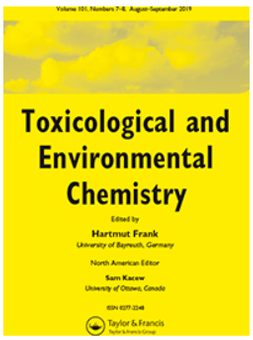

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Nanoregulation along the product life cycle in the EU, Switzerland, Thailand, the USA, and intergovernmental organisations, and its compatibility with WTO law

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ABSTRACT

Due to vast research programmes of industrial countries during the last two decades, our knowledge about the intrinsic properties of nanomaterials has increased considerably. However, 'nanoregulation' lags behind this progress. Key elements of nanoregulation are definition/scope and safety/consumer information. Safety information along the nano life-cycle is vital for the nanoparticle producer down to the industrial downstream user (product producer). However, nanodeclaration (in the sense of a label on the product for consumers) is not yet widely spread, in different geographic regions for different reasons. This is a case study for the EU, Switzerland, Thailand, the USA, and Intergovernmental Organisations. In addition, this study investigates inter- and governmental activities and the relationship between nanodeclaration and WTO rules. Non-compliance with WTO rules is a pretext for not introducing nanodeclaration in products. It is concluded that WTO rules do not exclude nanodeclaration.

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Nanoregulation; nanodefinition; nanodeclaration; WTO compliance

1. Introduction

What is so special about nanomaterials? Why are they so interesting? Why do governments and industry spend so much money on enormous research projects? The main reasons are the expected big economic opportunities. Exact sales figures of nanomaterials are not known, due to the lack of documentation on the use in many product areas. In order to address that lacuna, the Directorate-General Environment of the European Union commissioned a study to overview existing databases and to develop a methodology for a

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searchable nano database (Wijnhoven et al. 2010). In the Technology Assessment Switzerland (TA Swiss), a worldwide sales volume of two to 15 billion USD per year was estimated, depending on which definition is used (Möller et al. 2013).

Spending on public research has reached the level of billions of Euros worldwide; private sector spending is even higher than government spending. Research scientists are fascinated by the unique physicochemical properties of nanomaterials. As some governments and insurance companies are concerned about negative side effects on environmental health and safety, research studies have been performed on the safety of nanomaterials, but considerably less than on commercial nano applications. The NANoREG project, a common European approach to regulatory testing of manufactured nanomaterials, ended in 2017 (van Teunenbroek 2017). NANoREG was followed by many other research programmes on nanosafety, also in the context of Horizon 2020, with the acronyms of e.g. ACEnano, CERASAFE, ModCOMP, NanoFARM, Necomada, or npSCOPE (https://www.nanosafetycluster.eu).

Since 2006, the OECD Environment Directorate investigates the safety of manufactured nanomaterials (www.oecd.org/env/ehs/nanosafety), in particular, whether their chemicals test guidelines can be also applied to the testing of manufactured nanomaterials. The USA EPA does research on nanomaterials to help determine which nanomaterials may pose a risk and which may be expected to have little impact (www.epa.gov/chemical-research/research-nanomaterials). The Swiss National Science Foundation was commissioned by the Swiss Federal Council to carry out the National Research Programme NRP 64 «Opportunities and Risks of Nanomaterials». With an overall funding of 12 million CHF, between 2010 and 2015 23 research groups from all over Switzerland have examined major opportunities and possible risks pertaining to engineered nanomaterials throughout the different stages of their life cycle (Gehr 2017).

This article has two aims: The first is to give examples of existing nanoregulations in the EU, in Switzerland, Thailand, the USA, and international governmental organisations (IGOs). Safety of nanomaterials is an important issue. There is a need for information about nanoregulations for different stakeholders which are active in this field such as government officials, industry, and NGOs.

The second aim is to examine if the existing regulations and regulatory possibilities are compatible with WTO law.

2. Examples of global, regional and national nanoregulation

2.1. GHS labeling of hazardous chemicals versus product labeling for consumer information

The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) addresses classification of chemicals by types of hazard

and proposes harmonised hazard communication elements, including labels and relevant information in safety data sheets. It aims at ensuring that information on physical hazards and toxicity of chemicals be available in order to protect human health and the environment during handling, transport, and use of chemicals. The GHS also provides a basis for harmonisation of rules and regulations on chemicals at national, regional, and worldwide levels (https://www.unece.org/index.php?id=51896). Since 2013 a working group of the GHS Subcommittee of the UN studies the applicability of the GHS classification criteria to manufactured nanomaterials.

The Nordic Classification Group funded by the Nordic Council of Ministers conducted a project on four preselected nanomaterials. They found that the current GHS classification criteria for the five evaluated hazard classes were applicable to the generated data on single-wall carbon nanotubes (SWCNT), nano silicon dioxide, nano silver and nano zinc oxide (Larsen, Christophersen, and Andersen 2019). Specific target organ toxicity for repeated exposure was considered a highly relevant hazard class to be examined for all nanomaterials, especially for the lung. However, differences in toxicity exist between the various qualities related to production methods or impurity profiles of the same nanomaterials, which may result in different GHS classifications.

In contrast to GHS labelling, product labelling, e.g. of cosmetic products containing nanomaterials, aims to enable consumers to make an informed decision whether they want to buy such product or not. In the EU such an obligation applies to all nanomaterials in consumer products such as cosmetics and foodstuffs. The consumers may assume that these cosmetic products comply with legal requirements and are safe.

2.2. International governmental organisations

Nanoregulation means the regulation of manufactured nanomaterials as part of the regulation of chemicals. Numerous IGOs and multilateral environmental agreements are of great importance for the regulation of nanoproducts (see Table 1). The UN Strategic Approach to International Chemicals Management (SAICM) is the global platform for discussing nanosafety issues. SAICM has come up with a nanospecific resolution and has added new activities on nanotechnologies and manufactured nanomaterials to its Global Plan of Action. For a historical description of SAICM and its relationship to WTO law see Karlaganis and Liechti (2013). The WHO (2017) Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials – with a list of proposed occupational exposure limit values – constitute an important milestone (WHO 2017).

Table 1. Work of International Governmental Organisations on safety of nanomaterials.

IGO	International Governmental Organisations	Activities
BC	Basel Convention BC	The Conference of the Parties COP14 of BC *took note* of the report on issues related to waste containing nanomaterials and options for further work under the Basel Convention (see website of BC, Document UNEP/CHW/OEWG.11/15); *encouraged* Parties and others to undertake further research and develop other measures to generate the information needed to better understand the potential risks posed by waste containing nanomaterials; *invited* Parties and others to make available to the Secretariat, by end of 2019, information related to activities on nano waste, including case studies about and best practices relating to the management of waste containing nanomaterials; *encouraged* Parties to develop strategies for the environmentally sound management of nano waste.
ECOSOC	ECOSOC's Sub-Committee of Experts on the GHS (Globally Harmonised System of Classification and Labelling of Chemicals) on the applicability of GHS criteria to nanomaterials	A new item 'Review the applicability of GHS to nanomaterials' was included in the programme for the biennium 2013–2014. The Sub-Committee noted that the informal working group was following the progress of the work on safety of nanomaterials undertaken by the OECD and ECHA and that it intended to build on these outcomes to consider the applicability of GHS to such substances, see UN Committee of Experts on the Transport of Dangerous Goods and on GHS (UN Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals 2017).
FAO	Food and Agriculture Organisation of the United Nations	Assessment of food safety in food and food additives containing nanomaterials, see website of FAO.
ILO	International Labour Organisation	See WHO (2017).
IOMC	Inter-Organisation Programme for the Sound Management of Chemicals; secretariat at WHO	The IOMC organisations hold regular meetings together to ensure coordination of the chemical safety activities related to nanomaterials of the IOMC participating organisations, see website of WHO.
ISO	Technical Committee 229 Nanotechnologies of the International Organisation for Standardisation	See Section 2.2.
OECD	OECD Working Party on Manufactured Nanomaterials (WPMN) and Working Party on Nanotechnology (WPN)	The OECD Council adopted a resolution on the Safety Testing and Assessment of Nanomaterials in 2013 and amended it in 2017. The OECD WPMN (which was established 2006) has developed test guidelines and assessment methods related to nanotechnologies and manufactured nanomaterials. See website of OECD.

(*continued*)

Table 1. Continued.

IGO	International Governmental Organisations	Activities
SAICM	Strategic Approach to International Chemicals Management	Nano Resolution III/2-E was adopted at the third session of ICCM (ICCM3) in 2012, where nanoparticles were recognised as an emerging policy issue (EPI) and 13 activities linked to nanotechnologies were incorporated into the SAICM Global Plan of Action, see Karlaganis and Liechti (2013) and SAICM (2015).
UN Environment	Formerly UNEP, United Nations Environment Programme	A UN Environment report has identified nanomaterials as an issue having the potential to hugely impact society, economy and the environment. 'Iterative and responsive regulatory frameworks that apply the precautionary principle are needed to minimise the nano risks and ensure human health and environmental safety.' See UNEP (2017).
UNESCO	UNESCO (United Nations Educational, Scientific and Cultural Organisation), Division of Ethics of Science and Technology and its World Commission on the Ethics of Scientific Knowledge and Technology (COMSET)	One objective of the medium-term strategy of the Organisation is to 'promote principles and ethical norms to guide scientific and technological development and social transformation.' COMSET has published Policy Recommendations on Nanotechnologies and Ethics in a book. See UNESCO (2006).
UNITAR	United Nations Institute of Training and Research	UNITAR has developed a guidance document entitled 'Developing a National Nanotechnology Policy and Programme', available in English, Russian and Spanish, see UNITAR 2011. UNITAR also organised from 2012 to 2016 Swiss funded pilot projects on nanosafety in Armenia, Jordan, Nigeria, Thailand, Vietnam and Uruguay. UNITAR and OECD set up a partnership to undertake a series of mostly Swiss funded regional awareness-raising workshops on nanosafety. These workshops took place from 2009 to 2018 in the African region in Abidjan, Alexandria, Nairobi and Lusaka, in the Asia and Pacific Region in Beijing, Bangkok and Kuala Lumpur, in the CEE region twice in Lodz (Poland), in the GRULAC region in Bogotá, Kingston (Jamaica) and Panama City. See website of UNITAR/Chemicals and Waste Management.
WHO	World Health Organisation	WHO Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials, see WHO, Geneva. 2017.

2.3. Nanovocabulary of ISO

2.3.1. Definition related to scope

The legal definition of 'nano' obviously has an impact on the scope of a nanoregulation. Therefore, governmental committees and other stakeholders have been working for years and trying to agree on this matter. In this respect, the ISO Technical Specification ISO/TS 80004-1:2010(E)

and its second edition ISO/TS 80004-1:2015(E) are of importance. They were prepared jointly by the Technical Committee ISO/TC 229 *Nanotechnologies* and the Technical Committee IEC/TC 113 *Nanotechnology standardisation for electrical and electronic products and systems*. It introduces a hierarchical system and **divides nanomaterials in nanoobjects and nanostructured materials**. Furthermore, ISO provides a series of terms and definitions in the field of nanotechnologies:

- **Nanoscale:** Size range from approximately 1 nm to 100 nm (ISO/TS 80004-1:2015: Terms and definitions).
- **Nanomaterial:** Material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.
- **Nanoobject:** Material with one, two or three external dimensions in the nanoscale (ISO/TS 27687:2008).
- **Nanoenabled:** Exhibiting function or performance only possible with nanotechnology.

ISO takes into consideration that environmental, health and safety concerns do not abruptly end at 100 nm by using the word 'approximately' in the definition of nanoscale.

2.4. Nanoregulation in the USA

2.4.1. Definition

In Section 3 of the **Toxic Substances Control Act (TSCA)**, a reportable chemical substance is defined as a solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that it is manufactured or processed to exhibit one or more unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1 weight-% of any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension (EPA 2017b). This definition focuses on nanoscale materials that are intentionally manufactured or processed to exhibit unique or novel properties because of size in the 1–100 nm range. The definition of a reportable chemical substance is consistent with the ISO concept of a 'nanoenabled' property.

2.4.2. Regulatory approach

Like the EU and Switzerland, the USA have various statutes regulating the manufacturing, processing, distribution, use, and disposal of chemical

substances such as industrial chemicals, pesticides, foods and food additives, drugs, cosmetics, tobacco and tobacco products, nuclear materials, and munitions. The focus of this article is on chemical substances regulated by the TSCA which as an 'industrial chemical' law does not apply to certain tobacco products, nuclear materials, munitions, food, food additives, drugs, cosmetics, and substances used solely as pesticides.

To ensure that these nanoscale materials are manufactured and used in a manner that protects against unreasonable risks for human health and the environment, under TSCA the EPA pursues a comprehensive regulatory approach (EPA 2017a).

2.4.2.1. Information gathering rule. The EPA seeks to facilitate innovation while ensuring safety of the substances. It issued a final regulation (effective date 14 August 2017) requiring one-time reporting and record-keeping of existing exposure and health and safety information on nanoscale chemical substances in commerce pursuant to its authority under TSCA section 8(a). This rule requires companies that manufacture, import, or process certain chemical substances already in commerce as nanoscale materials, to notify EPA of certain information including specific chemical identity, production volume, methods of manufacture, processing, use, exposure and release information, and available health and safety data.

2.4.2.2. Premanufacture notifications (PMN). The TSCA requires manufacturers of new chemical substances to provide specific information to the EPA for review prior to manufacturing or introducing them to commerce. The EPA can take action to ensure that chemicals which may or will pose an unreasonable risk to human health or the environment are effectively controlled. Anyone who plans to manufacture (or import) a new chemical substance for a non-exempt commercial purpose, by section 5 of the TSCA is required to provide EPA with notice before initiating the activity. A pre-manufacture notice, or PMN, must be submitted at least 90 days prior to the manufacture of the chemical. PMN submissions require all available data on chemical identity, production volume, by-products, use, environmental release, disposal practices, human exposure, and existing test data.

EPA risk assessors consider all this information during the EPA new chemicals review process. There is a range of actions the Agency can take to ensure new chemicals do not present an unreasonable risk to health or the environment. Since 2005, the EPA has received and reviewed over 160 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes. The Agency has taken a number

of actions to control and limit exposures to these chemicals, including limiting the uses of the nanoscale materials, requiring the use of personal protective equipment and engineering controls, limiting environmental releases, and requiring testing to generate health and environmental effects data.

2.5. Nanoregulation in the European Union

2.5.1. Legal definition of 'nanomaterial' in the EU

On 18 October 2011, the European Commission (2011) adopted the following recommendation (2011/696/EU):

1. Member States, EU agencies, and economic operators are invited to use the following definition of the term 'nanomaterial' in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.
2. 'Nanomaterial' means a natural, incidental, or manufactured material containing particles in an un-bound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions are in the size range 1 – 100 nm.
3. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.
4. By derogation from point 2, fullerenes, graphene flakes, and SWCNT with one or more external dimensions below 1 nm should be considered as nanomaterials.

The same recommendation defines particle, agglomerate, and aggregate. The definition in point 2 may be determined on the basis of the specific surface area by volume (threshold 60 m^2/cm^3).

The definition might be reviewed; for more details of the review see the roadmap of the European Commission (2017).

The legal nano definitions for biocides, cosmetics, and food are slightly different.

2.5.2. Nano-specific regulations in the EU in different product categories

Table 2 gives an overview of nanospecific regulations in the EU in different product categories. Content labelling is required for biocidal products, cosmetic products, novel food, and food additives. The Biocidal Products Regulation (BPR) has specific provisions for nanomaterials.

Table 2. Product categories and regulatory frameworks for nanomaterials in the European Union (see European Commission's science and knowledge service 2017).

Product category	Definition	Approval procedure	Safety assessment	Content labelling	Guidance
REACH Chemicals	Reg. 696/2011	REACH Annexes adopted on 03.12.2018	REACH Annexes adopted on 03.12.2018		ECHA/NR/18/23
Biocidal Products	Reg. 528/2012	Reg.528/2012	Reg.528/2012	Reg.528/2012	
Cosmetic Products	Reg. 1223/2009	Reg.1223/2009	Reg.1223/2009	Reg.1223/2009	Reg.1223/2009
Novel Food	Reg. 2283/2015	Reg. 2283/2015	Reg. 2283/2015	Reg. 1169/2011	Reg. 2283/2015
Food Additives			Reg. 1333/2008	Reg. 1169/2011	Reg. 1333/2008
Plastic Food Contact Materials		Reg. 10/2011	Reg. 10/2011		
Active and Intelligent Food Contact Materials		Reg. 450/2009	Reg. 450/2009		
Food Information Provisions	Reg. 1169/2011			Reg. 1169/2011	
Medical Devices	Reg. 745/2017	Reg. 745/2017	Reg. 745/2017		

According to the BPR, the approval of the active substance does not cover the nanoform. A dedicated risk assessment is needed when the nanoform of active or non-active substances are used in a biocidal product. The label of the biocidal product must show the name of each nanomaterial followed by the word 'nano' in brackets (https://echa.europa.eu/regulations/nanomaterials-under-bpr).

During the REACH Committee on 26 April 2018, the member states voted for the draft Commission Regulation amending several annexes to REACH, adopted on 3 December 2018 and in force by 1 January 2020. The amendments clarify REACH registration requirements with regard to nanomaterials and address the knowledge gap on which substances registered under REACH are placed on the market as nanomaterials and at which quantities (see European Chemicals Agency 2018. Communication number 18/23 (2018); European Commission 2018. Commission Regulation 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006).

2.6. Nanoregulation in Switzerland

2.6.1. InfoNano federal information hub

An overview of nanoregulation in Switzerland (Table 3) is given on the web site of the Swiss Federal Authorities called InfoNano, see www.infonano.ch. It provides information on the opportunities and risks associated with nanomaterials, illustrates where nanomaterials are used, and describes the goals and milestones of the action plan for synthetic

Table 3. Product categories and regulatory frameworks for nanomaterials in Switzerland.

Product category	Definition	Approval procedure	Safety assessment	Content labelling	Guidance
REACH Chemicals	ChemO, SR 813.11	ChemO, SR 813.11	ChemO, SR 813.11		www.infonano.ch
Biocidal Products	OBP, SR 813.12	OBP, SR 813.12	OBP, SR 813.12	OBP, SR 813.12	www.infonano.ch
Cosmetic Products	VKos, SR 817.023.31	VKos, SR 817.023.31	VKos, SR 817.023.31	VKos, SR 817.023.31	www.infonano.ch
Food Additives	ZuV, SR 817.022.31	ZuV, SR 817.022.31	ZuV, SR 817.022.31	ZuV, SR 817.022.31	www.infonano.ch
Medical Devices	MedDO, SR 812.213	MedDO, SR 812.213	MedDO, SR 812.213		www.infonano.ch

nanomaterials. Key topics include guidelines on safe use, promotion of public dialogue, key research, and regulatory updates (Studer et al. 2015).

2.6.2. Action plan for synthetic nanomaterials

The Swiss Government approved the 'Action Plan for Synthetic Nanomaterials' in April 2008. This instructs federal offices to create the legal bases for the safe handling of nanomaterials. The Action plan indicates what work is necessary in Switzerland for the safe handling of nanomaterials. On 17 December 2014, the Swiss Government decided to continue the action plan until 2019.

2.6.3. Definitions

Switzerland also uses different definitions for nanomaterials in different ordinances. The definitions for industrial chemicals and for plant protection products are close to the ISO and the USA working definition. The definitions for nanomaterials in biocidal products, cosmetic products, and food follow the definition of the EU. The definition of medicinal products mentions a size range of 1 – 1000 nm, taking into account the opinion of many toxicologists that nanoparticles of e.g. 200 nm also have nano-like properties.

2.6.3.1. Industrial chemicals. Article 2 ChemO, Definitions, para. 2, lit. q, see Chemicals Ordinance, ChemO, SR 813.11:

> *Nanomaterial* means a material containing particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range of 1–100 nm, or a material where the specific surface area by volume is greater than 60 m^2/cm^3. A material is only considered to be a nanomaterial if it is deliberately produced to utilise the properties arising from the defined external dimensions of the

particles it contains, or from the defined surface area by volume of the material. Fullerenes, graphene flakes and SWCNT with one or more external dimensions below 1 nm are considered to be nanomaterials.

2.6.3.2. Biocidal products. Article 2 OBP, Definitions, para. 2, lit. m, see Ordinance on the Placing on the Market and Handling of Biocidal Products, OBP, SR 813.12:

> *Nanomaterial* means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions are in the size range of 1–100 nm; fullerenes, graphene flakes and SWCNT with one or more external dimensions below 1 nm are deemed to be nanomaterials.

2.6.3.3. Medical Devices. Applications for authorisation or adaptation of medicinal products in Switzerland must state whether the medicinal product contains nanoparticles. The following nanoparticle definition is used in this context: at least one dimension in the size range of 1–1000 nm and a function or mode of action based on nanotechnological properties (Medical Devices Ordinance, MedDO, SR 812.213).

2.6.4. Autonomous monitoring (Art.5 ChemO)

Manufacturers have to assess the risk of substances and formulations for human health and the ecosystem on the basis of existing data. There are no data requirements for existing substances (substances listed in EINECS, the European Inventory of Existing Chemical Substances). This applies to non-nanoscale and nanoscale substances.

2.6.5. Notification of new chemicals including nanomaterials

Manufacturers have to deliver data on toxicity and fate for non-nanoscale substances and nanomaterials to the authorities (tonnage threshold >1 t/a). Additional characterisation data for nanomaterials are needed (chemical composition, mean particle size and shape (mandatory), particle size distribution, specific surface area, crystal structure, aggregation status, surface coatings, and functionalisation (if available).

2.6.6. Reporting obligation

Since 2012, the Chemicals Ordinance (ChemO, SR 813.11) in Articles 48 and 49 includes a mandatory reporting obligation for substances and

preparations containing nanomaterials. This applies only to substances and preparations classified as dangerous according to GHS, to persistent, bioaccumulative, and toxic substances (PBTs) or to very persistent and very bioaccumulative substances (vPvB), and to special substances listed in the ChemV. Manufacturers of the substances and preparations must register them with the Notification Authority within 3 months after first placing them on the market. In the case of nanomaterials and of preparations containing nanomaterials, the registration application must include the following information: the composition, particle form and mean particle size and, where available, the number size distribution, specific surface area by volume, crystal structure, aggregation status, surface coating, and surface functionalization.

2.6.7. Reporting of biopersistent high aspect ratio nanoparticles (HARNs)

The reporting of biopersistent nanotubes and nanofibers with a length $>$ 5 µm is mandatory.

2.6.8. Declaration

With the exception of biocidal products (OBP, SR 813.12), foodstuffs (Verordnung des EDI vom 25. November 2013 über die zulässigen Zusatzstoffe in Lebensmitteln, Zusatzstoffverordnung, ZuV, SR 817.022.31), and cosmetics (Verordnung des EDI vom 23. November 2005 über kosmetische Mittel, VKos, SR 817.023.31), the current Swiss law does not include any special declaration obligations for nanomaterials.

Examples for nanofood additives in Switzerland (Möller et al. 2009, 59) under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) include amorphous silicon dioxide (E 551) as flow enhancer in spices; carotenoids (–β-carotene, lycopene) as dyes, and health-promoting ingredients in health drinks, micelles for encapsulation and increase of bioavailability of vitamins, ω-3 fatty acids and coenzyme Q10 in wellness, health, and sport drinks.

2.6.9. Safe handling

Since 2008, the Swiss Government has published a series of guidance documents for the safe handling of nanomaterials. They help to identify the possible risks posed by nanomaterials and communicate important safety information along the length of the production and delivery chain. Guidance documents are available on occupational health protection (SUVA 2012, 2018), 'precautionary matrix', material safety data sheet, disposal of industrial nanowaste, and prevention of major accidents.

2.7. Nanoregulation in Thailand

The following section is based on a presentation held by G. Karlaganis at the 5th Thailand International Nanotechnology Conference 2016 on 'Synergetic Nanotechnology for Innovations and Sustainable Developments'.

There are several factors contributing to nanotechnology development in Thailand, such as its geographical location in the heart of Asia and the availability of infrastructure, technical, financial, and human resources (see NANOTEC 2018, 'Nanotechnology development in Thailand'). In order to promote research and development, in 2003 the Thai Government established the National Nanotechnology Centre (NANOTEC) (NANOTEC 2018a, 2018b). As a government agency operating under the National Science and Technology Development Agency (NSTDA) in the Ministry of Science and Technology. NANOTEC has a dual role serving as a national research and development centre with laboratory units and as funding agency. The NANOTEC mission is to conduct and support research, development, design and engineering in nanotechnology, and transfer the technology to industrial and service sectors in a constructive manner to increase Thailand's competitiveness, to promote social awareness, and to improve the quality of life and the environment. During the years of 2012–2016, NANOTEC had launched 10 flagship projects including clean water, clean air, control released fertiliser, mosquito control (Figure 1), nano textiles, nano catalysts for energy, nano Mark, smart soil and nano biosensors. The flagship programmes last a maximum of 3 years and use three core platform technologies: Nano materials by design and synthesis, Nanoscale Characterisation by metrology, safety and standards, and Nano Systems by engineering and advanced manufacturing. Currently, NANOTEC has 5 research groups consisting of 16 teams: Advanced Nanocharacterization and Safety, Nanocatalysis and Molecular Simulation, Responsive Material and Nanosensors, Nanohybrids and Coating, and Nanoencapsulation.

Also, NANOTEC has developed the Thai National Nanotechnology Policy Framework 2012–2021, the NANOTEC Master Plan 2017–2021, the Nanotechnology Roadmap 2017–2021, and the Nanosafety and Ethics Strategic Plans 2012–2016 and 2017–2021. The Thai Nanosafety Strategic and Ethics Plan is a policy tool to define the directions for nanotechnology precaution and ethics. The plan focuses on three strategies: (1) Knowledge management, (2) Regulation and standards, and (3) Public participation. The extension version of the plan 2017–2021 was approved by the National Science Technology and Innovation Policy Office in 2017, and NANOTEC is one of many agencies helping to promote and

Figure 1. Dead mosquitos on a NNET NANO bed net. Locking a nano scale formulation to minimise the spread of mosquito borne diseases: Researchers at NANOTEC Nano Functional Textile Laboratory in Thailand have developed NNET NANO. They found a way to lock the nanoscale formulation of Deltamethrin into the fabric of bed nets, which will kill the mosquito within a few minutes, when it contacts the fabric. This nanoscale formulation is effective up to 5 years (instead of yearly recoating).

drive the strategic plan. The Nanosafety Alliance Section of NANOTEC is responsible for implementing activities that promote awareness of nanosafety and industrial standards. Activities such as interlaboratory comparisons, training, seminars, conferences, and exhibitions are organised on a regular basis (NANOTEC 2017).

Currently, there is no specific nanoregulation in Thailand. Existing regulations such as the Labour Protection Act 1998 and the Thai Hazardous Substance Act 1992 do not focus on nanotechnology. Section 4 in this Act on the definition of 'Hazardous Substance' means: 'Other substance either chemicals or otherwise which may cause injury to the persons, animals, plants, property or environment.' The decision was not yet taken whether selected nanomaterials are within the scope of the Thai legal acts 1992 and/or 1998. (ThaiLaws.com 2008)

NanoQ Certification is a project of the Nanotechnology Association of Thailand). It was officially launched in 2011 and is Thailand's answer to building consumers' confidence and setting industrial standards for nanotechnology-related products. NanoQ helps to distinguish between real and fake nanoproducts. Figure 2 shows a plastic water tank with silver nanoparticles, which received the award NanoQ. The label NanoQ demonstrates the presence of nanoparticles in the product, in this example the silver nanoparticles with antimicrobial properties.

Local companies wishing to obtain the NanoQ mark can forward their request to the Association which then works with NANOTEC to have

Figure 2. Water tank made from plastic embedded with silver nanoparticles demonstrated antimicrobial properties and received the approval of NanoQ labelling.

the product tested and verified. A yearly auditing process is also part of the NanoQ mark package. Several Thai companies have already received NanoQ labels for their products. Currently, the Nanotechnology Association of Thailand is urging companies in the paint, ceramics, textile, and household plastic industries to make inquiries on the possibilities of obtaining NanoQ labels for their products. The Nanotechnology Association of Thailand presented the first NanoQ label to Supreme Products on 27 September 2012 (Nanowerk 2012). The NanoQ label certified that a paint formulation for use in coating the inside of ambulances contains silver nano particles that have anti-bacterial activity.

On 11 May 2016, Kanzen International received the NanoQ label for its SmartCoat anti-bacterial spray. The NanoQ label confirms that the product contains titanium dioxide nanoparticles with anti-bacterial properties (NANOTEC 2016).

However, the list of NanoQ labelled products is not published on the website www.nanoassociation.or.th because of confidential business information. The authors of this article assume that the companies selling nanoproducts fear that competitors will copy their products if technical product information is published, and that the Thai companies do not fear stigmatisation, in contrast to industry in Europe. Recently, the board of the Association approved applications for the NanoQ label from interested companies that produce nanoparticles for use as raw materials. Previously, the NanoQ label was only given to products with anti-bacterial and water repellent properties.

Consumers in Asian countries like to buy nanoproducts because of the advantages of nanotechnological property improvement, such as

Figure 3. Number of nanoproducts in Thailand was available in the market, for example, i.e. nanosilver coated T-shirts, nanotitanium colour paint, nanosilicone colour paint, nano coated spray, nano sun protective white; nano active whitening cream, nano white masking cream.

antimicrobial, water repellent, and sustained release. In Asia, many products are advertised as nanoproducts, even if they are imitations. Nanoproducts in Thailand have been on the market for many years in various groups of products (Figure 3), e.g. nanofabric, nanosilver coated T-shirts, nano TiO2 colour paint, nano cosmetic products (e.g. sunscreens Figure 4) and cosmeceutical products and nano mosquito nets with nano encapsulation of insecticides.

Nanotechnology in Thailand has been developed for more than 16 years and has produced a number of nanoproducts in the market. Nonetheless, NANOTEC and NSTDA have realised the importance of sustainability. So, the Nanosafety Strategic Plan has been established in parallel as a guideline for sustainable development of nanotechnology in Thailand in order to maximise the benefits and minimise the risks of nanotechnology.

3. WTO law and nanoregulation

The General Agreement on Tariffs and Trade (GATT), the predecessor of WTO, was originally established because the contracting parties – amongst other things – recognised that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living and ensuring a large and steadily growing volume

Figure 4. NaNOMOS Sunscreen was formulated with nano mosquito repellent mixed with nanoTiO2 particles which showed the effect of mosquito repellent and maximised for sun protection.

of income. At the same time, the production and trade of goods was to be expanded in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns (Marrakesh Agreement, 1994, Preamble, para.1). Therefore, WTO law is mainly a search for an appropriate balance between trade liberalisation on one hand, and regulatory autonomy of the member states in protecting values important to them on the other (e.g. Marceau and Trachtman 2014). For this search to be successful, there must be not only a reduction of barriers to international trade, but also good governance at the national level (Van den Bossche and Zdouc 2017, 33–43, for an introduction to WTO law).

The search for this balance led to the conclusion of three main WTO agreements which deal with the regulation of trade in goods, notably the GATT 1994 and within its Annexe 1 A, the Agreement on Technical Barriers to Trade (TBT) and the SPS Agreement. Besides dealing with tariffs, import quotas, customs formalities, rules on unfair trade, as well as institutional and procedural rules, WTO law includes basic rules on non-discrimination, market access, and the conflict between trade liberalisation and other societal values and interests (Van den Bossche and

Zdouc 2017, 39–43). This section will focus on these three areas respectively on those three agreements, in the search for guidance on the regulation of labelling nanoproducts, as some of the provisions are simultaneously applicable while others are mutually exclusive (Marceau and Trachtman 2014, 353). Whereas GATT 1994 deals with regulatory measures concerning goods in general, TBT addresses technical regulations such as mandatory labelling and standards, while SPS addresses sanitary and phytosanitary measures which aim at protecting human, animal and plant life and health as well the environment and can also apply to labelling (Cheyne 2012, 310).

3.1. General trade liberalisation principles

General trade liberalisation rules laid down in GATT 1994 apply to all trade measures, including non-tariff barriers like labelling. Concerning technical and sanitary regulations, the TBT and SPS agreements impose various additional regulatory constraints on government actions (Marceau and Trachtman 2014, 353; WTO 2001. *EC-Asbestos*, para. 80).

3.1.1. Non-Discrimination

In WTO law, there are two basic elements of the non-discrimination rule; one is the outward element of non-discrimination: (1) the most favoured nation (MFN) treatment obligation (Van den Bossche and Zdouc 2017, 305–340), and the second is the inward element (2), the national treatment (NT) obligation (Van den Bossche and Zdouc 2017, 341–414). Whereas GATT 1994 deals with these rules in two separate provisions, TBT and SPS combine them in one single article each.

The *MFN treatment obligation* basically requires WTO Members to grant equal treatment to all other WTO Members, in other words, it prohibits a country to discriminate *between* other countries. The key provision dealing with the MFN treatment obligation for measures affecting trade in goods is *Article I.1 GATT 1994* which holds that any advantage, favour, privilege or advantage granted by a Member to a product of any other Member is to be accorded immediately and unconditionally to the 'like' product of all other Members. The same notion is taken up in *Article 2.1 TBT* which requires treatment no less favourable than that accorded to 'like' products originating in another country to be accorded. *Article 2.3 SPS* reflects the obligations and provides that Members shall ensure their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail including between their own territory and that of other Members. Furthermore, sanitary and phytosanitary measures are

not to be *applied* in a manner which would constitute a disguised restriction on trade.

The *national treatment obligation* basically requires WTO Members to grant equal treatment to foreign and domestic products; in other words, it prohibits a country from discriminating *against* imported products. *Article III.4 GATT 1994* provides that imported products 'shall be accorded treatment no less favourable than that accorded to products of national origin', so as to avoid protection of domestic production. The prohibition against discrimination applies to 'like' products within the internal regulation of WTO Members. The same notion is taken up again in *Article 2.1 TBT* which requires treatment no less favourable than that accorded to like products of national origin […].

In the case of trade in nanoproducts, the question arises whether these and products which do not contain nanoparticles are 'like'. As the Agreements do not define the meaning of 'likeness', the WTO Appellate Body has developed an approach, derived from the *Border Tax Adjustment* report, in which the four main general criteria for analysis consist of: (1) the properties, nature, and quality of the products: (2) the end-uses of the products; (3) consumers' tastes and habits in respect of the products, and (4) the tariff classification *(*WTO 2001. *EC-Asbestos,* para. 101). The determination of these criteria is crucial in finding out whether a competitive relationship between imports and domestic products in the marketplace is likely to be influenced *(*WTO 2001. *EC-Asbestos,* para. 114). Evidence about the extent to which products can serve the same end-uses, and the extent to which consumers are – or would be – willing to choose one product instead of another to perform those end-uses, is highly relevant in assessing the 'likeness' of those products under Article III.4 GATT 1994 *(*WTO 2001. *EC-Asbestos,* para. 117). In the so-called TBT-Trilogy of 2012 (WTO 2012a. *US-Clove, US-Tuna II (Mexico)*, and *US-COOL)*, the Appellate Body for the first time had the opportunity of clarifying that the determination of 'likeness' under Article III.4 GATT 1994, being a determination about the nature and extent of a competitive relationship between and among the products at issue, also applies to Article 2.1 TBT (WTO 2012c. *US-Clove,* 2012, para. 120). It also held that in examining whether products were 'like', all relevant evidence had to be evaluated, 'including evidence relating to health risks associated with a product' (WTO 2012c. *US-Clove,* para. 118, confirming WTO 2001. *EC-Asbestos,* para. 113). Concerning the less favourable treatment of 'like' products, the Appellate Body continued that the mere existence of a detrimental impact on competitive opportunities of the imported products in the relevant market is not yet sufficient to establish a violation of Article 2.1 TBT. As long as a

technical regulation does not *de jure* discriminate against imports, all the particular circumstances of the case needed to be scrutinised carefully, in particular whether the technical regulation is even-handed, in order to decide whether the detrimental impact on imports stems exclusively from a legitimate regulatory distinction instead of reflecting discrimination against imports (WTO 2012c. *US-Clove,* para. 215).

These cases are highly significant for the law on labelling of products and therefore crucial to the effort of reconciling trade with other legitimate policy goals such as health or the environment (see for a summary of the cases: Cottier et al. 2013, 505–521). Whether WTO dispute settlement bodies would consider nanoproducts to be 'like' conventional products or not will need to be decided case by case. In the case of biotechnology products, the question was left open by the panel (WTO 2006. *EC-Biotech* paras 7.2418–7.2421). Concerning the 'likeness' of asbestos fibres with certain other synthetic fibres, the Appellate Body made it clear that carcinogenicity or toxicity does constitute a defining aspect of the physical properties of asbestos fibres and that this highly significant physical difference needed to be taken into account (WTO 2001. *EC-Asbestos* para. 114) and thus suggested they are not 'like'. It continued to note that under Article III.4 GATT 1994, evidence relating to health risks may be relevant in assessing the competitive relationship in the marketplace between allegedly 'like' products (WTO 2001. *EC-Asbestos* para. 115). As will be shown in Section 3.3, even if less favourable treatment between domestic and imported 'like' products should be determined, there can be justifications.

3.1.2. Rules on market access

Besides rules on customs duties and on other duties and financial charges, WTO law also contains rules on import restrictions and other non-tariff barriers such as labelling. As a general rule according to Article XI GATT 1994, quantitative restrictions and other measures – including non-tariff barriers such as labelling requirements – on importations and exportations are forbidden, but can in certain cases be justified (Van den Bossche and Zdouc 2017, 482–629).

The TBT applies to technical regulations and standards and explicitly mentions labelling as an example for a technical regulation, if it is mandatory (TBT Annexe I.1). At the outset, the TBT recognises in its preamble that no country should be prevented from taking measures necessary (amongst others) for the protection of human, animal, or plant life or health and of the environment at the level it considers appropriate under certain conditions. For this reason, besides the non-discrimination obligation discussed above, Article 2.2 TBT provides that technical

regulations must not be prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means that technical regulations are not allowed to be more trade restrictive than necessary, taking account of the risks non-fulfilment of the regulation would create.

The SPS applies to the sanitary and phytosanitary measures listed in its Annexe A including labelling requirements directly related to food safety. These and their distinction to TBT measures will be dealt with in the next section. In its preamble, the SPS also reaffirms that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal, or plant life or health under certain conditions. For this purpose, Article 2.2 SPS provides that measures must only be applied to the extent necessary to fulfil their purpose of protecting protect human, animal, or plant life or health and that they are either based on scientific principles or meet the exception foreseen in Article 5.7 SPS. Article 2.3 SPS continues that measures must not arbitrarily or unjustifiably discriminate nor be applied in a manner which would constitute a disguised restriction on international trade. In addition, these measures are to be based on a risk assessment which takes available scientific evidence into account (Articles 5.1 and 5.2 SPS). In assessing these risks, Members are to determine the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such a risk, taking all the relevant factors into account (Article 5.3 SPS). Annexe A(1) contains a list of definitions of SPS measures which will be discussed in the next section. In *EC-Biotech* (paras 7.287–344), the panel clarified that food is a 'substance taken into the body to maintain life and growth', and thus a 'substance which a human being or an animal consumes for nutritional reasons may be classified as food.' Annexe A(5) explains that the *appropriate* level of protection a sanitary or phytosanitary measure should achieve to protect human, animal or plant life or health within its territory, is that level deemed appropriate by the Member itself, therefore not by the WTO dispute settlement bodies. The case law of the WTO Appellate Body reiterates that it is undisputed that WTO Members have the right to determine the level of protection of health they consider appropriate in a given situation under GATT 1994, TBT and SPS (Marceau and Trachtman 2014, 382–386).

Both the TBT and the SPS provide that Members need to notify planned measures to other Members through the WTO secretariat. Article 2.9 TBT requires Members to notify a new technical regulation whenever a relevant international standard does not exist or the technical content of a proposed regulation is not in accordance with the technical content of relevant international standards, and if the technical

Table 4. Goals of SPS measures.

	To protect what?	To protect from what?
a)	Animal or plant life or health	Risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms
b)	Human or animal life or health	Risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feed-stuffs
c)	Human life or health	Risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
d)	The Member State	The entry, establishment or spread of pests.

regulation may have a significant effect on trade of other Members. Article 7 SPS obliges Members to notify any changes in their sanitary or phytosanitary measures.

3.2. The relationship between the relevant agreements

As discussed above, both TBT and SPS set out rules for measures which aim at protecting (amongst others) human, animal, or plant life or health, including the environment, and are therefore very similar. However, according to Article 1.5 TBT, the provisions of TBT do not apply to sanitary and phytosanitary measures as defined in Annexe A of the SPS, even if they take the form of technical regulations or standards. It is the *purpose* of a measure that qualifies it as an SPS measure (see Van den Bossche and Zdouc 2017, 938).

This becomes clearer by taking a closer look at the definitions in Annexe A(1) which holds that an SPS measure is any measure applied according to Table 4.

As set out above, TBT mainly applies to technical regulations and standards in general. However, measures addressing risks arising from additives, contaminants or toxins in foods, beverages or feed-stuff qualify as SPS measures, and therefore, according to Article 1.5 TBT, TBT does not apply. Nonetheless, although SPS and TBT are basically mutually exclusive, the panel recognised in *EC-Biotech* that a measure can pursue more than one purpose – one that falls within the definition of SPS measures and one that does not. It therefore held that to the extent a measure is applied for a purpose not covered by Annexe A(1), it (also) falls under the scope of TBT (WTO 2006. *EC-Biotech,* para. 7.167).

The relationship between GATT 1994 and TBT/SPS is different and not mutually exclusive. If a panel finds a measure to be consistent with TBT, it still has to examine whether it is also consistent with GATT 1994. According to Article 2.4 SPS, if a measure is found to be compatible with the SPS, it shall be (rebuttably) presumed to comply with the obligations of GATT 1994 which also apply to SPS measures (Van den Bossche and Zdouc 2017, 898). For examples on nano consumer products, see Tables 5 and 6.

Table 5. Selected Nano consumer products on the EU and Swiss market and their relationship to WTO law.

Nano consumer products subject to TBT measures	Nano consumer products subject to SPS measures	Nano consumer products possibly subject to both or either / or TBT and SPS measures
European Market: Sports equipment (tennis rackets, golf clubs, and bicycles) containing carbon nanotubes bound within the equipment, see SRU (2012), page 74.	Swiss Market: Amorphous nano silicon dioxide SiO2 (E 551) as food additive that can be identified as engineered nanomaterial in powdery foods as a separating agent, flow aid and anti-clumping agent, see Möller (2009), page 28.	Swiss Market: PET bottles with optimised oxygen and carbon dioxide barrier mainly used for beer and fruit juices usually coated with a nanolayer of amorphous carbon or silicon oxide, see Möller (2009), page 41.
European Market: Textiles (e.g. socks) containing biocidal nanosilver particles, see SRU (2012), page 76.	Swiss market: Micelles as food additive in the form of nanocapsules for Q10, antioxidants and flavourings and other fat-soluble substances. Micelles can consist of polysorbate 20 (E432) or polysorbate 80 (E433) with a diameter of 30 nm. These micelles may contain vitamins, omega-3 fatty acids, coenzyme Q10, isoflavones, flavonoids, carotenoids, plant extracts, essential oils, preservatives, colours or bioactive substances. see Möller (2009), page 32.	Swiss Market: Composite films to improve the barrier features against oxygen, water vapour and aromatic substances (especially for snacks, potato crisps, sweets and baked goods): this involves plastic foils (especially PP but also PET, PA, PE, PVC and cellulose) that are covered with a nanolayer of aluminium, aluminium oxide, or silicon oxide, see Möller (2009), page 39.
Swiss market of cosmetics: Sun UV blockers containing nanotitanium dioxide or zinc oxide; Body lotion containing nanoliposomes with coenzyme Q10 and vitamins, see Möller 2013, page 26.	Nanocapsules available at the global market as food supplements. They involve micelles made of polyglycerol fatty acid ester that contain a high percentage of long-chain polyglycerol fatty acid esters, see Möller (2009), page 33.	Global market: Antimicrobial packaging with biocidal effective substances (mainly nanosilver) providing protection against bacteria and fungi by incorporating or coating nanosilver. see Möller (2009), page 35.

Table 6. Selected Nano consumer products in Thailand subject to tbt measures.

Mosquito net covered with nanoparticles for repelling mosquitos (e.g. Tiger or Malaria mosquitos); producer is a Thai company called 'Netto', www.nettogroup.com
Anti-bacteria nanosilver composite formulation for use as resin composite for inside ambulance, certified with the label nanoQ of the Nanotechnology Association of Thailand. Supreme Products Co. Ltd. www.supremeproducts.co.th , http://www.supremeproducts.co.th/news-inner.php?id=130, http://www2.nanotec.or.th/en/?p=4014
NaNOMOS Lotion Mosquito Repellent. NANOTEC Thailand, 06 October 2016, https://www.nstda.or.th/th/all-newsletter/184-newsletter-nstda-news/4766-nstda-newsletter-7y2-news7
NaNOMOS Sunscreen. The technology licence was transferred to a Thai company in order to develop a production process.
DOS Life nano silver embedded plastic for water containers, certified with the label nanoQ of the Nanotechnology Association of Thailand. 1 July 2016 http://dos.co.th/newsandevents/detail.php?pid=1381; 20 July 2016 http://m.prachachat.net/news_detail.php?newsid=1468989502

3.3. 'Other' legitimate policy goals and the precautionary approach

Apart from the basic rules on trade liberalisation, WTO law also provides a set of rules that reconcile the conflict between liberalisation and

other societal values and interests of WTO Members, technically often referred to as 'exceptions', but in substance rules for the protection of legitimate policy goals – such as consumer protection, human or animal life or health, or the environment – other than trade liberalisation. These justify deviations of WTO Members, under specific conditions, from the basic rules of non-discrimination and market access (Cottier, Oesch, and Fischer 2005, for an in-depth analysis).

Article XX GATT 1994 contains one of the most important sets of these rules. It consists of two distinct parts: First it contains an exhaustive list of specific motives and conditions for creating trade barriers, listed in paragraphs (a) to (j). In the regulation of labelling of nanoproducts, three of these paragraphs could be relevant: measures which are (a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health; and (g) for the protection of the environment. Second, Article XX contains a general provision, the so-called *chapeau*, which in addition deals with the manner in which measures are to be applied.

To make sure that labelling regulations are consistent with Article XX GATT 1994, regulators must take three steps into consideration: (1) the measure must pursue one of the specific objectives listed in paragraphs (a) to (j); (2) the measure, depending on the specific paragraph, must either be necessary to achieve the objective or, in the case of protection of the environment, it must 'relate to' the pursuit of the policy; and (3) in addition the measure must *be applied* in accordance with the chapeau (Cottier, Oesch, and Fischer 2005, 429). Basically, the chapeau prohibits the application of a (otherwise legitimate) measure that would constitute an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. In other words, measures which primarily aim at protecting domestic industry are forbidden. The Appellate Body has explained that the chapeau serves to ensure that Members' rights to avail themselves of exceptions are exercised in good faith to protect interests considered legitimate under article XX GATT 1994, not as a means to circumvent one Member's obligations towards other WTO Members (WTO 2007. *Brazil – Retreaded Tyres,* para. 215).

As shown above, Article 2.2 TBT provides that technical regulations must not be prepared, adopted, or applied with a view to or with the effect of creating *unnecessary* obstacles to trade. The article continues that, for this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non fulfilment would create. Similar to Article XX GATT 1994, the article then offers a list of such legitimate objectives. The

difference here is that the list is not exhaustive but is introduced by the wording: 'Such legitimate objectives are, inter alia'. Besides the protection of human health and safety, animal and plant life and health, and the environment, the prevention of deceptive practices is also explicitly included in Article 2.2 TBT. According to the Appellate Body, the objectives listed in Article 2.2 TBT (merely) provide a reference point for further legitimate objectives. It continued to confirm that the provision of consumer information on origin is a legitimate objective within the sense of Article 2.2 TBT (WTO 2012b. *US-COOL,* para.370*)*.

The SPS neither contains an exhaustive list of legitimate objectives as in Article XX GATT 1994 nor an indicative list as in Article 2.2 TBT. It does, however, in Article 5.7, allow WTO Members to provisionally adopt 'precautionary' health or plant measures according to the available relevant information in cases where the relevant scientific evidence is not sufficient.

In international environmental law, it is often assumed that the precautionary principle is gradually developing into an 'emerging principle of international environmental law'. On the one hand, the precautionary principle cannot be given direct effect in WTO dispute settlements, as the WTO dispute settlement bodies only have the capacity to determine rights and obligations under WTO rules. On the other hand, WTO Members are obliged to respect all their obligations at the same time, and a precautionary principle would be of equal hierarchal value to the WTO Agreements which would need to be recognised by the WTO adjudicating bodies under international law. For the undisputed right of Members to determine their own appropriate level of protection under GATT 1994, TBT and SPS can be seen as an indication or a component of the precautionary principle, allowing Members to deviate from the basic rules in order to meet their defined level of protection (Marceau and Trachtman 2014, 400–401). In other words, WTO Members can even to some extent apply the 'precautionary principle' as a kind of 'safety first' approach to deal with scientific uncertainty (Ward 2002).

4. Discussion and conclusions

The knowledge about the safety of nanomaterials has increased considerably in the past decades due to large research programmes. Nanoregulation has been developed in industrial countries, especially notification procedures to inform Government Authorities when industry places nanomaterials on the market.

Nanoinformation is crucial for nanosafety along the life cycle of nanomaterials. Transparency on nanocontent offers advantages for producers,

downstream users, and consumers of nanoparticles. However, there are differences in the perception of nanoproducts between Asia and Europe.

Consumers in Asian countries like to buy products with nanoparticles because they appreciate their advantages. Therefore, many products are advertised as being nano, even if they are imitations. Thailand has therefore introduced the certification system 'NanoQ' which helps to distinguish between genuine and fake nanoproducts. Nonetheless, Thai industry is against an obligation of declaring nanocontent, fearing to force companies to disclose confidential business information which could then be copied.

In the European Union and Switzerland, industry often fears harm through stigmatisation if companies have to declare nanoparticles in consumer goods. Many of them prefer not to label their products even if they do contain nanoparticles. GHS classification for dangerous substances is only used for chemicals, biocides, and plant protection products. Cosmetics do not need to be classified according to GHS. However, product labelling in order to inform the consumer about the content is useful. A product label indicates the presence of nanomaterials in a product independently from its hazard. However, declaration of nanomaterials has only been introduced for a few product categories, such as cosmetics and biocides. The authors are convinced that such regulation is necessary to protect human health and the environment from hazards and risks arising from nanomaterials and to assure the consumers' right to know whether they are buying products with nanomaterials or not.

In spite of the different perceptions in Asian and European countries, neither of them are keen on declaring nanoparticles in products and regularly argue that mandatory labelling requirements, as technical barriers to trade, would be incompatible with WTO law.

So far, a globally harmonised regulation for manufactured nanomaterials does not exist. In particular, no final science-based working definition of nanomaterials has been internationally agreed upon. Nonetheless, work is well underway and ISO's definition for the private sector provides an effective foundation for the meantime. The well-designed gathering of information forms the first step in adaptive risk assessment and regulation. Legal provisions – existing and future ones – that allow for the explicit inclusion of nanomaterials and the declaration of their existence in national and regional legislation add clarity and encourage the safe handling of manufactured nanomaterials along the whole nano life cycle, starting at the workplace where nanomaterials are produced, continuing to the final phase when nanomaterials end up in the environment.

For the protection of workers at the workplace where nanomaterials are manufactured, the WHO has already developed valuable guidance.

For products not covered by the GHS classification and labelling requirements, information for consumers, for example by way of declaration, is still lacking. The same goes for the management of nanowaste.

A promising future avenue for progress in nanosafety may be the application of GHS classification criteria to nanomaterials and the full implementation of information requirements in the material safety data sheets to all downstream users of nanomaterials.

This contribution offers some examples of existing nanoregulations and has demonstrated that future legal amendments can well be structured in a way that is compatible with WTO law, as long as the various disciplines under GATT 1994, TBT, and SPS are respected. Avoidance of discrimination of imported products will be of importance, and restrictions must not go beyond what is necessary to achieve the regulatory purpose of protecting consumers, health, or the environment. It goes without saying that legal measures must not serve protectionist purposes to the benefit of domestic industries.

Disclosure statement

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