



## Suspicious paralysis over new nanotechnology labelling and registry

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**The battle for influence between industry and environment protection and consumer organisations impacts nanotech transparency rules**

Brussels is a lobbyists' paradise: the city has approximately 20,000 of them. Their influence is far reaching and affect how nanotechnologies are regulated; for example, in the debate pertaining to the introduction of compulsory labelling and the implementation of a nanotech product register. These are designed to inform consumers and authorities which industrial products contain nanomaterials. Their introduction requires new legislation that has been the object of intense debates over the past few years between the European Commission, industry, consumer representatives and environment protection organisations. The Commission has been so slow to move that it has been accused of blockading the regulatory process.

Typically, political pressure works in favour of greater regulation of nanotechnologies. However, it appears that industry lobbyists manage to neutralise such trend by making their voice heard in the right places. It has led a group of environmental protection NGOs to [denounce](#) the Commission's bias towards industry's economic interests. The Commission is accused of disregarding environmental health and safety concerns and the public right to know. As a result, there are concerns that the political decision in relation to the forthcoming nanotech transparency legislation may not be based on evidence and on the [precautionary principle](#).

**Addressing public concern with transparency**

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Nanotechnology is one of the six key technologies the Commission has deemed decisive for this century. For years the European Parliament has been pushing for more transparency in the market for nanomaterials. As the Commission alone has the right to propose new laws the ball lies squarely at its feet. Yet, the Commission is not taking action. Out of frustration over stalemate in Brussels, four EU member states have taken matters into their own hands. They have either introduced compulsory registration of nanomaterials or are in the process of so doing. France was the [first country](#) in the world to do so, followed by Belgium, Denmark and Norway.

Nanomaterials offer technological opportunities, which consumers also gain from, according to the website of the European Consumer Association ([BEUC](#)). It recognises that nanomaterials have, however, been tested too little before being marketed. BEUC therefore demands “better” regulation and more transparency for consumers.

These demands are also echoed by environment protection groups. “Society is worried about nanomaterials,” says Vito Buonsante, law and policy advisor, health and environment, of [ClientEarth](#) in Brussels, Belgium. “Citizens have a right to be able to find out where these substances are present,” he says. Unlikely support comes from Christa Klass, an MEP representing the Christian-Democratic Group, CDU. “It doesn’t hurt the consumer to see something labelled “nano”. “If people know it won’t do them any harm then there’s no problem, and if they don’t want to buy nano products, it enables them to make that decision,” she explains.

While the Commission fails to act, nothing happens. Instead, we just see another round of reports being issued. In November 2014 the Directorate General of Internal Market, Industry, Entrepreneurship and SMEs (DG industry), published an [evaluation](#) which compares the costs and benefits of a Europe-wide register. It is a key document on which some of the regulatory decisions will be made. This is not really a new approach. [UBA](#), the German Environment Agency has devoted time and effort to the same question in a 142-page [report](#) published in March 2014.

The UBA report concluded that between 38,000 and 58,000 businesses would be affected by the introduction of a European ‘nano-register’; which represents about 5% to 8% out of a total of 770,000 companies surveyed. More than half the 4.1 million expected notifications would relate to varnishes, paints and dyes. Nanoparticles are often used as filler materials in these products. They are used to increase scratch resistance, as an additive for air purification, as UV protection, or for special effects, such as iridescent paints.

### **Alleged regulations blockade**

Investigations into why the Commission does not act – despite political pressure from several sides – leads to mention of the word ‘blockade’. DG Industry shares jurisdiction with DG Environment. The fact that these two directorates have difficulty reaching agreement came to light back in 2011. At the time, it was a matter of defining what constitutes a nanotechnology, which was to form the very basis of regulation, as initially reported by [nanomagazin.net](#).

It was months before the DGs started entering negotiations. It would be an understatement to say the outcome equated to ‘a sell-out’. At the time, Henrik Laursen, an official from the Chemical Unit at DG Environment diplomatically referred to the agreement finally reached as a “political” settlement. Neither industry nor environmentalists nor consumer protection groups are pleased with the definition. Industry complains the definition is so broad that even dust from the Sahara would be encompassed. Meanwhile, consumer groups and environmentalists both regard the definition as too broad.

Although an agreement was reached back then, there is still no sign of a positive outcome when it comes to new labelling rules and the introduction of a registry to enhance transparency of nanotechnology products.

The trouble is that DG Industry apparently still sees its role as “...to minimise the demands of regulation on businesses,” says Carl Schlyter, a member of the European Parliament representing the European Green Party, “even though a sustainable business model can only function when accompanied by the trust of consumers.” Schlyter is both a member of the European Parliament and was vice-chair and a member of the European Parliament [Committee](#) on the Environment, Public Health and Food Safety.

These claims are further compounded by Brussels insiders. Two well-informed Brussels sources, who wished to remain anonymous, have independently claimed that two employees of DG Industry have placed a spanner in the works. Allegedly, the delays may be partly linked to the involvement of Otto Linher, the deputy head of the EC's Chemicals Industry Unit, at DG Industry and of Finnish delegate, Maila Puolamaa, policy officer at the European Commission. Both hold responsibility for nanotechnology; but they do not occupy the highest positions in the hierarchy of the DG for Enterprise and Industry.

However, Linher does not want the extended time period it took to come to an agreement over nanotech regulations to be perceived as a blockading mechanism. "There are discussions here in the Commission over whether or not a register makes any sense," says Linher. Instead, he sees it as a matter of a "normal decision-making process."

### Evidence-based policy

Before introducing a register, an objective cost-benefit analysis is required. In Linher's view, the evaluation of UBA, the German Environment Agency, of the effects of nanotech is too imprecise. According to the UBA, within the space of five years implementing compulsory registration would cost the paint industry around 6–10 million working hours, the similarly heavily affected paper industry about 3–4.5 million hours and the textile industry around 1–2 million hours. And Linher believes that the figures relating to the costs amount to "speculation."

The total cost to industry would equate to an estimated €2.3 billion, as calculated by Carolin Kranz, senior manager corporate and governmental relations of the German chemical company BASF, based in Ludwigshafen, Germany. By comparison, the turnover of German companies with nanotechnology-based products came to €14.3 billion Euros, in 2011. This lead such industries to legitimately question how much is gained by introducing transparency measures.

Yet, it is the Commission's latest evaluation of the cost of a register that will be taken into account. A register designed to make the use of nanomaterials transparent would give rise to costs of between €3,000 and €10,000 with respect to every nanomaterial, and also cost businesses two to three working days, says Marco Camboni, senior consultant with the British independent consultancy, RPA, in Norfolk, UK. He was the author of the evaluation on the effects of a register commissioned by the EC. These estimated costs are inflated, according to Tatiana Santos, **senior policy officer, chemicals and nanotechnology** of the [European Environmental Bureau](#), Brussels, Belgium. She says she discovered they were lower when she inquired into the matter with the French authorities.

However, these costs all come as a result of companies having to characterise their materials. ClientEarth's Buonsante, counters by saying they would have to do that anyway. In fact, businesses already perform checks on the substances they manufacture. However, in the case of nanomaterials they would need to define additional parameters. For instance, it could hinge on the specific surface area or the length of the nanofiber, as toxicity can depend on such variables.

### Administrative quagmire

Besides additional costs and expenditures, the ambiguous nature of regulations are also the butt of most industry complaints. Christophe Zunève, REACH & CLP Manager at the speciality chemical manufacturer Clariant France, says that during the first year of the French nano-register the reports cost him a month's work.

In addition, repeated difficulties in communication could arise. For instance, this could happen when the material has been purchased externally and incorporated into a product. "What should you register it as in such cases?" asks Zunève, adding that there is no standardised methodology for analysing nanomaterials. For example: different methods of measuring particle size actually produce different results. Zunève is furthermore anxious that hackers could break into the database and get hold of trade secrets.

Other in industry representatives concur. "Registers have a negative impact on innovation," chips in BASF's Claudia Kranz. She describes measures to increase transparency in the realm of nanotechnology as "activism." She also believes a register would not serve to promote transparency both because it would be extremely difficult to implement, and also because it would be far too broad in scope. "You don't hear concern being expressed that

hazards result purely from issues relating to physical size,” says Kranz. “We are asking ourselves why there are moves to put nanomaterials under scrutiny while other, perhaps more poisonous materials, are not being scrutinised.”

Choosing the right format for a register is, moreover, a question of examining the various options. The registers already introduced by some EU member states indeed indicate that the rules can be very varied. They can serve to inform the consumer, the authorities, or both. Linher expressly mentions another option: no regulation. He believes the outcome “...could go any way”.

### Regulatory process

The intense industry lobbying appears to be having an impact. Linher, at least, seems impressed: “Costs in the billions really does amount to a very powerful argument,” he says. By way of comparison, he states this represents a tenth of the actual costs resulting from the EU regulation concerning chemicals, known as [REACH](#). This regulation requires manufacturers and importers to make toxicological data about their chemicals available to the authorities. Prior to implementation the chemical industry fought vehemently against the introduction of REACH.

Linher argues that despite the high costs involved, no toxicological information would be forthcoming; only information concerning which products contain nanomaterials. “You have to ask whether the costs are proportional to the benefits,” he adds. This echoes an argument previously given by Steffi Friedrichs, director general of the Nanotechnology Industries Association, an active Brussels ‘nano-lobbyist’.

So is it above all the interests of industry that are leaving their mark on the new official EC commissioned evaluation? That is what is suggested by the report’s opening thesis: namely that it is not generally accepted that there is too little information about nanomaterials. Amongst the stakeholders, it is industry alone, which refuses to accept this.

Ultimately it will not be the DG Industry officials in charge of nanotechnology who decide whether the Commission draws up draft legislation on a register for nanomaterials. Nor will they decide how it looks if the decision is positive. Linher emphasises that “The decision will be taken at the level of the Commissioners and the Cabinet.” When asked, Linher confirms that the Commissioners will make their decision on the basis of the official evaluation of the effects of a register. But he adds that the politicians remain free to go for an option other than the one recommended in the report.

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