

“ONE SIZE FITS ALL” DOESN'T FIT AT ALL

POLICY NOTE



Written by David Clement

Executive Summary

The following is a policy note published by the Consumer Choice Center.

In many ways, various governments have passed regulations with a “one size fits all” mentality.

More often than not, however, this approach wrongly limits consumer choice, and more importantly creates tremendous externalities which are often left unaddressed.

The goal of this policy note is to highlight instances where the “one size fits all” approach has failed consumers.

This document will be regularly updated with further examples of policy failure included as time passes.



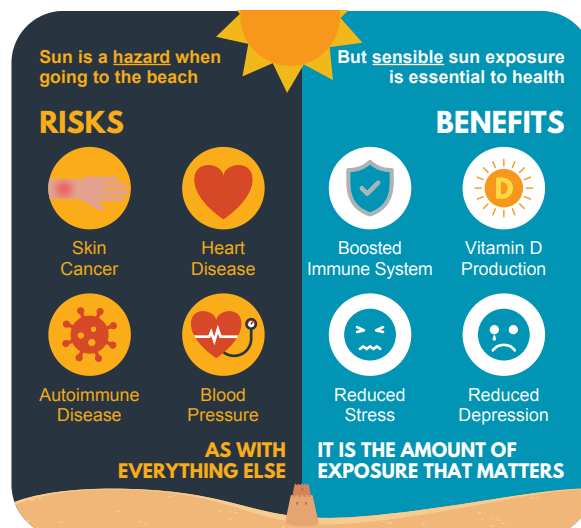
RISKS VS HAZARDS

Much of the “one size fits all” approach can be summarized as a failure to properly understand the difference between hazards and risks. This is an incredibly important distinction when policymakers are crafting laws aimed at protecting consumers, and in many instances public health. The purpose of public policy and consumer regulations should be to manage risk, and not to prioritize hazard avoidance.

Risk-based regulation considers exposure to hazards. For instance, the Sun is a hazard when going to the beach, yet sunlight enables the body’s production of vitamin D and some exposure to it is essential to human health.

As with everything else, it is the amount of exposure that matters. A hazard-based regulatory approach to sunlight would shut us all indoors and ban all beach excursions, rather than caution beach-goers to limit their exposure by applying sunscreen. The end result would be to harm, not the protection of human health.

The same logic of hazard-based regulation is all too often applied in crop protection regulation, where it creates equally absurd inconsistencies. For instance, if wine was sprayed on vineyards as a pesticide, it would have to be banned under EU law, as alcohol is a known and quite potent carcinogen at high levels of consumption. All this is rationalized through an inconsistent and distorted application of the precautionary principle.



In essence, hazard-based regulation advocates would endorse outlawing all crop protection methods that cannot be proven completely safe at any level, no matter how unrealistic — a standard which, if applied consistently, would outlaw every organic food, every life-saving drug, and indeed every natural and synthetic substance. By ignoring the importance of the equation $\text{Risk} = \text{Hazard} \times \text{Exposure}$, hazard-based regulation does not follow a scientifically sound policy-making approach.



CASE STUDIES

MODERN CHEMICALS & HUMAN HEALTH

Both Per- and Polyfluoroalkyl substances (PFAS) and Perfluorooctanoic acid (PFOA), which are man-made chemical compounds, have come under intense scrutiny over the last 3 decades. PFOA, in particular, was heavily scrutinized, and that has resulted in billions of dollars in [lawsuits](#) that have been popularized to the point where Hollywood has dramatized the issue of PFOA/C8 and human health. There are examples of where PFOA represents a significant hazard, and risk, to human health, and those issues should not be understated or misrepresented.

That said, the response from legislators in regards to these man-made chemical compounds perfectly embodies the failures of the “one size fits all” approach. Most recently, [the PFAS Action Act](#), which would direct the EPA to designate PFOA and PFOS as hazardous substances, passed in the House and is under review in the Senate. The issue with this piece of legislation is that not all of these man-made chemicals carry the same risk, which varies wildly depending on their use and exposure levels.

This regulatory approach is problematic, first because these chemicals have been mostly phased out where they aren’t deemed necessary. A [2018 Toxicological Profile for Perfluoroalkyls by the Agency for Toxic Substances & Disease Registry](#) says that “industrial releases have been declining since companies began phasing out the production and use of several perfluoroalkyls in the early 2000s.” In addition to that, a [CDC report](#) shows that since 2000, “mean blood levels of PFOS have declined approximately 84 percent and mean blood levels of PFOA have declined about 70 percent,” and [recent reports](#) are showing that bodies of water contain only trace amounts of PFAS, and they have been [declining](#).

By moving to classify all PFAS and PFAO as hazardous, legislators are attempting to ban/significantly restrict over [5,000](#) chemical compounds, despite the fact that only some of them are worthy of such treatment. By declaring these chemical compounds, as a category, to be hazardous, legislators risk causing an incredible ripple effect of externalities by eliminating the use of these chemicals where it is necessary.

Examples include but are not limited to:

1 Necessary medical equipment: these chemical compounds are vital for contamination-resistant gowns and drapes, implantable medical devices, stent grafts, heart patches, sterile container filters, needle retrieval systems, tracheostomies, catheter guide wire for laparoscopy and inhaler canister coatings. To declare these chemical compounds hazardous, without evaluating the risk associated with each compound's use, puts lifesaving medical technologies in jeopardy and patient safety at risk.

2 Consumer items: these chemicals are foundational for the creation of everyday consumer products like cell phones. PFAS helps stabilize the cell phones that are in everyone's pockets. As cell phones and 5G technology continue to grow and require faster speeds at smaller sizes, these compounds are involved in everything from producing semiconductors to helping cool data centers for cloud computing. Removing these chemicals from the production process, despite the fact that when used in this way they present no risk to humans, will drastically disrupt supply chains and inflate costs for the [275 million](#) smartphone users in the USA.

To put it simply, classifying all PFAS as hazardous is akin to banning mercury from being used in thermometers because it is harmful when ingested, or banning chlorine from being used in pools because it is harmful if you eat it. A more appropriate response would be to evaluate these chemicals based on the risk they present, and how they are used, rather than lumping them all together with a heavy-handed ban.

CANNABIS PRODUCT CLASSES IN CANADA

The Canadian Federal Government legalized adult-use cannabis in 2018. Simply put, the negatives of prohibition significantly outweighed the negatives of legalization. Put another way, the government acknowledged that a hazard based approach (prohibition) was misguided and rightly abandoned that position. Cannabis, as it is commonly consumed, is an intoxicant and consumed via combustion and inhalation. Combustion and inhalation obviously present a hazard to consumers, although for cannabis its use does have medicinal and wellness benefits, which have long been documented. That said, after abandoning the hazard approach and repealing prohibition, the Cannabis Act proceeded to then embrace the "one size fits all" approach in regards to the numerous product classes that exist for cannabis consumption.

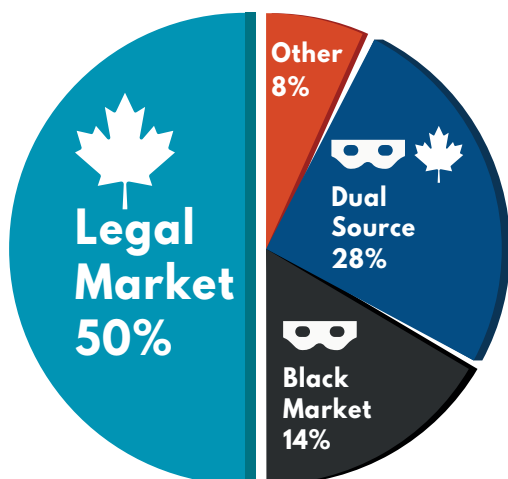
For example, the Cannabis Act essentially treats all products derived from the cannabis plant equally, regardless of the risk they pose to consumers. For example, there are numerous legal cannabis products that do not involve any form of combustion and inhalation, predominantly edibles and beverages. Unfortunately, because of the way in which the Cannabis Act is written, all products are subject to tobacco-style consumer regulations in terms of outlet access, marketing restrictions, and plain packaging.

This one size fits all approach is misguided for several reasons. The first is that it completely ignores the continuum of risk presented by these different products. A cannabis CBD beverage with no THC in it, which presents almost zero risk to consumers, is as tightly regulated as high THC dried flower. Ironically, these regula-

tions have been taken so far to the point that the warning labels on cannabis beverages often include health warnings about the danger of smoking cannabis.

The consequence of this “one size fits all” approach is that consumers are being restricted from accessing reduced-risk products, which clearly limits consumer choice, but more importantly undermines one of the core goals of legalization: the elimination of the black market. As of August 2020, the legal cannabis market only [accounted](#) for 50% of all cannabis purchases in the country, which demonstrates that the black market is still alive and well.

CANNABIS PURCHASES IN CANADA IN 2020



In summary, the government needs to acknowledge that cannabis products vary in the risk they present to consumers, and legislation should be crafted in accordance with those risk profiles.

TALC/BABY POWDER

One topic that has been elevated to various high-profile lawsuits and actions has been whether a brand of Johnson & Johnson’s baby talcum powder, made from the mineral talc, contained trace amounts of asbestos, a known carcinogen.

In the processing of mining talc, there have been circumstances in which the source material contained trace elements of asbestos and related minerals. Since the 1970s, the US Food & Drug Administration has required testing for asbestos and has routinely published [guidance](#) and outlines on testing requirements.

Talc is used in a variety of cosmetic and medical products, whether baby powder, surgical gloves, make-up, or various plastics.

In many highly publicized trial cases in the past four years, plaintiffs and their attorneys have sought to convince judges and juries that asbestos-tainted talc was found in baby powder, which led to cases of ovarian cancer. This has been ongoing despite the fact that dozens of scientific studies [have yet to prove](#) a definite link between modern-day talc and any cancers.

The same has been [echoed](#) by the American Cancer Society, and the same conclusion was reached by a wide-ranging 2014 study [published](#) in the Journal of National Cancer Research Institute.

While a 2020 ruling in New Jersey awarded as much as \$4.7 billion to plaintiffs and their attorneys, a September 2021 jury ruling [found](#) that the talc in baby powder was not liable for a plaintiff’s ovarian cancer, leading to even more confusion in the courts about this complicated question.

The hazard involved in this situation deals less than the final product — consumer baby powder products used mostly by women and for babies, which are [routinely tested](#) by the FDA and other agencies — and more to do with the source talc and any contaminants found bonded to it.

The general hazard is a trace of particles of asbestos that may or may not be in the talc and could become carcinogenic. But considering the intense testing and removal of unwanted materials from the initial mineral, both by companies and government agencies, it has so far been determined that there is only a heightened risk with intense exposure over prolonged periods of time, which is likely not possible in current cosmetic or medical use.

As such, the general risk is incredibly low, if not absent. As one [recent paper](#) from the journal of Gynecologic Oncology published in August 2021 found, “given the rarity of ovarian cancer in the general population, the small increase in relative risk translates to a very low increase in absolute risk.” The American Cancer Society is [blunter](#): “There is very little evidence at this time that any other forms of cancer are linked with consumer use of talcum powder.”

Despite the scientific evidence, several prominent legal firms have [recruited](#) for billion-dollar class-action lawsuits, using plaintiff testimonies and their own research to demonstrate a causal link between baby powders and ovarian cancers.

The FDA, in response to these lawsuits, has conducted [several](#) briefings and public meetings on the claims. Johnson & Johnson, out of an abundance of caution, agreed to [voluntarily recall](#) one of its baby powder products after it tested positive for “sub-trace levels” of asbestos (no greater than 0.00002%). By all accounts from the literature, and from [regulations](#) from the US Occupational Safety and Health Administration, this is a negligible amount found in ordinary consumer products or workplace settings. While it is generally a hazard — as are any traces of asbestos

— it does not classify as a risk.

That said, with a lower burden of proof found in civil lawsuits and trials, many plaintiff attorneys have used the “one size fits all” approach to mount large cases against consumer product companies.

This has resulted in vastly exaggerated claims, billion-dollar payouts, and general neglect of the scientific evidence furthered by independent labs and by the US government’s own agencies. Expert witnesses, paid by plaintiff attorneys, are [brought in](#) to provide their own tests and testimony to convince the jury. In the most recent trials, juries have [sided against](#) the plaintiffs because the causal link was not found to be strong enough.

The issue with subjecting scientific studies and evidence to civil trials, particularly within the “one size fits all” approach of judging risk, is that the lower burden of proof neglects science and elevates personal testimony or slick presentations above the facts. As more consumer products enter the market, and legal firms see more opportunities to sue these companies for payouts, regardless of the science, we can only expect that yet more misunderstandings of risk will continue to be perpetuated and practiced in our court systems, and ultimately acted on through poor regulations.

GLYPHOSATE

In the area of crop protection, glyphosate has caused significant policy conversations in North America and Europe. The herbicide has been accused of causing health risks, [despite a large amount of scientific evidence pointing to the opposite](#). The glyphosate conversation is emblematic for a confusion of the difference between hazard and risk. While it is true

that directly ingesting glyphosate would be a considerable health risk, it is also clear the product is not meant to be ingested, and that assessing health risks is about dosage. When environmentalist groups in Germany made a statement about glyphosate residues in beer constituting health risks, the German Federal Institute for Risk Assessment [issued a response](#) that explained that in order for glyphosate residues in beer to constitute a health risk, a consumer would need to drink 1,000 litres in one day.

Glyphosate is now being banned by an increasing number of European nations, leaving farmers with a reduced tool box for controlling herbs, and affecting food safety. The one-size-fits-all solution to pesticide-reduction does not take into account the needs of farmers and consumers. A middle ground solution is the use of smart sprayers, and effective uses of genetic engineering, which over time reduce the overall amount of pesticides used in the farming sector. [For reference](#), lots of advances have already been made: Since the 1960s, pesticide use per acre has been reduced by 40%, pesticide persistence has been cut in half, and the amount of active ingredient has been reduced 95%. Adding to that, 55% of pesticides are less toxic than vitamin C, 89% are less toxic than Ibuprofen, and 98% are less toxic than caffeine and Aspirin.

Unfortunately, the glyphosate model of confusing hazard and risk is applied to an increasing amount of crop protection tools. Insecticides such as neonicotinoids are under fire for "harming bees", a notion that has also been scientifically debunked. Not a day goes by that the concept of bee or overall insect population loss drives the conversation on crop protection. This remains a fact in both Europe and the United States. In the US, the 'Bee Informed Loss & Management

Survey' has played a key role in perpetuating the misinformation about bee population losses, largely through the fact that only a small fraction of beekeepers participate (less than 10%) in the survey. In fact, backyard beekeepers, more heavily affected by losses in general, distort the final results — a fact unknown to many of the reporters on the 'Bee Informed' press releases, until the release of the final survey much later. Added to that, the 'survey,' as the name suggests, is not a scientific study on the total number of bees, but rather takes the participants at their word, accepting their self-reported numbers they provide in their responses. This survey is not representative of a phenomenon of bee population decreases.

As the Washington Post reported in two separate articles in 2015 - '[Call Off the Bee-pocalypse: U.S. Honeybee Colonies Hit a 20-Year High](#)' and '[Believe It or Not, the Bees Are Doing Just Fine](#)', the hysteria of global bee declines are simply inaccurate. Any curious person can do this themselves: visit the UN's Food and Agricultural Organization's (FAO) website, select "beehives" in the visualized data section, and click on any country or region. Most countries and regions have a steady upwards trend in the prevalence of bees. In the United States, the bee population is actually set to double in the coming years compared to the 1960s. The bottom line is: [honey bee populations are increasing](#). That said, both in Europe and in the United States, officials are peddling the myth of declining bee populations through the use of chemical pesticides, notably neonicotinoids, known as neonics.

The European Commission's own website on '[What's behind the decline in bees and other pollinators?](#)' first asks the question 'Why are pollinators declining?', then

adds "currently, there is no scientific data giving the full picture". Yet, neonics continue to be blamed for insect declines which is why they are outlawed in many EU member states — despite the fact that countries such as France [have had to pause their bans](#) for the fear of losing their sugar beet industry. [According to the Environmental Protection Agency](#), a March 2018 USDA [report](#), and reports from [Canada](#) and [Australia](#), there has been no proven link between neonics and harm to bee populations. Conversely, they are essential to maintain a productive farming system, which equals food security and price stability for consumers.

The situation is similar for sulfoxaflor, a systemic insecticide that is used in certain areas as an alternative to neonicotinoids. Still blamed for a non-existent decline in honeybee populations, the substance [has since been found](#) to have no effect on those same honeybees in a realistic exposure scenario.

Once again, blanket bans on crop protection tools are justified with unproven claims about hazards, and the misrepresentation of risks. These bans end up hurting consumers in the availability, quality, and prices of their products.

ABOUT THE AUTHOR

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David holds a BA in Political Science and an MA in International Relations from Wilfrid Laurier University. Previously, David was the Research Assistant to the Canada Research Chair in International Human Rights.

David has been regularly featured on the CBC, Global News, The Toronto Star and various other major Canadian news outlets.



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