Dilemmas of economic interests versus protection of human health and the environment influenced by the need to manage innovation.

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CONTENT

I. Introduction.

The actual economic situation and the growing awareness of environmental and health concerns are at the basis of an increasing number of innovative projects. Inherent to the innovative character of these initiatives is the uncertainty on possible risks and their influence on the actual societal organization. It is important that before bringing innovations to the market, regulation should happen in order to avoid irreparable damage or negative impact on humanity or environment. On the other hand, if we want to guarantee welfare, the economic system, including trade, should also be taking into consideration. An interdisciplinary understanding of the topics at hand is necessary, not only to analyze the applicability of existing rules, but also for the development of new legislation.

As Henk Ten Have of COMEST stated "*The current revolution in science and technology has led to the concern that unbridled scientific progress is not always ethically acceptable."*[1] The Commission on the Ethics of Scientific Knowledge and Technology (COMEST) is one example of the overall growing interest in balancing economic and scientific interests with ethical (societal) standards. Protecting the human health, the environment and the world rises on the agenda.
This increasing importance of protection is partially based in the evolution of our society into more and more risk aversion. The public is concerned about several new developments and about the impact thereof on the quality of life, rights and freedom. The development and implementation of effective risk management is a permanent challenge. Not only has each new technology or concept its own particularities and its own set of risks, there are also huge differences risk perception across countries, individuals and social groups.[2] But if we cannot manage this risk perception, it might well become an obstacle to innovation and evolution.

On the basis of an analysis of REACH this paper aims to give some insight in the challenges and bottlenecks of new legislation adopted in line with the changed priorities in society. REACH is however a complex and technical regulation. The many official and semi-official interpretations of the regulation create uncertainty. Changes and interpretations are often influenced by different stakeholders, adding to the complexity, and reducing transparency and stability.
To give you a concrete idea of these issues, we will analyse the role of the precautionary principle, how transparency and stability influence the effectiveness of the regulation and the impact of REACH on the world economic system.

[1] TEN HAVE, H. e.a., *Ethics of Science and Technology, Explorations of the frontiers of science and ethics*, United Nations Educational, Scientific and Cultural Organization, France, 2006, p. 6, unesdoc.unesco.org/images/0014/001454/145409e.pdf (last visited on 11 March 2010).
[2] SMITH, R., *The Dangers of Risk aversion*, United Kingdom, The Royal Academy of Engineering, 2007, p. 4, www.raeng.org.uk (last visited on 20 March 2010).

The result could be that this paper raises more questions and discussion than it provides answers. However, discussions amongst stakeholders often give new views leading to creative ideas. Hopefully this document can be a small contribution in the process.

II. REACH: an example of a new approach.

Governance of risks and protection of human health and the environment have become important in our society. But developing an acceptable risk management is not easy, certainly not if the risks are uncertain.

The REACH regulation was approved on 18 December 2006. It replaces the old outdated chemical rules and harmonizes chemical legislation in Europe. For this purpose some innovative concepts were introduced. For example a chemical is no longer considered safe until the opposite is proved, companies now have to prove the safety of the substance.

These concepts are supported by several principles that were explicitly incorporated in the regulation: the Precautionary Principle (article 1), the Substitution Principle (article 55 and 62), No Data – No Market (article 5) and the Right to Know (article 33), plus in socio-economical area respecting free trade, supporting innovation and enhancing competition (article 1).[3]

Or in other words, the REACH[4] regulation combines economic objectives with the aim to provide a high level of protection of human health and the environment, whilst enhancing competitiveness and innovation.[5]

1. The Precautionary principle

REACH formally recognizes the precautionary principle as a tool to achieve its environmental and health objectives. Article 1 (3) explicitly mentions that the provisions of REACH are "underpinned by the precautionary principle".

a) What is the precautionary principle?

Several[6] definitions exist, varying in wording and in strength. The comparison of these definitions gives us an overview of the most important elements:

- All refer to the essence of the principle: prevent, eliminate, reduce, avoid and control pollution, damage or harm to the environment, the people, the 'world';
- Most refer to risk assessment and the fact that inadequate or inconclusive scientific evidence is not a reason to postpone control and safety measures;

[3] The references to the articles is not exhaustive.

[4] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 nd Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, *O.J. L* 396 of 30 December 2006, p 3 – hereinafter referred to as REACH

[5] Preamble 1 REACH Regulation

[6] HOPPENBROUWERS, M., *The Precautionary Principle*, Leuven, Master International Environmental and Energy law, 2007, p 1-2, not published.

- Some refer to economic feasibility, through taking into account socio-economic contexts, polluter pays, cost-effectiveness of the measures
- Very few mention sustainable development and co-operation between parties.

For the purpose of this paper the precautionary principle will be defined as[7]:
"When human activities may lead to harm that is scientifically plausible but uncertain, we shall prevent, diminish and control their impact.
Harm refers to damage to humans, animals, plants and/or the environment that is:

- *Threatening to life or health,*
- *Serious or effectively irreversible*
- *Inequitable to present or future generations."*

The assessment of the harm should be based in scientific analysis. However the analysis should reflect the complexity of our world, consider the uncertainties and take into account that causal relations are not always linear. In other words: the scientific analysis should use the newest insights and put itself under ongoing reflection/review.

b) Where do we find the precautionary principle in REACH?

Besides the clear mentioning of the principle in article 1 (3) of REACH, one can find reference in other articles and annexes. Also in the guidance documents[8] of ECHA[9] is the principle present. A few examples are mentioned below.

Article 57 (f) REACH describes substances of equivalent concern. These are substances for which there is scientific evidence of probable serious effects to human health and the environment. The word "probable" is important. Scientific evidence should point out that harm by these substances is plausible but not certain.
The concept of "equivalent concern" is especially useful in cases where it is difficult to estimate risk using traditional risk assessment methodologies, but where there is a probability of risks and effects of concern from which ecosystems should be protected. The guidance on identification of Substances of Very High Concern (SVHC) explains the concept further.[10] Another reason to decide that protection is necessary is that if the harmful effects occur, these will be difficult or impossible to reverse.[11] Thus it is the dual uncertainty caused by lack of evidence and knowledge

[7] Ibid., p 3.
[8] Guidances provide interpretations of the REACH obligations, but are not legally binding documents. They have been developed by different stakeholders: industry, Member States and NGOs with the objective to advice on good practices and how to fulfil the obligations under REACH. The final version of a guidance is approved by ECHA and the Commission, whereby they follow the majority of the Member States in case of dissenting opinions.
[9] ECHA: European Chemicals Agency
[10] ECHA, Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern, June 2007, p. 23, http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.pdf (last visited on 30 March 2010).
[11] Ibid., p 24.

up to what level the substance is safe and the ignorance of the consequence that justify precaution. In fact this is applying the precautionary principle.
A similar reasoning is used to define "future equivalent concern" relating to on the moment unidentified properties of some dangerous substances, but on which already some scientific evidence is available that leads to concern. A concrete example is the lack of knowledge on how a chemical substance will behave in the environment. The guidance clearly encourages authorities "*to employ the underlying principle*"[12], i.e. the precautionary principle.

c) The story of the button on the jacket or dissenting opinions on SVHC[13] in articles.

Taking into account the cultural, individual and social differences in risk perception, a harmonised rule like REACH could create some issues between social groups and between member states. When some group or state would find it necessary to implement more strict risk management based on the precautionary principle, i.e. harm is scientifically plausible but uncertain, this is nearly impossible.

A concrete example is the actual dissenting opinion of six member states concerning the calculation of the concentration of SVHCs in articles.[14]
Article 7 (2) of REACH sets a threshold for notifying ECHA, in case SVHCs are present in an article: *"... b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w)."*
The only definition of an article in REACH can be found in article 3 (3): *"article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".*
Only the guidance contains a brief description of complex articles:
"An article is to be understood as the article as produced or imported. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported".[15]
Then the ECHA guidance document states that the limit of 0,1% weight by weight should be calculated in relation to the complex article as produced or imported. This means compared to the total weight of the whole "composed" article. Producers and importers have an economic interest in calculating the limit to the whole composed article.
However, and despite this economic advantage, six members states - Sweden, Denmark, Austria, Belgium, France and Germany – disagree with the interpretation of ECHA of article 7 (2) in the guidance. According to the dissenting member states, the precautionary principle is ignored in the interpretation of ECHA concerning the calculation of the limits of SVHC. These states are

[12] Ibid., p 33.
[13] SVHC: Substances of Very High Concern
[14] Article 7 (2) REACH
[15] TEMANORD REPORT, *REACH Trigger for Information on Substances of Very High Concern (SVHC) – An Assessment of the 0.1% Limit in Articles*, Copenhagen, © Nordic Council of Ministers, 2010, p. 21.

convinced that the limit value should relate to individual articles, parts or materials that a complex article consists of.
The concentration threshold of 0,1% weight by weight calculated in relation to a complex article differs considerably from the same calculation in relation to individual articles or parts of a complex article.[16] It leads to arbitrary differences in application depending on whether the article is marketed as a separate part or integrated in a complex article. An example is the case of SVHCs in plastic shoes. The slipper of Bjorn Borg contains in the strap over the foot and between the toes 8,40 % of DPB (a Phtalates) what is classified as a SVHC. Calculated to the whole shoe, the limit of 0,1 % w/w is however respected.
The member states have, in line with their dissenting views, not endorsed publication of the parts of the Guidance that relate to the interpretation of the limit.
Can they do that? The text of article 7 (2) of REACH[17] leaves room for interpretation. Since a guidance is not legally binding and a complex article is not defined in the REACH regulation, one could argue that the interpretation of article 7 (2) of REACH as laid down in the guidance disregards the precautionary principle. The interpretation of the dissenting member states leads to more prudent and safe handling of SVHC in articles. Indeed the limit will be attained faster compared to part of the article then to the complex article as a whole.[18]
On the other hand, the fact that REACH is based on article 95 of the EC Treaty[19], is an argument that will probably be used when defending the actual calculation method. Some stakeholders could claim that the procedure for deviation from a harmonization rule must be followed.
The REACH regulation harmonizes an important part of the chemical legislation in Europe and in principle member states cannot deviate from it. Except when they follow the procedure and when the proposed regulation does not disturb the working of the internal market and that their motivation is based on new scientific evidence and specific problems. Then the Commission has to accept and approve the deviating rule. In practice it will be impossible to attain approval for a deviation from REACH on the national level.
The European court will probably have the last word in this discussion.

d) How many substances should be on the candidate list for authorisation?

In future chemicals included in the list of substances subject to authorisation[20] cannot be placed on the market or used without authorisation. The aim of the authorisation is *"to ensure that risks*

[16] Dissenting views on the Guidance on requirements for substances in articles, received from Austria, Belgium, Denmark, France, Germany and Sweden, 18 p., available on guidance.echa.europa.eu/guidance_en.htm (last visited on 2 April 2010).
[17] The notification provisions in Article 7(2) will enter into force June 2011 – article 7 (7) REACH.
[18] TEMANORD REPORT, *REACH Trigger for Information on Substances of Very High Concern (SVHC) – An Assessment of the 0.1% Limit in Articles*, Copenhagen, © Nordic Council of Ministers, 2010, 115 p.
[19] EC Treaty, Nice consolidated version
[20] Annex XIV REACH

from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically viable".[21]

The first step in the authorisation process is the inclusion of a SVHC in the candidate list. At this moment the candidate list contains 16 substances[22], much to the dissatisfaction of several stakeholders, not only NGOs, but also six member states[23].
These six states formed an informal working at the CARACAL[24] meeting in March 2009 and developed a list with 478 substances making it easier for Member States to select the most relevant substances for inclusion as SVHCs on the Candidate List.[25] This list is also inspired by the SIN list[26] made by ChemSec. ChemSec[27] is a non-profit organisation focussing on hazardous substances and willing to speed up the legislative processes for protection against SVHCs.
Both the action of the six Member States and the SIN list are in sharp contrast with the inclusion of only 16 substances on the official candidate list of ECHA. It is also an example of the influence society and its norms and culture can have on the opinion of authorities, i.e. that member states suggest a faster and more severe list than what the regulator is actually proposing. Both the SIN list and the member state's list are based on scientific evidence and a practical application of the precautionary principle in all cases of uncertainty.

Recently, Vice President Tajani and Commissioner Potočnik have followed up a request of the European parliament to speed up the process on authorization and visited ECHA. *"They are taking action to make progress towards the registration of chemicals and the management of substances of very high concern."*[28]

[21] Article 55 REACH
[22] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp
[23] This group of Member States, including the Netherlands, Germany, Austria, France, Sweden and Denmark, has now agreed on a list of 478 substances, corresponding to 90 percent match with the SIN List.
[24] CARACAL: Competent Authorities for REACH and Classification and Labelling
[25] www.chemsec.org/list/latest-on-sin
[26] SIN = Substitute It Now
[27] The International Chemical Secretariat
[28] Commission press release, Chemicals: New European Commission determined to make REACH a success Brussels, 25 March 2010, IP/10/360, http://ec.europa.eu/commission_2010-2014/tajani/headlines/press-releases/index_en.htm.

2. The principles of transparency and accountability.

Respecting the REACH obligations should lead to safe handling and use of chemicals. The objective is clear, but the complexity lies in attaining the targets. Guidance documents and fact sheets provide supplementary information to the legal text trying to assist regulatees in meeting their obligations.

The fact that such extensive explanation is necessary and even not always sufficient leads to the conclusion that the Rule of Law[29] is not always respected.

In this paper we will focus on the principle of transparency and of stability. Two examples are described to concretize the complexity and the confusion.

a) Big discussions on small material.

REACH applies to substances regardless their size, shape or physical state. Consequently nanomaterials are subject to the regulation despite the fact that there are no specific provisions for these nanosized substances and that specific issues surface. The result is that different opinions existed and still exist. Following is an overview, demonstrating some of the important issues.

In December 2007 ECHA declares at the NanOSH Conference in Helsinki[30]: "*REACH treats both, the bulk material and the nanosized material as the same substance".* The Agency added that this, however, does not prevent the registrant from identifying dangerous properties of this substance depending on its size and classify the different types accordingly.
In practice such a statement does not help. It creates an ambiguous situation for companies. Could insurance companies, for example, impose separate risk assessment with such a statement of the Agency, when the nanomaterial is considered to have fulfilled the requirements because its bulk form did? Would not assessing the nanosized substance separately be judged 'bad management'?

It is paramount to keep in mind that nanoparticles differ from their larger forms, although their chemical structure is the same. They have enhanced or different properties: toxicity, chemical or photo-reactivity, persistence, solubility, bio-accumulation, explosion, etc. One year later, December 2008, a report "Nanomaterials in REACH" is published[31]. It is recognised that the

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[29] RULE OF LAW
1. The government and its officials and agents are accountable under the law;
2. The laws are clear, publicized, stable and fair, and protect fundamental rights, including the security of persons and property;
3. The process by which the laws are enacted, administered and enforced is accessible, fair and efficient;
4. Access to justice is provided by competent, independent, and ethical adjudicators, attorneys or representatives, and judicial officers who are of sufficient number, have adequate resources, and reflect the makeup of the communities they serve.
(the World Justice Project, http://www.worldjusticeproject.com/rule-of-law-index/)

[30] Hoppenbrouwers M., If you lose them, you'll never find them again, Master Thesis International Energy and Environmental Law, Leuven, 2007-2008, p 2 (not published).

[31] Nanomaterials in REACH, Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH) 15-16 December 2008, Brussels, 16 December 2008
Doc. CA/59/2008 rev. 1, http://ec.europa.eu/index_en.htm.

registration for substances at nanoscale can be more complex[32], especially when the same substance exists in the nanofrom as well as in the bulk form.
"In such a case not only the information of the substance in the bulk form should be included in the registration dossier, but also any information regarding intrinsic properties where the properties of a substance in the nanoform differs from the bulk form, any different classification and labelling, any different chemicals safety assessment as well as all identified uses (see also Annex VI.3 of REACH) and relevant exposure scenarios for the nanoform of the substance."[33]
But even still at this moment, the Technical Guidance on substance identification[34] considers that *"the current developments in nano-technology and insights in related hazard effects may cause the need for additional information on size of the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD".*

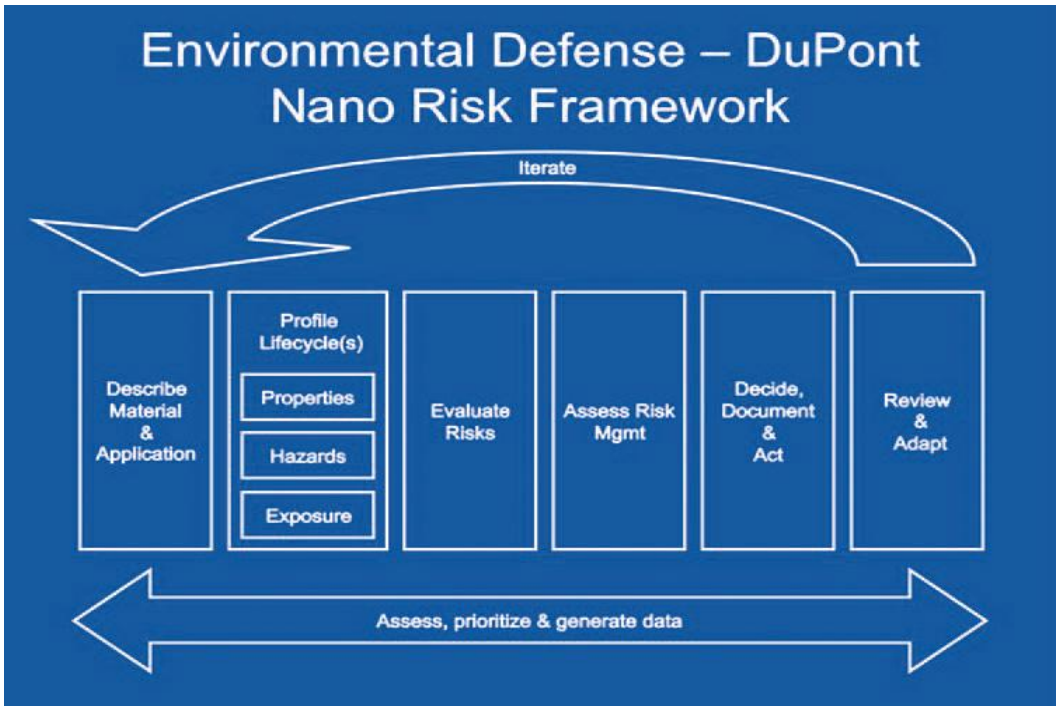
In line with the statement of ECHA in 2007 that a registrant can classify substances on properties related to size and classify the substances differently although the chemical identity is the same, we can conclude that the sameness analysis is in the hands of the registrants.
Nevertheless, the outcome of this analysis is not at the discretion of potential registrants but must be in line with the substance definition, information related to molecular and structural formula, composition and other relevant provisions of REACH. Any decisions taken by SIEFs may therefore also be challenged, e.g. by ECHA during the compliance check.
Quite some room for interpretation thus, and this is certainly not to the benefit of transparency and effectiveness. This ambiguity has already led to two groups of companies using different criteria to submit data on carbon nanotubes to ECHA. One group is planning to classify the carbon nanotubes as different substances and the other group will register the nanotubes as a form of bulk graphite so that they will not need to submit a separate registration dossier.[35] We are still far from a transparent and stable policy and regulation in this matter.

Several stakeholders are also concerned that most nanomaterials will escape registration because of the volume requirements. Despite the assurance by the chemical industry that most substances at nanoscale are produced in high volumes[36], the "public" remains concerned.
To prevent and/or counter a negative public opinion, some private initiatives were taken: the Nano Risk Framework of Dupont and Environmental Defense and the ISO standard on nanotechnologies.
Trying to protect their research and development in nanotechnology, Dupont, a transnational chemical company has developed together with Environmental Defense, a non-profit

[32] This is the case for phase-in and non-phase-in nanomaterials, although the report only refers to phase-in nano when mentioning the extra complexity.
[33] Ibid. p 8.
[34] ECHA, Guidance for the identification and naming of substances in REACH, June 2007, p 28,
[35] Nanomaterials cause classification headache for Reach, RSC, 16 June 2009, www.rsc.org/chemistryworld/News/2009/June/16060901.asp, (last visited on 14 March 2010)
[36] Ibid. p 13.

environmental advocacy group the "NANO risk framework". The objective of the framework is to manage and reduce potential risk during the whole lifecycle of nanomaterials[37] by:
- identifying potential hazards to human health and the environment
- assess the potential release and exposure to nano's
- manage risks to workers, consumers, the general public and the environment during production, use and disposal.

The 3 elements (hazards, properties and exposure) work together in the sense that they point out were the highest risk is[38] and where eventually compensation is possible.[39]
The framework is on several aspects in line with the stipulations in REACH.



Another self-regulating initiative was taken by the International Standards Organisation (ISO). They are working on approximately 20 standards related to nano[40] with the objective to *"[ensure] that the full potential of nanotechnology is realized and that nanotechnology is safely integrated into society. Standards will help create a smooth transition from the laboratory to the marketplace, promote progress along the value chain... and facilitate global trade."*[41]

[37] Contract letter of August 30, 2005, www.environmentaldefense.org
[38] Nano Risk Framework, Environmental Defense and Dupont, www.nanoriskframework.org, p 27-83
[39] Ibid. p 83
[40] TC/229 – Nanotechnologies, www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?Commid=381983&development=on
[41] ISO/TC229 N 230, *Business plan ISO/TC 229 Nanotechnologies*, 23 April 2007, isotc.iso.org, p 1

To achieve results ISO will liaise and coordinate with, for example, the European Community Joint Research Centre, OECD and APEC.[42]

The Competent Authorities of the Member States state in their report that "companies and industry associations are encouraged to continue and intensify their own actions and assist authorities in elaborating the relevant information".[43] Self-regulation thus, as they believe it will help to gain confidence in the pro-active role of industry to ensure the safe use of substances at nanoscale.

b) The dilemma of reacted or unreacted monomers.

REACH exempts polymers from registration. Polymers consist of monomers. Are the latter then also exempted?

The first REACH legal challenge was initiated even before the regulation entered into force. Three European companies (from France, Germany and the United Kingdom) and one USA company started the procedure in the United Kingdom, but their complaint was quickly referred to the European Court of Justice for a preliminary ruling.[44]

Two questions were raised. The first question was if the monomer substances, referred to in article 6(3), are these reacted or unreacted monomers or both? The second question was if the application of Article 6(3) is irrational, discriminatory or disproportionate?

Both questions demonstrate again that the texts of REACH are not that transparent and that some topics[45] could lead to discussions on free trade. Without going to far into technical details, following are some points of interest within the framework of this paper.

Article 6 (3) of REACH obliges a manufacturer or importer to register monomers (or any other substance) that are not already registered if:

- the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
- the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

Thereby one should remember, referring to the definition of a polymer in article 3 (5) of REACH, that a polymer is composed of monomer units, which have reacted to form that polymer.[46]

Unreacted monomers must[47] anyway be registered inasmuch as they constitute substances on their own.

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[42] Ibid., p 10

[43] EUROPEAN COMMISSION, Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH), Brussels, December 2008, Doc. CA/59/2008 rev. 1, 21p, http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf (last visited on 2 april 2010).

[44] Case 558/07, Reference for a preliminary ruling: High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) - United Kingdom, 7 July 2007, http://eur-lex.europa.eu/Result.do?RechType=RECH_celex&lang=en&code=62007J0558 (last visited on 14 March 2010)

[45] Par. 32, Case 558/07

[46] Article 3 (5) of REACH.

The Court concludes on the basis of above that "*the concept of 'monomer substances' in Article 6(3) of the REACH Regulation relates only to reacted monomers which are incorporated in polymers"*.[48]
Consequently the monomers fulfilling the conditions of article 6(3) should be registered, with the remark that it only concerns monomer substances which have not yet been registered up the supply chain and that only monomer substances with their own characteristics as they existed before the polymerisation should be registered.[49]

Concerning the second question if the requirements are irrational, discriminatory or disproportionate, the applicants stated that importers faced difficulties because it is particularly difficult to get information from non-European manufacturers and because the costs for registration is not proportionate to the quantities imported.
The Court stated that importers and European manufacturers are treated the same way and that consequently the burden is not heavier for manufacturers from outside the Community or importers.[50]

To summarize: the European Court of Justice confirms that REACH applies to reacted monomers and dismisses claims of unfairness against importers.

3. Trade in chemicals threatened or not?

In 2006 Asia expressed concerns on REACH at the WTO meeting. The list contained for example remarks on mandatory substitution of substances, requirements for monomers in polymers, guidelines and procedures.
But China was creative and found another solution then putting forward claims. In 2008 the China Chamber of Commerce of Metals Minerals & Chemicals Importers & Exporters has decided to open a representative office in Helsinki, Finland.[51]

Another example of the problems that non-European countries encounter, is following citation of a complaint Argentina filed with the WTO in 2008.
"The recent introduction of the pre-registration period for chemical substances and preparations has highlighted the limited capacity of the EC authorities and the European Chemicals Agency (ECHA) to provide adequate technical assistance to potential users. When difficulties arise due to the complexity of the REACH Regulation, the lack of proper technical assistance serves to

[47] Article 6(1) and (2) of the REACH.
[48] Par. 27 Case 558/07.
[49] Par. 34 Case 558/07
[50] Par. 67 Case 558/07
[51] HELSINGIN SANOMAT, Chinese chemical industry to open office in Helsinki, www.hs.fi/english/article/Chinese+chemical+industry+to+open+office+in+Helsinki/1135230365022 (last visited on 5 April 2010).

heighten the confusion and concern of companies seeking to comply with REACH , particularly those that are small and medium-sized. In addition to being faced with costs that are difficult to estimate, these companies also suffer from a lack of straightforward information on the way the system works. This situation constitutes a serious impediment to the continued presence of such companies in the European market."[52]

Plus, non-European governments claim that REACH is de facto an incentive for downstreamusers to look for suppliers within the European Union rather than import their chemicals. Or are the difficulties importers of preparations (mixtures) encounter when having to register these preparations not hindering free trade? Importers often claim that it is impossible to know the full composition of the imported preparation due to the complexity of the supply chain and the reluctance of the non-European producers to share what he considers confidential business information.

But several transnational companies reacted differently. They decided to respect the obligations of REACH in all their production plants across the world. Business wise this makes sense. It (sometimes) is more costly and less efficient to adapt production in line with the export destination of the substances and at the same time problems with import in Europe are avoided. This strategy will give those companies also a competitive advantage for trade with Europe and for coming regulations in other countries. Indeed, REACH has a considerable influence on the development of new chemical regulation throughout the world. Several non-REACH countries decided to adapt rules similar to the REACH stipulations. One example is Turkey. In December 2009 a new chemical legislation was implemented.[53] The fact that Turkey is aiming at membership of the European Community certainly was one of the reasons for this action, but we see similar initiatives in other regions of the world. In the USA the Toxic Substances Control Act is under review and REACH is considered to be a "benchmark".

Countries, like Malaysia, Korea or Taiwan hope to boost the export of chemicals by adapting chemical management regimes in line with REACH. China tried to improve the legal controls on dangerous chemicals, as well as the enforcement of the rules.[54] Japan also reviewed his law on the Control of Examination and Manufacture of Chemical Substances in line with REACH.[55]

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[52] This communication, dated 25 June 2008, is being circulated at the request of the delegation of Argentina, http://docsonline.wto.org/GEN_highLightParent.asp?qu=REACH&doc=D%3A%2FDDFDOCUMENTS%2FT%2FG%2FTBT%2FW289.DOC.HTM&curdoc=3&popTitle=G%2FTBT%2FW%2F289, (last visited 13 March 2010).

[53] Turkey aligns chemical laws with EU REACH and CLP, *Chemical Watch*, February 2010, p 10

[54] Efforts are being made to improve both the legal controls on harmful chemicals as well as their enforcement. The Environmental Protection Act, amended in 1989, underpins chemicals management. Regulations on the control of safety of dangerous chemicals, which established directories of dangerous chemicals and highly toxic chemicals, were amended in 2002. Environmental management of chemicals controlled by the 1994 law on import and export of toxic chemicals which requires registration of chemicals featured on a list of severely restricted chemicals. Five highly toxic pesticides were banned from production, circulation and use last year. A notification system for new chemicals before production and import was established in 2003.

[55] Japan also reviewed its chemicals management laws last year, with a report issued in December 2008 concluding that an amendment is needed to its 1973 Chemical Substances Control Law which was also amended in 1986 and 2003. The law requires pre-manufacture and import notification for new chemicals as well as regulation of specified

This evolution will make the issues that one might have concerning REACH and free trade void. After all, if similar regulation is adapted on a global level one could hardly argue that REACH is hindering free trade.

III. REACH: impacting more than chemicals.

With all the new technologies and with the growing consciousness of the need to protect life and environment, an intelligent approach towards regulating is necessary. Regulators cannot disregard tendencies in society, power and influence of businesses and industry, and political power. A delicate balance is needed.

It is clear that in REACH these elements are present and that the European authorities strive for a balance in respect for the environment, human health and economic welfare. However, the practical application is not so obvious.

Due to its complexity REACH suffers from a lack of transparency and stability. Some economic actors use this to their advantage, often supported by politicians. One example is the calculation of the SVHC limits in articles, whereby the calculation method confirmed in the actual guidance is more beneficial for the industry than the method proposed by the dissenting member states.

Although the inclusion of the precautionary principle as a basis for risk management, for authorizations and restrictions of chemical substances is positive, the practical implementation is weakened by the influence of some stakeholders. This influence is formalized in the guidances and practices. For example: the approach of ECHA to nanoforms of substances follows the tendancy in industry: from "no-new-substance" in 2007, to recognizing the complexity of nanoparticles in 2008.

Some actors in industry were trendsetters by their different approach to nano and its potential risks. The chemical company DuPont together with Environmental Defense, developed in 2005 "NANO risk framework". They jointly called for broad collaboration by interested stakeholders to identify and address potential environmental, health, and safety risks of nanotechnology following the framework.

The International Standards Organisation (ISO) started in 2006 with developing standards related to nano with the objective to integrate nanotechnology safely into society.

Both initiatives are examples of self-regulation and have certainly influenced the political and regulatory views on the subject.

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classes of chemicals, such as persistent, bioaccumulative and toxic or eco-toxic chemicals. The main effect of the planned amendment, which was submitted to the Japanese parliament at the end of February and could be adopted by June, is to extend requirements to all industrial chemicals under a phased risk assessment programme. The intention is to combine priority assessment. Those deemed to be a priority will need to comply with mandatory data requirements. The new chemicals notification scheme will also be modified to require planned production volume and use information in order to carry out risk screening for these substances. *Chemical Watch*, opzoeken

Also outside Europe companies and states become increasingly aware of the power and influence of social norms. Several transnational companies decide to follow REACH regardless their location and for all their products. This strategy is of course based on economic interests, but will nevertheless have an influence on the overall acceptance of the "REACH idea". This makes it less probable that claims of hindering free trade are submitted or won.
For similar reasons several countries around the world adapted regulations with obligations similar to those in REACH.
One could state that free trade is no longer an absolute goal on itself, but has become more of a means to support and bring well-being. This well-being includes respect and conservation of the environment and human health, as well as respect for the limited natural resources of the world.
Regulators, politicians and businesses cannot ignore the public opinion and social or cultural norms. Command and control is no longer sufficient. Regulatory effectiveness is based on a consensus amongst regulatees that backs the regulatory position. Then the regulation will be followed and respected[56] to the benefit of all.

Much more can be said and written on this topic, but we can already conclude that REACH is a courageous initiative and brings change in the management of chemicals, even beyond its European territory. It is also a good learning experience for all the new technologies that still have or will have to be regulated. To name a few: nanomedicine, phytoremediation and phytoattenuation, stem cell, cloning, property of human tissue, artificial life, etc.

[56] Abstraction made of the difficulty to obtain such a consensus

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