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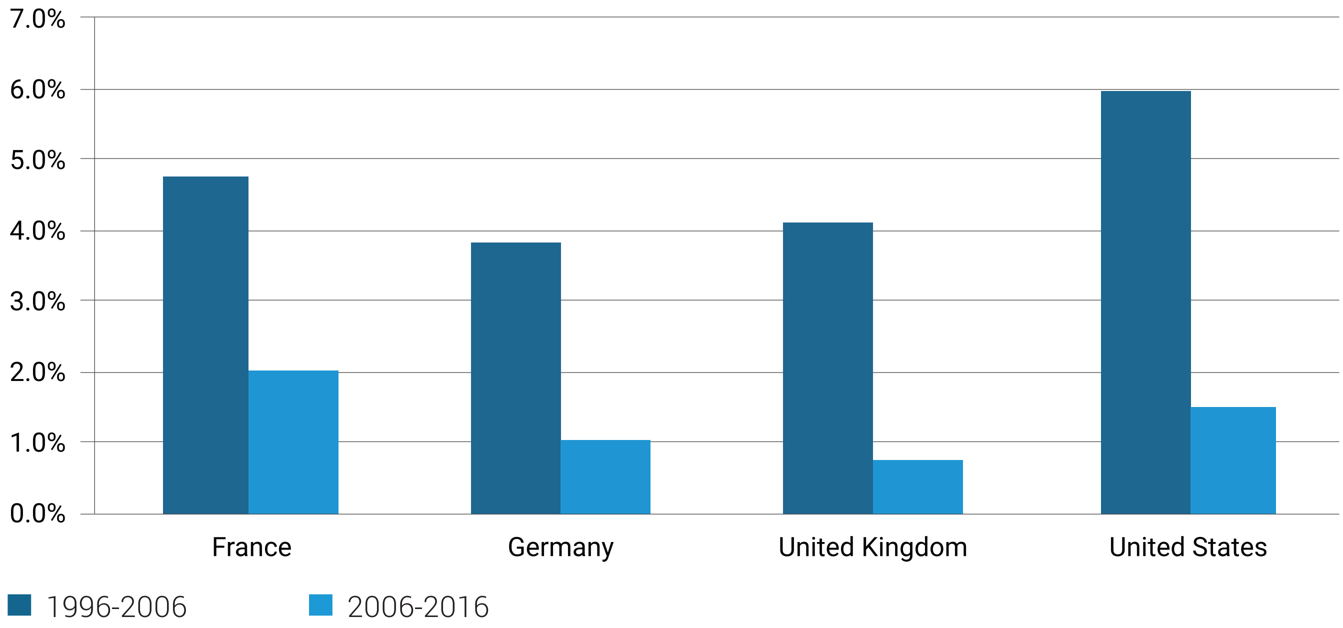
INTRODUCTION

In recent years, innovation has become synonymous with digital companies such as Apple, Google and Amazon.[1] The Internet, the smartphone, and the cloud have transformed daily life and the way we do business, and artificial intelligence and machine learning will continue the process.

Nevertheless, overall productivity growth remains sluggish. The reason is simple: The digital sector of the economy, where innovation today is focused, is still far smaller than the physical sector. Even today, we spend much more time interacting with the physical world than with the digital world. The chairs we sit on, the food we eat, the cars we ride in, are all made of physical materials, not intangible bits and bytes. According to recent research, digital industries such as communications, entertainment, and finance comprise only 30 percent of the economy, while physical industries such as manufacturing and construction comprise 70 percent.[2]

Unfortunately, productivity growth in manufacturing has slowed to a crawl in most industrialized countries. For example, in Germany, manufacturing output per hour rose only at a 1 percent annual rate between 2006 and 2016, compared to a 3.8 percent annual gain between 1996 and 2006 (Figure 1).

FIGURE 1: Manufacturing Productivity Slowdown (annual growth rate by decade)



Data: Conference Board

For that reason, innovation in the physical world – not just the digital world – is essential for our economic future. The creation and use of new materials can reduce the cost of construction of buildings and infrastructure; lead to lighter, more fuel-efficient cars; and make our clothing and furniture more comfortable and durable.

Moreover, the development of new materials that can be 3D printed – not just polymers, but metals, ceramics, and glass – will broaden the scope of additive manufacturing, lower the price of essential consumer goods, and create new markets for customized products. Indeed, innovation in materials may help foster the rebirth of local manufacturing – small, versatile manufacturing plants that can provide a variety of customized products to local markets, reduce the need for imports, and generate new manufacturing jobs.

From this perspective, an important aspect of innovation policy should emphasize and encourage innovation in materials. But that leads to two competing priorities. New materials – and new uses for existing materials – can be a tremendous boon for growth and job creation. But some materials can also have adverse health or environmental consequences, depending on how they are used. Thus, regulation of materials is essential.

> **Effective and growth-enhancing regulation of innovative materials requires a balancing act between science-based regulation on the one hand and the precautionary principle on the other hand.**

Now, both of these have become loaded terms in the public policy debate, but they do articulate some important fundamental ideas. Science-based regulation expresses the belief that regulation should be based on the best available quantitative scientific evidence, taking into account the associated probabilities. This type of regulation considers actual harm to human health or the environment, not just the potential for harm.

By contrast, the precautionary principle expresses the belief that "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically."[3] Since an innovation, by definition, is new and therefore has uncertain impacts, the precautionary principle is often cited in arguments against innovation.

To illustrate these two different approaches, we will look at the case of the regulation of silicones. Silicones include a broad class of polymers used in thousands of products – from protective coatings on aircraft to bacteria-resistant medical devices to renewable energy technologies such as wind turbines and solar panels. Silicones are also an important component of many personal care products, such as shampoos, and essential for innovative electronic products.[4]

Regulators have long been concerned about silicones,because of their potential impact on human health and the environment. In this paper, we will compare the science-based regulatory approach of the Canadian and Australian governments with the regulatory approach of the European Chemicals Agency (ECHA), which is informed by the precautionary principle. We will show how the approach to silicone regulation has broad implications for growth and innovation.

BACKGROUND

The term "silicone" was originally coined in 1901. However, the production of silicones in large quantities was part of the great post-World War II industrial boom, driven in the United States by companies such as General Electric and Dow Corning, and in Germany by Wacker Chemie AG. Indeed, much of the post-war growth of manufacturing jobs in the United States and Europe was tied in some way to innovative consumer and industrial products that relied on silicones.

In particular, we will focus on three different silicone materials called "siloxanes" – octamethylcyclotetrasiloxane (also known as "D4"), decamethylcyclopentasiloxane (also known as "D5"), and dodecamethylcyclohexasiloxane (also known as "D6"). D4, D5, and D6 are all odorless, tasteless, and non-greasy liquids that have been used as bases for personal care products such as deodorants and makeup products, as well as to make polymers for many other consumer and industrial products.

In recent years, regulators have rightfully looked at the potential health and environmental risks posed by D4, D5, and D6. One important issue was the direct impact on human health, including reproductive risk. Another issue was the potential for these chemicals to accumulate in the environment rather than break down, including accumulating in marine life.

SILICONE REGULATION IN CANADA AND AUSTRALIA

In January 2009 the Canadian Ministers of Environment and Health issued "screening assessments" for D4, D5, and D6 as a part of the country's Chemicals Management Program (CMP). These assessments found that the three silicone materials do not pose a risk to human health. However, at that time, Canadian regulators found D4 and D5 to be harmful to the environment and biological diversity. As such, both substances could possibly have been subject to regulatory measures to lessen the substances' impact on the environment.

These assessments relied primarily on laboratory studies and were explicitly based on the precautionary principle rather than provable harms. As the D5 report noted:

The physical-chemical property, bioconcentration and ecotoxicity profiles for D5 do not provide a consensus basis for a weight of evidence. There are some uncertainties as to whether D5 poses the potential to cause ecological harm.

Despite this uncertainty, the report went on to conclude:

….a reasonable level of precaution is required and as such it is concluded that D5 may have the potential to cause ecological harm when released to the Canadian environment, particularly for long-term exposures near discharge zones.

In other words, in the absence of consensus scientific evidence, Canadian regulators initially opted for the precautionary approach.

After objections from industry, based on scientific studies, these conclusions were then reconsidered by a review board. The board, composed of three independent toxicological experts, reviewed a wealth of available data, including new studies that showed the real-world behavior of D5. After a thorough evaluation of all of the data, the review board issued its report in 2011, and found that:

Taking into account the intrinsic properties of Siloxane D5 and all of the available scientific information, the Board concluded that Siloxane D5 does not pose a danger to the environment.[7] …..There is no evidence to demonstrate that Siloxane D5 is toxic to any organism tested up to the limit of solubility in any environmental matrix. The Board is of the view that Siloxane D5 will not accumulate to sufficiently great concentrations to cause adverse effects in organisms in air, water, soils, or sediments. Furthermore, the Board concluded that, based on the information before it, the projected future uses of Siloxane D5 will not pose a danger to the environment.

Ultimately, based on the findings of the Board of Review, Environment Canada decided that restricting the use of D5 in the marketplace was not warranted.[8]

For D4, the Canadian government took a very targeted approach to managing any environmental risk posed by the substance. A government-funded environmental monitoring study, which measured real-world concentrations of D4, D5, and D6 in the environment, found very low levels of D4 in Canadian surface waters.[9] Rather than restricting or banning the substance's use in consumer or industrial products, the Canadian government required certain facilities that use D4 to implement pollution prevention plans.[10]

Canada's approach on D4, D5, and D6 has been further bolstered by the Australian Government's draft scientific determination on silicone materials released in March 2018. It, too, evaluated all the available science on siloxanes and applied a "weight-of-evidence" approach to its assessment. This included a review of environmental monitoring data that provided an accurate view of the substances' actual effect on the environment. The Australian government ultimately concluded that "[t]he direct risks to aquatic life from exposure to these chemicals at expected surface water concentrations are not likely to be significant" and have proposed taking no regulatory action to curtail the use of D4, D5, or D6 in commerce.[11]

SILICONE REGULATION IN THE EU

The European approach to silicone regulation in particular, and chemicals regulations in general, relies much more heavily on the precautionary principle. Consider the wording of the 2006 REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals), which is the underlying document creating the ECHA and governing chemicals regulation in the EU:

This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.[12]

This statement of purpose does not distinguish between existing materials that have been in widespread use and new materials.

Under this rubric, the ECHA is engaged in several different regulatory actions involving D4, D5, and D6. ECHA has already restricted the amount of D4 and D5 in "wash-off" personal care products, such as shampoos. Moreover, the agency is also considering restricting the use of D4 and D5 in household cleaning products and personal care products designed to be left on the body.

> Unlike in Canada, the European law does not require regulators to examine real-world data about how these materials behave in the environment.

The basis of both regulations is that these materials exhibit hazardous properties according to certain laboratory results.

Instead, European regulators rely primarily on laboratory studies and use screening criteria as proxies for environmental behavior.

ECHA is also considering whether to designate them as substances of very high concern (SVHC).[13] SVHC designation would require:

- Producers and importers of items containing the silicones to register with the ECHA if the substance is present in quantities over one ton per year and the substance is intended to be released under normal or foreseeable conditions;[14]
- Producers and importers of items containing the silicones to notify the agency if the substance is present in amounts over one ton per producer per year and the substance is present in items above a concentration of 0.1 percent. The information must include the identity of the silicones in the items, the use of the silicones, and the amount, among other things;
- Silicone suppliers to provide their customers with a safety data sheet in an official language of the country where the substance is sold;[15] and
- Suppliers of silicone mixtures that contain more than 0.1 percent by weight to provide their customers with a safety data sheet upon request.

An SVHC designation effectively creates a "blacklist" and could be viewed as an initial step to regulating a substance at a global level through the Stockholm Convention.

IMPLICATIONS OF THE ECHA APPROACH TO SILICONES

We note that the latest version of the ECHA strategic plan does not contain the term "precautionary principle." Indeed, the agency stresses, "Our decisions are science based and consistent." However, the precautionary principle is still written into the underlying regulation.

From this perspective, the comparison of the European approach to silicone regulation with the Canadian approach will give some indication of how the ECHA balances scientific evidence with the precautionary principle.[16]

The outcome could tell us a lot about growth and innovation going forward. In the narrow sense, silicones help enable an important group of products and industries both globally and in the European Union.

> A 2016 industry report indicated that total sales of silicones products to Europe accounted for €3 billion in 2013.[17]

The largest consumers of silicones were the industrial processes, construction, and personal care and consumer products sectors. If restrictions on D4, D5, and D6 are excessively tightened, that will have the effect of driving up consumer prices and forcing manufacturers to formulate their products in alternative, less satisfactory ways.

But that's really just the tip of the iceberg. Siloxanes such as D4, D5, and D6 have been in use for decades, so their accumulation in the environment in excessive quantities, if it is happening, should be measurable and stable. As the Canadian Board of Review noted,

Because Siloxane D5 has been used in commercial and industrial applications for a relatively long time – more than 30 years – and, given its rates of dissipation and transformation in the environment, current concentrations of Siloxane D5 are at a quasi-steady-state.

If ECHA moves to restrict these materials based on a precautionary attitude rather than on real-world scientific evidence, this does not augur well for the regulatory attitude to new materials with less of a track record.

Indeed, the broader danger is that a strict precautionary approach to chemical regulation, as would be implied by tighter regulation of silicones, would have negative implications for the rebirth of manufacturing jobs in Europe and the U.S. These jobs are based around the application of new technologies such as 3D printing, which themselves rest on the creation of new and reformulated materials.

Under the precautionary principle, the companies that manufacture and use new materials will have to prove their lack of impact on the environment before they even go into use.

It is worth thinking about, for example, whether such essential materials as steel – to name an important material innovation of the past – would have passed ECHA's precautionary standards when it was first introduced. After all, the early steel manufacturers would not have been able to prove that the material did not harm the environment.

Note that we are not advocating that new materials be put into use without testing. There should be a reasonable and science-based set of standards for assessing toxicity and potential environmental impact. But these should be straightforward enough to allow for rapid innovation, and based on an assessment of a robust data set – not a selection of only a few studies that do not capture actual risk to humans or the environment.

CONCLUSION

We see that there are two approaches to the regulation of silicones such as D4, D5, and D6. One approach, used by Canada and Australia, relies on science-based evidence to ascertain potential risks to the environment and human health. Their assessments consider all available evidence and make a determination based on real-world environmental and health effects. The other approach, used by Europe, fails to adequately consider the weight of the evidence and introduces the precautionary principle as a key reason to restrict the use of these silicones.

We conclude that the European approach is more likely to slow down innovation in materials and should not be adopted by non-EU countries. The hazard-based regime in Europe creates not just a regulatory problem, but an economic one, because innovation in materials has historically been an important source of economic and job growth, and is likely to be so in the future – if the regulators allow it. The question now remains: Will other nations adopt the risk-based approach used in Canada and Australia or the precautionary approach employed in Europe? Based on our analysis, the Canadian and Australian approach strikes the best balance of protecting human health and the environment, while fostering product innovation and economic growth.

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