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# Restrictions on the use of lawfully marketed products and the EC's Internal Market

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Both individual freedoms and the freedom of trade are regularly set aside in pursuit of regulatory objectives. These include environmental protection, public health, national security, consumer protection etc. The room for manoeuvre for States to set such restrictions on activities and (use of) products, is generally referred to as 'regulatory autonomy'. There are many variants of course in the way the exercise of such autonomy interferes with trade. This paper, and the conference where it was delivered, focuses on just one of those: restrictions on the use of products which have been lawfully produced (i.e. in accordance with any product standards which may apply to the product at issue) and where consumers are subsequently restricted in their use of them.

This article highlights firstly the overall legal context which forms the backdrop of the debate.[1] It subsequently identifies the core elements in ensuring the legality of any future restrictions to the Internal Market, based on non-trade objectives.

## 1. The core legal context.

*[ SHE legal history ]*

The right of the state to set limits to the exercise of ownership rights, has traditionally been recognised, stretching back as far as Roman law. The Roman law maxim of *sic utere tuo*,[2] was recognised in international law, too, in the 1920s litigation between the United States and Canada over air pollution (caused by the latter). This *Trail Smelter* case highlights a number of factors which make a large part of regulatory interventions by States fairly uncontested: where the damage to someone else's property as a result of someone else's action is clearly mapped, one should not stand for it and indeed those who suffer damage are uncontestedly entitled to seek compensation. The same goes of course for damage to one's health. Occupational and public health and safety laws, developed from the 20th century onwards were precisely designed to prevent such damage from occurring, rather than waiting until the damage occurred. They were joined, in a later stage, by environmental laws. Together they are often referred to as SHE, or EHS legislation: Safety, (occupational) Health, and Environment.

*[ Less clearly established SHE risks ]*

As increasing laws mopped up the clearly established health and environmental concerns, governments' attention began to focus on less clearly established SHE risks, which gave rise to the precautionary principle: the rule, established in regional environmental laws such as in the EU, that lack of absolute scientific certainty is no excuse for inaction in the SHE area. Some national agencies and indeed judges have come to interpret this principle as a 'when in doubt, opt out' or 'when in doubt, don't do it' approach — an example not followed by the European Institutions.[3] Over and above the more uncertain risks, regulators are now also

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[1] Reference is also made to the contribution of Dr Vedder in this volume.

[2] Sic utere tuo ut alienum non laedas, or Nec utere tu ut alienum laedas : one shall not use one's property in such a way as to cause damage to someone else's property.

[3] European Commission Communication on the precautionary principle, COM (2000) 1.

having to tackle a number of 'modern' SHE challenges, such as climate change, obesity, new technologies (e.g. nanotechnology, and prior to that, biotechnology) …

*[The tension between regulatory law and other rights ]*

The exercise of regulatory autonomy typically raises tensions with two other sets of rights, namely the freedom to trade, and the freedom of the individual to exercise his own fundamental rights to privacy, enjoyment of property etc. This means that regulatory interventions will have to take account of two different sets of laws, each covered by a variety of legal instruments, which may and often do, vary depending on the jurisdiction in which one operates:

— Laws and Treaties aimed at the free movement of goods: including but not limited to the Agreements establishing the World Trade Organisation; the European Community (formerly the European Economic Community; at the national level, relevant constitutions (e.g. the 'commerce clause' in the United States Constitution; the Belgian Economic and Monetary Union in the Belgian Constitution)…; and

— Laws and Treaties aimed at protecting fundamental rights: including but not limited to the European Convention on Human Rights – ECHR; the Treaty on European Union (including the European Community – which has important regulatory powers over and above free trade provisions, but also e.g. the Charter on Fundamental Rights); relevant constitutions.

*[The balancing act ]*

The balancing act between freedom of trade and individual freedoms, on the one hand, and the protection of health sought by the regulators, weighs more in favour of the regulators, where the regulation does not just impact upon the freedom of the individual whom is being regulated, but also involves the impact of the *lack* of regulation on the individual freedoms and health of others. The latter may be minors, employees working in the environment where the harmful activity takes place, fellow users of infrastructure etc. Moreover, in many health-related interventions, the authorities will invoke the impact which a lack of action would have on future health costs, as part of the benchmarks against which regulatory intervention will be set. This featured very heavily, for instance, in the impact assessment studies which accompanied REACH, the EU's new chemical policy.[4]

*[The importance of European regulation ]*

In the European context, whether regulators act within the law in the public health field, is to a large degree determined by European law. National restrictions on the use of goods then become what is called 'pre-empted'.[5]
It is noteworthy that EU law rarely imposes restrictions which directly regulate the *use* of a product (e.g. smoking bans, or minimum age requirements, or restrictions for environmental

[4] Regulation 1907/2006.
[5] See e.g. G. VAN CALSTER, 'Export restrictions - A watershed for Article 30', *European Law Review*, 2000, 335-352; and G. VAN CALSTER, 'The harmonisation of national environmental standards in the EC – Highlight or demise for common European environmental values?', *Environnement & Société*, nr. 26 (2001), special thematic issue 'Normes et environnement', 19-26..

reasons): amongst others for reasons of subsidiarity, the EU's preferred method of regulation of products, are product standards.[6]

*[The high status enjoyed by human health protection, and the protection of the environment]*

Whenever one reviews the legality and political attainability of authorities' intervention with recourse to public health as well as environmental arguments, one has to be aware that both enjoy a high status in EC law. Article 152(1) EC states that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities; similarly, for environmental protection Article 6 EC provides *Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3, in particular with a view to promoting sustainable development.*

Public health in particular has been repeatedly underscored by the European Court of Justice as trumping free trade (see e.g. the *Pfizer* and *Alpharma* judgments[7]), and in general the ECJ has held that, if the European Commission is to be able to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion.[8] National jurisdictions have taken a similar line.

*[The discipline required of regulatory authorities – and scientific proof ]*

However, the exercise of the aforementioned discretion is not excluded from judicial review. According to settled case-law at the ECJ, in the context of such a review the Community judicature must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of assessment or a misuse of powers.[9]

In particular, where a party claims that the institution competent in the matter has made a manifest error of assessment, the Community judicature (i.e. the Court of Justice) must examine whether that institution has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached.[10]

A similar requirement for scientific discipline exists at the level of the World Trade Organisation, with the Agreement on Sanitary and Phytosanitary Standards, for instance, requiring objective science, subject to peer-review, to be the basis for regulatory standards. The *WTO* has however recognised that 'maverick science', i.e. non-mainstream research, may form the basis for restrictive measures, provided it is objectively verifiable. The Agreement on Technical Barriers to Trade, from its side, insist that trade restrictive measures must not be 'more restrictive than necessary' to reach the goals of regulatory policy which they seek to achieve. A similar test applies to the proportionality assessment of restrictions on human rights enjoyments, at the level of the European Convention on Human rights.

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[6] While the process of producing them is of course regulated by a wide variety of process-related laws.
[7] Case T-13/99, *Pfizer v. Council* [2002] ECR p. II-3305,Case T-70/99 *Alpharma* v Council [2002] ECR II-3495.
[8] Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557 ('*IQV*'), paragraph 75.
[9] Case 98/78 *Racke* [1979] ECR 69, paragraph 5, and Case C-16/90 *Nölle* [1991] ECR I-5163, paragraph 12; see also see *Alpharma* v *Council*, paragraphs 177 to 180.
[10] Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14.

## 2. The low uptake of restrictions of use for environmental purposes, in both European and national law

When reviewing restrictions of use for environmental purposes, it becomes fairly immediately apparent that very little recourse is made to them, either by national or by European authorities. The *Mickelsson* Case below is one of very few examples (restrictions on the lighting of bonfires in private gardens in some Member States, another).

In the case of European law, this is in no small measure due to subsidiarity considerations. The instrument of choice for European environmental law are Directives which are either process-based or relate to product standards. Those that are process-based, are all the so-called 'procedural' or 'horizontal' laws which aim to regulate (in the main) manufacturing processes likely to have an impact on the environment. The preference for product standards as a legal instrument is a legacy of the early stages of EC environmental law, when the European Commission had to justify its interference in national environmental matters by reference to the Internal Market implications of divergent national environmental laws (this is prior to the introduction of an environmental title proper in the Treaty). Evidently, many of the product standards have an immediate impact on the question as to whether further, specific restrictions to use have any residual value. Consider e.g. the case of noise pollution. Where EC law already provides for a noise emission standard for mopeds, it sharply reduces the need for the introduction of local laws to deal with the nuisance caused by the revving engines.

Further restrictions to use for environmental purposes which are not an implied consequence of EC-defined product standards, are considered to be apt only in the face of local circumstances, and therefore fall foul of the subsidiarity principle (which suggests or indeed in the case of EC law, proscribes, that regulatory action be taken as close as possible to the level where it is going to have the maximum impact. In the case of the EC this has led to a general presumption against the EC being the appropriate level for action).

Indeed there are other areas of regulatory concern where restrictions of use have either taken flight some time ago or are being increasingly mooted, and which may well inspire more such examples in the environmental sector. As the examples below illustrate, public (and occupational) health and safety for the time being would seem to be the driving factor behind these initiatives:

‡ Telecoms, health and use restrictions: see e.g. the tendency in a number of schools to scale back or completely remove the use of wireless internet technology; government guidelines on the safe use of mobile phones; restrictions on the *installations* of mobile phone masts;
‡ Public safety, human health and use restrictions: these relate in particular to road safety, and refer to e.g. the obligatory wearing of cycling helmets, and the prohibition of MP3 players in traffic;
‡ Food and health: e.g. limiting sales options in fast food restaurants (mooted only so far, as far as the author is aware), restrictions on the use of alcohol and tobacco products;
‡ Infotainment and health, e.g. the widely publicised idea of the German federal government to prohibit paintball, or sales restrictions on computer games (in particular because of their violent or sexually explicit contents);
‡ Healthcare, and general welfare: e.g. restrictions on points of sales for medicines, restrictions on the use of nanotechnology in food processing.

As a result of there not being all too many examples of use restrictions for environmental purposes at the national level, inevitably of course there is not much ECJ case-law on them either.[11] In *Commission* v *Austria* (Tiroler lorry restrictions),[12] Austria was rapped for not having even considered less trade-restrictive alternatives to far-reaching use restrictions, other than a ban on specific types of transport during specific periods. This judgment underlines the need for sound and properly prepared science as a requirement for use restrictions with trade impact to be kosher. Whereas in the *Tiroler* case though the trade impact of the measure was clear, this is different in those cases were restrictions of use are applied indiscriminately and without even a hint of protectionism. It is in this context that calls have been made to simply regard such modalities or restrictions of use as not being covered by the prohibitions of Article 28 and 29, much like in the case of 'modalities of sale' in the *Keck* route. In *Commission* v *Italy* (motorcycle trailers),[13] the Court refused to rule on that question, opting instead for a market access test. If restrictions of use (in the case at issue: a prohibition) has a considerable influence on the behaviour of consumers, it affects the access of that product to the market of that Member States and falls foul of Article 28 EC. However the Court granted Italy the right to introduce the ban on public interest /mandatory requirements grounds, in the process however giving Italy a very easy ride on the least-trade restrictiveness test (it would seem that the Commission could have pressed Italy more on the issue of proportionality).

*Mickelsson*[14] is the case which might shed some light on the exact room for Member States to seek restrictions to use (as opposed to *Italy* v *Commission* - moped trailers, which concerned a product prohibition). Swedish jet-ski regulations prohibit the use of personal watercraft other than on a general navigable waterway or waters in respect of which the local authority has issued rules permitting their use (on the basis of environmental considerations). Kokott AG opined already on 14 December 2006 that restrictions of use, as long as they are not product-related, apply to all relevant traders operating within the Member State and affect in the same manner in law and in fact, the marketing of domestic and import products, do not qualify as quantitative restrictions to trade. However the Court has still not judged on the matter, neither has the case been struck off the register.

[11] Dr Vedder's text offers a complete review of the issues at stake in the relevant cases that are of interest.
[12] Case C-320/03, *Commission* v *Austria*, [2005] ECR I-9871.
[13] Case C-110/05, not yet reported in ECR.
[14] Case C-142/05, *Aklagaren* v *Percy Mickelsson and Joakim Roos*.

## 3. Core elements to ensure the soundness of restrictions to use, based on human health and environmental considerations

The above analysis[15] in summary shows that regulatory authorities both at the national and at the EU level enjoy a high level of discretion when putting in place product restrictions and /or restrictions of use; that in doing so, they need to take due account of sound science; and that any such restrictions needs to take account of the principle of proportionality.

The test which Member States[16] ought to pursue when considering the legality of restrictions of use, ought to focus on the most objective elements of the exercise:

> *Whether the decision is based on sound science; and*
> *Whether the decision is proportionate, i.e. whether based on that sound science, there is not a less trade or individual freedom-restrictive alternative which could equally effectively reach this result*

[15] And indeed and extensive body of both doctrine and case-law.
[16] And eventually the ECJ where disputes arise.