazards of all chemicals is needed, and the safety risks associated with their use needs to be assessed. Unregistered chemicals not yet known to be dangerous might be contained in articles, and unintentionally exposed to people or otherwise released into the environment.

3. **Amending the authorisation provisions so that they apply to all chemicals with intrinsically hazardous characteristics of very high concern – such as those with endocrine disrupting properties or otherwise similar to CMR, PBT and vPvB chemicals.**

REACH authorisation requirements for chemicals of 'very high concern' are limited to: (1) chemicals expressly listed (i.e. chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR), persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB)) that fulfil specified criteria; and (2) chemicals, such as those having endocrine disrupting properties or which are PBT or vPvB chemicals that do not fulfil the specified criteria, which are identified as causing 'serious and irreversible effects to humans or the environment'.

WWF believes that chemicals of very high concern, such as those with endocrine disrupting properties that impact on hormone systems or those which accumulate in living organisms, are, by their very nature, undesirable. It is not appropriate to undertake the extensive and prolonged tests that would be necessary to show that they cause 'serious and irreversible effects to humans or the environment' when their inherent qualities indicate a threat to human health and the environment.

4. **Amending the authorisation provisions so that the use of registered chemicals that have intrinsically hazardous properties of very high concern may be authorised only where: (1) safer alternatives are not available; (2) it is shown that the economic benefits to society outweigh the risk to human health or the environment; and (3) measures to minimise exposure are put in place.**

Under REACH, a manufacturer, importer or downstream user shall be authorised to use a chemical of very high concern if its use is 'adequately controlled'.[46] If use of a chemical of very high concern cannot be adequately controlled, authorisation may be granted if (1) it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the chemical and (2) there are no suitable alternative chemicals or technologies.[47]

In WWF's view, the only way to control the risks arising from the intrinsically hazardous properties of chemicals of 'very high concern' is to eliminate exposure where possible by stopping the use of such chemicals and using safer alternatives when available. Measures to minimise exposure should be considered 'adequate' only if safer alternatives are not available and the economic benefits outweigh the health and environmental risks.

[46] REACH Article 57(2), together with Annex I, section 6.
[47] REACH Article 57(3).

3. The World Trade Organisation and its Agreements

Industrial chemical production worldwide is worth in excess of US$1.7 trillion annually, of which 30% is traded internationally. Most industrial chemical production and demand is concentrated in developed countries, although it is on the rise in developing countries, with global production expected to increase by 63% over the next decade.[48] Set out below is a brief description of the institutional arrangements and agreements governing the international trade in products, which would include chemicals and articles (such as finished products) containing chemicals regulated by REACH.

3.1 The WTO

Since 1995, the World Trade Organisation (WTO) has provided the institutional framework for international trade relations governed by the WTO Agreements – a package of international treaties aimed at promoting global trade liberalisation. The WTO's Membership is made up of 146 industrialised and developing countries and – as it is known for WTO purposes – the European Communities. Between Ministerial Conferences convened every two years, WTO Members regularly meet in Geneva in councils, committees and working groups dedicated to specific WTO Agreements or issues. Members are assisted by a Secretariat, headed by a Director-General.

WTO Members who feel that their trade benefits under the WTO Agreements have been undermined by another Member may complain to the WTO's Dispute Settlement Body. The Dispute Settlement Body – comprising all WTO Members – resolves disputes with the assistance of *ad hoc* panels of experts and, on appeal, Members of a permanent group of seven international trade lawyers known as the Appellate Body.

3.2 WTO Agreements

REACH could be covered by provisions in at least two of the WTO Agreements: the General Agreement on Tariffs and Trade 1994 (GATT) and the Agreement on Technical Barriers to Trade (TBT Agreement). It would be possible for REACH to be challenged under both the GATT and the TBT Agreements, although it would probably be assessed first for compliance with the more specialised Agreement, the TBT Agreement.[49]

Interpretation of WTO Agreements

WTO dispute settlement panels and the Appellate Body assess the WTO consistency of measures on a case-by-case basis, interpreting words in the WTO Agreements in terms of their ordinary meaning read in their context and in the light of a given Agreement's object and purpose.[50] While several WTO disputes have generated interpretations of provisions in the

[48] RCEP Report, para 1.10.

[49] *See European Communities – Trade Description of Sardines* WT/DS231/R Panel Report adopted 23 October 2002 ('*Sardines Panel*)'; *Asbestos*; *EC Measures Concerning Meat and Meat Products* Complaint by the US, Report of the Panel WT/DS26/R/USA *('Hormones Panel')*; *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, Report of the Appellate Body adopted 25 September 1997, WT/DS27/AB/R.

[50] 1969 *Vienna Convention on the Law of Treaties*, 11 UNTS 331; 8 ILM 679 (1969) (the "Vienna Convention") is recognised as describing customary rules of interpretation of public international law for the purposes of Article 3.2 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"). *See Gasoline*, pp 10-11; *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, pp.6-7 ('*Japan – Alcoholic Beverages'*).

GATT – which could be expected to be followed in the future[51] – only a limited number of provisions in the TBT Agreement have been analysed in WTO disputes to date.[52]

Given that the GATT and the TBT Agreement are separate agreements expressing similar rules in different ways, it is difficult to generalise about Members' obligations under both Agreements. A word or phrase in a particular provision of the GATT does not necessarily have the same meaning where it appears elsewhere in the GATT or in the TBT Agreement.[53] It is, however, likely that the provisions in both Agreements would be interpreted 'harmoniously', with a view to avoiding any conflict between them.[54]

Scope of WTO Agreements

The GATT applies to several types of measures affecting international trade in products, while the TBT Agreement applies only to 'technical regulations', 'voluntary standards' and 'conformity assessment procedures' governing products. A 'technical regulation' is defined as being a document that lays down mandatory product characteristics or their related processes and production methods including the applicable administrative provisions.[55] The TBT Agreement defines 'conformity assessment procedures' as procedures used to determine that relevant requirements in technical regulations are fulfilled.

REACH is likely to fall within the meaning of a 'technical regulation'.[56] In a past WTO dispute (the *Asbestos* case), the Appellate Body described a French ban on the sale of white asbestos and white asbestos-containing products, and its accompanying administrative procedures governing exemptions, as a 'technical regulation'. To the extent that the French law required products to be 'asbestos-free', and set out the basis upon which asbestos-containing products could be exempted from that requirement, it was found to lay down product characteristics for an identifiable group of products.[57]

The Appellate Body in the *Asbestos* case confirmed that for a measure to be a 'technical regulation', it must be applicable to an identifiable product, or group of products. Technical regulations need not 'apply to "*given*" products which are actually *named*, *identified* or *specified* in the regulation.'[58] The Appellate Body concluded that 'there may be perfectly sound administrative reasons for formulating a "technical regulation" in a way that does *not*

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[51] Although adopted panel reports, for example, are binding only on the parties to the dispute, the Appellate Body has acknowledged that they 'are an important part of the GATT *acquis*. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute.' *Japan – Alcoholic Beverages*, p 14.

[52] In *Asbestos*, the Appellate Body considered the meaning of technical regulation, but did not complete the analysis, *see* para 83. *European Communities – Trade Description of Sardines* Report of the Panel and Report of the Appellate Body adopted 23 October 2002, WT/DS231/AB/R ('*Sardines*'), did not analyse Article 2.2 because it decided against the EC on the basis of other TBT provisions.

[53] *See Asbestos* para 89, where it said that what constitutes a 'like product' for the purposes of one provision in the GATT is not necessarily the same as for another provision in the GATT or other WTO Agreements.

[54] *See Korea - Definitive Safeguard Measure on Imports of Certain Dairy Products*, Appellate Body Report para 81, WT/DS98/AB/R, adopted on 12 January 2000; *Gasoline* p. 23 on 'principle of effective treaty interpretation'. *See* also *Indonesia – Certain Measures Affecting the Automobile Industry*, Report of the Panel adopted 23 July 1998, WT/DS54/R; WT/DS55/R; WT/DS59/R; WT/DS64/R para 14.28 and *Turkey - Restrictions on Imports of Textile and Clothing Products*, Panel Report paras 9.92 ff, WT/DS34/R, Panel Report and Appellate Body Report adopted on 19 November 1999 re 'presumption against conflict'.

[55] Annex 1, TBT Agreement.

[56] REACH Article 6.

[57] *Asbestos* paras 71-75.

[58] *Asbestos* para 70.

expressly identify products by name, but simply makes them identifiable – for instance, through the "characteristic" that is the subject of regulation.'[59]

Accordingly, even with WWF's proposed amendment to REACH's calculation of volume of chemicals in articles on a cumulative basis, REACH's registration requirements would be a 'technical regulation'.[60] WWF's amendment would identify products by reference to the fact that they contain a chemical – a characteristic which is a sufficient basis upon which to identify the group of products covered by REACH's registration requirements.

Finally, the process of evaluating technical dossiers submitted with registration applications[61] is likely to be an example of a conformity assessment procedure within the meaning of the TBT Agreement. Consistent with the definition of 'conformity assessment procedure', evaluation of dossiers determines whether the REACH requirements for registration have been fulfilled.

[59] *Ibid.*
[60] *See* WWF Amendment 2.
[61] REACH Title VI, Chapter 2.

4. Proportionality of REACH

Some WTO Members claim that REACH would violate WTO rules because it is not 'proportionate' to its aims. In particular, they consider REACH to be more trade-restrictive than necessary to achieve its objective.[62]

Under the TBT Agreement, a 'technical regulation' must not be more trade-restrictive than necessary to fulfil a legitimate objective – such as the protection of human health or safety, animal or plant life or health, or the environment – taking account of the risks that non-fulfilment of that objective would create (TBT Article 2.2). Similar WTO requirements of 'necessity' – generally referred to as 'proportionality' requirements[63] – apply to conformity assessment procedures (TBT Article 5.1.2) and trade measures applying to products in general (GATT Article XX(b)).[64]

Whether REACH is 'proportionate' to its aims – namely, whether it is more trade-restrictive than necessary to achieve a high level of health and environmental protection – is likely to depend on whether there are alternative measures reasonably available to the EU which are less restrictive of trade but which still achieve REACH's objectives.[65] Each step in a WTO assessment of the proportionality of REACH's registration and authorisation requirements, with WWF's amendments, is set out below.

4.1 REACH's objective

In assessing the proportionality of REACH's registration requirements, a WTO adjudicator would first consider whether a measure's objective brings it within the category of measures covered by the relevant WTO rules.

The multiple objectives of EU chemicals' regulation set out in the European Commission' 2001 White Paper are reflected in REACH's recitals and Article 1.[66] One of REACH's objectives is to ensure a high level of health and environmental protection through the application of the precautionary principle.[67]

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[62] *See* representative for Japan, TBT March Minutes, para 31 and TBT November Minutes, para 23, Japan TBT July Minutes para 53. TBT November Minutes, para 23 states: 'His [Japan's] delegation had fully understood that the proposed regulation had, as legitimate objectives, the protection of human health and the environment. However, Japan had concerns as it would be more trade restrictive than necessary and would have a negative impact on trade and investment of non-European WTO Members.' *See also* representatives of Chile TBT March Minutes para 39 and of Mexico TBT July Minutes para 52. On the draft REACH proposal, *see* UK response to the Internet consultation, para 64, http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/contributions.htm.

[63] Note that 'proportionality' is used here in a generic sense to refer to the range of WTO provisions that call for an assessment of the relationship between trade measures and their objectives. For an analysis of 'proportionality' in the WTO, and a comparison with proportionality in EU law, *see*: Axel Desmedt, 'Proportionality in WTO law', *J.I.E.L.* 2001, 4(3), 441-480; Jan Neumann and Elisabeth Turk, 'Necessity revisited: proportionality in World Trade Organisation law after *Korea - Beef*, *EC - Asbestos* and *EC – Sardines*', *J.W.T.* 2003, 37(1), 199-233.

[64] E.g. GATT Article XX; TBT Article 2.2. *See* further: World Trade Organisation, Committee on Trade and Environment, "GATT/WTO Dispute Settlement Practice Relating to GATT Article XX, Paragraphs (b), (d) and (g)", *Note By The Secretariat*, WT/CTE/W/203, 8 March 2002.

[65] *Asbestos*, para 171, citing *Korea Beef* para 166, adopting standard in *United States – Section 337 of the Tariff Act of 1930*, Report of the Panel adopted 7 November 1989, BISD36S/345 ('*US – Section 337*').

[66] *See* above, section 2.2.

[67] REACH recitals, such as recital (3), (4), (52), (61) and (104), together with Article 1, which refers to the Communication from the Commission on the precautionary principle, COM(2000) 1 final, 2 February 2000.

The objective of a high level of health and environmental protection is likely to place REACH's registration and authorisation requirements among the following category of measures:

- the protection of human health or safety, animal or plant life or health, or the environment, under Article 2.2 of the TBT Agreement;
- the protection of human, animal or plant life or health, under GATT Article XX(b);
- the conservation of exhaustible natural resources, under GATT Article XX(g).

4.2 Assessing the relationship between a measure and its objective

Having confirmed that a measure's objective brings it within the category of measures covered by the relevant WTO rules on proportionality, a WTO adjudicator would then examine the *relationship* between the measure and its objective.[68]

The relationship between a measure and its objective is expressed in different ways in the GATT and the TBT Agreement. Under Article 2.2 of the TBT Agreement, technical regulations must not create *unnecessary* obstacles to international trade.[69] An unnecessary obstacle is a technical regulation which is 'more trade-restrictive than necessary' to fulfil a legitimate objective. In the absence of any guidance on how TBT Article 2.2 should be interpreted,[70] it is reasonable to assume that it would be read in a manner consistent with the term 'necessary' under GATT Article XX.[71]

Under the paragraphs of GATT Article XX most likely to be relevant to REACH, Members may adopt measures *necessary* to protect human, animal or plant life or health (paragraph (b)), or *relating to* the conservation of exhaustible natural resources (paragraph (g)).

In the context of GATT Article XX, 'necessary' has been interpreted by the WTO Appellate Body to mean a measure 'which entails the least degree of inconsistency with other GATT provisions'[72] or which is the 'least trade-restrictive' measure reasonably available to the WTO Member to achieve its objective.[73] A 'necessary' measure should be distinguished from one 'relating to' an objective. The phrase 'relating to' requires a 'substantial' or 'close and genuine' relationship between the measure and its objective.[74] In past disputes, measures 'relating to' an objective have been characterised as those 'primarily aimed at' the conservation of exhaustible natural resources.[75] In other words, the end should justify the means.[76]

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[68] *Gasoline* and *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Panel Report and Appellate Body Report, adopted on 6 November 1998, WT/DS58/AB/R (*US – Shrimp I*); *see* also *Sardines* para 286, referring to Panel at para 7.171.

[69] TBT Article 2.2. Equivalent provisions apply to technical standards (Annex 3, para E) and conformity assessment procedures (Article 5.1.2).

[70] *Sardines Panel* considered it in passing, but not decided under Article 2.2. *See Sardines* para 313.

[71] *See* above, section 3.2

[72] *Asbestos*, para 171, citing *US – Section 337* and *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, Report of the Appellate Body adopted on 10 January 2001, WT/DS161/AB/R; WT/DS169/AB/R, ('*Korea Beef*').

[73] *Malt Beverages*, Report of the Panel adopted 19 June 1992, BISD 93S/206, ('*Malt Beverages*') para 5.52 and *Korea Beef* para 163.

[74] *Gasoline* p 19, cited in *US – Shrimp I*, para 135 ff.

[75] *Gasoline*, p. 12; although this is not a 'litmus' test, p 19.

[76] *US – Shrimp I*, para 135 ff.

Under GATT Article XX, it is easier to show that a measure 'relates to' an objective than to show that it is 'necessary' to achieve its objective.[77] However, the TBT Agreement would require an assessment of what is 'necessary', and its application is likely to be considered before GATT Article XX.[78] Accordingly, it is appropriate to assess REACH in terms of whether it is 'necessary' to fulfil its objective, as opposed to the easier standard of 'relating to' its objective.

4.3 Alternative less trade-restrictive measures

An alternative to REACH's proposed registration requirements (with WWF's amendments) which would be less-restrictive of trade would be to limit the scope of registration requirements to high volume ranges (e.g. greater than 100 tonnes), or to narrower categories of chemicals (e.g. 'dangerous' chemicals within the meaning of the Dangerous Substances Directive, or chemicals on their own as opposed to chemicals contained in articles).

Similarly, an alternative to REACH's proposed authorisation requirements (with WWF's amendments) which would be less-restrictive of trade, would be the authorisation requirements set out in the REACH proposal as it now stands. REACH limits the scope of authorisation requirements to a narrow category of chemicals – those identified as causing serious and irreversible impacts on human health and the environment – even in circumstances where the socio-economic benefits do not outweigh the risk to health or the environment and where safer substitutes are available.

4.4 Achieving a high level of human health and environmental protection through 'adequate control'

The EU is entitled to choose the level of health and environmental protection it wants to achieve through REACH. It is only the method employed to achieve that objective that can be assessed for WTO-consistency.[79]

In WWF's view, limiting registration requirements to a narrow category of chemicals produced in high volumes would not achieve a high level of health and environmental protection. As noted above, even in small amounts, hazardous chemicals are capable of causing serious harm to people and the environment. WWF maintains that, without basic information about the range of toxic effects on the environment of all chemicals produced in quantities between one to ten tonnes each year, it will be impossible to understand how widely-used chemicals interact with the environment.

WWF believes that authorisation requirements that do not require substitution where a safer alternative exists are not alternative measures that would achieve the high level of protection the EU has chosen to pursue. As noted above, WWF maintains that the only way to control the risks arising from the intrinsically hazardous properties of chemicals of 'very high concern' is to eliminate exposure where possible by stopping the use of such chemicals and using safer alternatives when available.

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[77] *Gasoline*.
[78] *See* above, section 3.2.
[79] *Asbestos* para 168: 'it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation.'. *See* also *US – Gasoline* p 15, *Salmon*, para 199. *See* also SPS Article 2.1 referring to the 'right' of WTO Members to take SPS measures, and discussion in *Hormones* para 172.

The *Asbestos* case has reinforced the fact that Members are entitled to determine the level of protection of health that they consider appropriate in a given situation.[80] In that case, France's chosen level of protection was to 'halt' the spread of asbestos-related health risks through a ban on white asbestos, subject to exceptions. However, Canada argued that 'controlled use' of white asbestos was a reasonably available alternative which would be less trade-restrictive than the French ban, while serving the same end.[81] The Appellate Body observed that the efficacy of controlled use had not been demonstrated, justifying a conclusion that controlled use would not allow France to achieve its chosen level of health protection.[82]

In particular, the Appellate Body stated:

> In our view, France could not reasonably be expected to employ any alternative measure if that measure would involve a continuation of the very risk that the [measure] seeks to "halt". Such an alternative measure would, in effect, prevent France from achieving its chosen level of health protection. On the basis of the scientific evidence before it, the Panel found that, in general, the efficacy of "controlled use" remains to be demonstrated. Moreover, even in cases where "controlled use" practices are applied "with greater certainty", the scientific evidence suggests that the level of exposure can, in some circumstances, still be high enough for there to be a "significant residual risk of developing asbestos-related diseases." The Panel found too that the efficacy of "controlled use" is particularly doubtful for the building industry and for [do-it yourself] enthusiasts, which are the most important users of cement-based products containing chrysotile asbestos. Given these factual findings by the Panel, we believe that "controlled use" would not allow France to achieve its chosen level of health protection by halting the spread of asbestos-related health risks. "Controlled use" would, thus, not be an alternative measure that would achieve the end sought by France. [83]

The findings in the *Asbestos* case could be contrasted to the conclusions reached in an earlier GATT dispute (*Thai Cigarettes* case) which examined cigarette import restrictions aimed at protecting the public from harmful ingredients in imported cigarettes, and to reduce the consumption of cigarettes in Thailand.[84] In that case, strict, non-discriminatory labelling and ingredient disclosure regulations were considered an appropriate alternative measure that would allow the Thai government to control and inform the public of cigarette content.[85] A ban on cigarette advertising combined with restrictions on supply were considered appropriate alternative means by which to control cigarette consumption.[86] These measures, the Panel found, were 'reasonably available to Thailand to control the quality and quantity of cigarettes smoked' which could achieve the same health policy goals of the Thai import ban.[87]

4.5 Taking account of risk

Underpinned by the precautionary principle, REACH's registration requirements (with WWF's amendments) would be expected to generate data on the hazardous properties of all industrial chemicals, and the means by which people and the environment are exposed to them. In the EU's view, this would facilitate the assessment and management of the risks that the use of industrial chemicals poses to health and the environment.[88] Some WTO Members have described REACH's approach to risk assessment as taking a 'hazard-based', rather than

[80] *Asbestos* para 168.
[81] *Asbestos* para 173.
[82] *Asbestos* para 174.
[83] *Asbestos* para 174, footnotes omitted.
[84] *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, Report of the Panel adopted on 7 November 1990, BISD 37S/200 ('*Thai Cigarettes*'), para 76.
[85] Ibid para 77.
[86] Ibid para 78.
[87] Ibid para 81.
[88] *See* above, section 2.2.

a 'risk management', approach to chemicals regulation. A 'hazard-based' approach, they argue, violates WTO rules.[89] However, there is no express distinction between 'hazard-based' and 'risk management' regulatory approaches under WTO rules. Neither term is used in the TBT Agreement or the GATT.[90]

'Risk' is nevertheless relevant to an assessment of proportionality under TBT Article 2.2 and GATT Article XX. An assessment of whether a measure is 'more trade-restrictive than necessary' to fulfil a legitimate objective under Article 2.2 of the TBT Agreement must take account of 'the risks non-fulfilment of the legitimate objective would create'. The concept of 'risk' is not expressly referred to in GATT Article XX, although past adjudicators of WTO and GATT disputes have considered 'risk' of harm relevant to their assessment of the least trade-restrictive measure.[91]

The need to protect people and the environment from the risk of harm caused by industrial chemicals – sharing the same properties as those known to be hazardous or having novel properties not yet assessed for their impact on human health and the environment – is one of the reasons for REACH's registration requirements. Some industrial chemicals have been shown to harm nervous systems, reproductive capacity and hormone systems of living organisms, including humans, and to have significant adverse impacts on our natural environment.[92] Other industrial chemicals could also harm people and the environment. The nature of the 'risk' of harm cannot be known until the chemicals are tested for hazardous properties, and the means by which people and the environment will be exposed to them have been identified.

Whether there is a risk of harm can be the subject of debate among scientific experts and still be used to justify a measure as being no 'more trade-restrictive than necessary' to fulfil its objective under the WTO rules. The WTO's Appellate Body has found that WTO Members are not required to rely on majority scientific opinion when taking account of risks under TBT Article 2.2 or GATT Article XX. In the *Asbestos* case, the Appellate Body stated that: '[i]n justifying a measure under Article XX(b) of the GATT 1994, a Member may … rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.'[93]

In the *Asbestos* case, the Appellate Body drew on its conclusions in a dispute concerning a challenge (the *Hormones* case) to an EU ban on hormone-treated beef and beef products under another WTO agreement – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). In the *Hormones* case, the Appellate Body characterised 'risk' as 'not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.'[94] The Appellate Body acknowledged the overall relevance of the

[89] *See* representative for Australia, TBT July Minutes, para 51. *See* US non-paper, www.chemicalspolicy.org/downloads/US%20nonpaper.doc.
[90] In the context of the *Hormones* case, the Appellate Body specifically concluded that 'risk management' was not a concept reflected in the SPS Agreement, *Hormones* para 181.
[91] *See Asbestos Panel* para 8.200-8.203, and following. The Panel's conclusions in this respect were upheld by the Appellate Body, *see* Asbestos para 166 ff. *See* also *Thai Cigarettes.*
[92] *See* above, section 2.1.
[93] *Asbestos* para 178.
[94] *Hormones* para 187.

precautionary principle in the SPS Agreement, confirming that an analysis of the SPS requirement concerning sufficient scientific evidence should 'bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned.'[95]

Although the Appellate Body's observations in the *Hormones* case were limited to the SPS Agreement, the *Asbestos* case subsequently applied relevant elements of the Appellate Body's reasoning to GATT Article XX(b).[96] It would be reasonable to expect that consistent reasoning would also be applied to an analysis of 'risk' under Article 2.2 of the TBT Agreement.[97]

4.6 'Common interests and values'

In past WTO disputes, the Appellate Body has said that assessing whether a measure is 'necessary' requires a 'process of weighing and balancing a series of factors'.[98] The more 'vital and important' the 'common interests or values' represented by a measure's objective, the easier it will be to accept the measure as 'necessary'.[99] In the *Asbestos* case, the Appellate Body observed that 'the preservation of human life and health' was a value 'both vital and important to the highest degree'.[100]

Some WTO Members have noted that they share REACH's objective of ensuring a high level of health and environmental protection from the harm caused by industrial chemicals.[101] Accordingly, REACH could be described as pursuing a vital and important objective which is a common interest and value of WTO Members. As such, it should be easier to accept that REACH is necessary to achieve its objective in accordance with WTO rules.

[95] *Hormones* para 124.
[96] *Asbestos* para 178.
[97] *See* above, section 3.2.
[98] *Korea Beef* para 164; *Asbestos* para 172.
[99] *Ibid.*
[100] *Asbestos* para 172.
[101] *See* e.g. TBT July, November and March Minutes.

WWF's Chemicals and Health Campaign
Along with wildlife around the world, we are being subjected to an uncontrolled and dangerous global experiment. Exposure to hazardous man-made chemicals is putting us all at risk. Our children and wildlife are especially vulnerable. WWF's Chemicals and Health campaign is seizing a once in a lifetime opportunity to put an end to this threat, by asking people to help us ensure forthcoming European chemicals legislation brings chemicals under control.

WWF is calling for hazardous man-made chemicals to be properly regulated – replaced where safer alternatives exist, or banned where necessary.

Campaigning together
WWF has joined forces with two campaign partners, the National Federation of Women's Institutes and The Co-operative Bank.

As the largest women's organisation in England and Wales, the National Federation of Women's Institutes is working for a safer future for our children and grandchildren.
www.womens-institute.co.uk

Through its Customers Who Care campaign, The Co-operative bank is calling for the phase-out of persistent and bioaccumulative chemicals.
www.co-operativebank.co.uk/cwc

The mission of WWF – the global environment network – is to stop the degradation of the planet's natural environment and to
build a future in which humans live in harmony with nature, by:

- conserving the world's biological diversity
- ensuring that the use of renewable resources is sustainable
- promoting the reduction of pollution and wasteful consumption

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