

The European Union's Biocidal Products Regulation Benefits Only Bureaucrats

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KEY TAKEAWAYS

The EU controls the sale of biocides—products that control or destroy germs or viruses—through its Biocidal Products Regulation (BPR).

The folly of the BPR is illustrated by the fact that it restricted the import into the EU of isopropyl alcohol wipes during the COVID-19 pandemic.

The U.S. and U.K. should oppose the BPR model, which prioritizes bureaucratic processes, and the U.K. should take advantage of Brexit to diverge from the BPR.

The European Union controls the sale of biocides through its Biocidal Products Regulation (BPR). A biocidal product contains a substance that is designed to control or destroy a harmful organism, often a germ or virus. The BPR is a one-size-fits-all model for biocides. It puts simple products containing tried and tested chemicals through a bureaucratic process that would be more appropriate for complex products containing new substances. The U.S. Trade Representative has warned that the BPR is one of many EU technical barriers to trade.

During the COVID-19 pandemic, the BPR has had the perverse effect of restricting the supply of isopropyl alcohol wipes in the EU. The BPR illustrates why many EU member states have low economic growth. Working together, the U.S. and the U.K. should press

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the EU to amend the BPR to eliminate the technical barriers to trade it creates. The U.K. should diverge from the BPR. Both the U.S. and the U.K. should oppose the broader EU model behind the BPR that prioritizes bureaucratic process above growth, jobs, consumer choice, and common sense.

The Problem of Non-Tariff Barriers to Trade

The benefits of lowering, or eliminating, restraints on international trade are clear. By making goods and services cheaper, reducing restraints increases the purchasing power of consumers. Restraints benefit only a few politically privileged producers: Reducing restraints benefits consumers as a whole. The wisest course of action in trade is to act for the benefit of the many consumers, not merely a few producers.

Restraints on international trade come in many forms. After the Second World War, tariffs (taxes imposed on an import) imposed significant costs on trade. Over the following decades, tariff levels fell dramatically, especially in the developed world. But in recent years, a new kind of restraints on trade—non-tariff barriers—have increased dramatically. Non-tariff barriers generally consist of rules imposed by governments that have the effect of making it more difficult or expensive for consumers to buy the goods or services they prefer.

Many studies have highlighted both the significance of non-tariff trade barriers and the rising costs imposed by such barriers. A November 2019 paper by the U.S. Trade Commission found that the “ten years since the end of the Great Recession has been characterized by the rise in the number of [non-tariff measures, or NTMs].... NTMs are estimated to be on average three times more costly than tariffs.”¹ To promote free trade today, the U.S.—and the world as a whole—must focus less on cutting tariffs, and far more on reducing rules that, intentionally or not, are subtly rebuilding the walls that free traders tore down after 1945.

The EU’s Non-Tariff Barriers

The U.S. Trade Representative (USTR), in its 2020 “National Trade Estimate Report on Foreign Trade Barriers,” notes that the U.S. “faces a proliferation of technical barriers to trade in the EU.”² The EU is certainly far from the only offender in this regard: The World Trade Organization (WTO) has recorded a litany of complaints about U.S. barriers to trade.

But as the USTR notes, exporters in the U.S. and other nations face barriers selling into the EU in part because these barriers are part of a wider EU strategy:

The EU's approach to standards-related measures, including its conformity assessment framework, and its efforts to encourage governments around the world to adopt its approach, including European regional standards, creates a challenging environment for U.S. exporters. In particular, the EU's approach impedes market access for products that conform to international standards as opposed to European regional standards...even though international standards may meet or exceed the EU (or third country) regulatory requirements. U.S. producers and exporters thus face additional burdens in accessing the EU market not faced by EU exporters and producers in accessing the U.S. market.³

The EU has a one-size model—and that one size is what fits the EU. By trying to impose their regulations onto other countries that may have little choice in the matter, the EU is practicing imperialism by regulation. The EU first makes it harder for other nations to sell into the EU, and then encourages those other nations to adopt its rules, even if those rules are inconsistent with their values or not appropriate to their needs. Adopting the EU's rules may make it easier for those other nations to sell into the EU, but also burdens them with all the costs the EU has imposed on itself—while, in effect, simultaneously handing over rulemaking control to the EU.

The EU's Biocidal Products Regulation

A biocidal product contains a substance (usually a chemical compound) that is designed to control or destroy a harmful organism (often a germ or virus). In common parlance, a biocide is a germ killer. We all use biocides every day, from soaps to wet wipes to household cleaners, and we owe the vast improvement in our life spans and health in considerable part to biocides.

Like any chemical, natural or artificial, biocides can be harmful if used wrongly. The EU controls the sale of biocides through its BPR, which was adopted in 2012 and implemented in 2013. Active substances in a biocidal product must, with certain exceptions, be approved at the EU level, while the product containing the active substance can be authorized at either the EU or the national level.

As is often the case with EU rules, the BPR purportedly seeks to achieve many aims. It intends to “harmonise the market at Union level,” “simplify

the approval of active substances and authorization of biocidal products,” and promote “the reduction of animal testing,” among other ends.⁴ These aims sound reasonable, and the EU is certainly not the only entity that imposes controls on the sale of biocides. However, with regulations, the devil is often in the details.

The USTR has repeatedly expressed concerns that the EU regulation of chemicals generally “results in requirements that are either more onerous for foreign producers than for EU producers or simply unnecessary.” It comments specifically that these issues “have [also] arisen under other EU regulations, including under the Biocidal Products Regulation.”⁵

The Process Required for Approval Under the BPR

The BPR requires prospective sellers to submit a dossier containing information about their product and a Letter of Access (LoA) that allows them access to data about the biocidal chemical(s) in the product.⁶ Information is required on the physico-chemical properties and analytical methodology of the product, its efficacy, its effect on human health and the environment, and a range of specific further requirements depending on the specific substance(s) in the product.⁷

The dossier then moves through a six-stage process that assesses the adequacy of the dossier itself, and then another six-stage process that assesses the product described in the dossier. If the application is successful, the process ends with approval by the European Commission.

The fees involved in this process are considerable: The European Chemicals Agency (ECHA) alone requires the payment of a 40,000 euro fee (approximately \$48,000)—simply to *accept* a new dossier.⁸ The process is also time-consuming: ECHA allows for a 365-day evaluation period, and any requests for additional information to the applicant will extend this period.⁹

The BPR process is a one-size-fits-all model for biocides. It puts relatively simple products containing tried and tested chemicals through a bureaucratic process that would be more appropriate for complex products containing entirely new substances.

In theory, it is possible to seek BPR approval at the national level instead of throughout the EU. But because securing national-level approval in all 27 EU member nations is extremely expensive, the room the EU allows for national sovereign discretion is more apparent than real.

The Costs Imposed by the BPR

The costs imposed by the BPR are significant, and many—even given the evident complexity of the BPR—are far from obvious.

- Many suppliers do not have the experience to compile a dossier and must therefore hire consultants.
- LoAs are not free: They must be purchased from the owner of the testing data. Because no new animal testing can be done, owners of LoAs based on testing done years or decades ago effectively control access to today's EU market.
- In order for the application to be considered, the supplier must have representation, such as through a legal entity in one of the EU member states. Suppliers outside the EU must employ a consultant in the EU to fulfill this obligation, and this comes at a cost.
- Many suppliers are not set up to run ECHA-mandated tests on efficacy, storage requirements, and substance stability. They must employ outside labs that meet the requirements of the BPR application, as recommended by ECHA, to do these tests. There are a limited number of such labs. The gateway through which applications must pass to secure EU approval is thus narrow.
- The competent authority that actually analyzes the dossier must be paid to do the assessment. The ECHA also imposes an annual fee, and suppliers must pay renewal fees as well.

An Example of the BPR's Unreasonable Barriers

An American critical environments business with manufacturing and distribution in the U.S. and U.K., which manufactures and sells a wide range of cleaning and related products, began in 2019 to seek approval to sell a wipe saturated with isopropyl alcohol (IPA) in the EU. There is nothing exotic about a wipe. IPA is a well-known and well-tested chemical that—especially in the age of COVID-19—is used around the world.

Yet the EU, in the midst of a global pandemic when consumers were clamoring for sanitizing wipes, required this firm to follow the laborious BPR

process for its wipes. The firm estimates that—not including staff time—it has spent at least 230,000 euros (about \$280,000) to date on the process, most of it in fees to consultants and outside labs to provide information that is already readily available on IPA, such as its viscosity and surface tension. Two-and-one-half years later, it has yet to gain approval to sell its alcohol wipes in the EU under the BPR.¹⁰

It is reasonable for the EU to have some controls on biocides. But EU regulation of the complexity of the BPR for products like IPA wipes in the middle of a global pandemic is indeed unreasonable. By imposing high costs on firms attempting to enter the EU market, the BPR reduces supply to, and increases costs for, EU consumers. Its costs discriminate against smaller firms in favor of large, existing EU suppliers. By requiring EU-specific tests, the BPR imposes a technical barrier on trade on foreign suppliers.

Finally, new chemicals run a serious risk of being cost-prohibitive in the EU under the BPR because these substances (unlike IPA) have not yet been approved. The BPR is not just bad for today's EU consumers: The costs it imposes are unknowable because it is damaging innovation that would benefit tomorrow's consumers as well.

What the U.S. and the U.K. Should Do

The United States and the United Kingdom should:

Press for mutual recognition of testing by the EU. The point of testing should be to get an accurate result, not to employ a particular protocol if other protocols are equally satisfactory and less expensive. The U.S. and the U.K. should use the WTO to pressure the EU to accept the mutual recognition by all parties of testing conducted in labs certified by competent U.S., U.K., or national-level authorities within the EU, thereby creating a regime of testing equivalence and giving suppliers a wider range of labs from which to choose.

- **Use the WTO to lodge cases against the EU.** The EU is unlikely to change the entire basis of the one-size-fits-all BPR model. To the extent that the BPR infringes on commitments the EU has made under the WTO (including the requirement that foreign suppliers have a legal presence inside the EU), the U.S. and the U.K. should work through the WTO to bring the EU back into line with those commitments.

- **Tear down U.S. and U.K. non-tariff barriers.** The U.S. and the U.K. have erected, or failed to remove, many of their own non-tariff barriers. The EU is not the only offender in this regard. The EU is unlikely to be impressed by Anglo-American leadership by example, but if the U.S. and U.K. promote trade freedoms and profit as a result, this may in time encourage the EU to liberalize its own system as a way of competing with other, more dynamic, economies. A U.S.–U.K. Free Trade Agreement is one major way to achieve this objective.¹¹
- **Resist all applications of the EU model outside the EU.** The U.S. and the U.K. can only bring the EU under pressure to change the BPR if they oppose its spread, both in their own markets and around the world. The EU’s approach is one of imperialism by bureaucratic rulemaking. The U.S. and the U.K. need, in part through a U.S.–U.K. Free Trade Agreement, to offer a better model of trade by mutual recognition of reasonable standards.

The United Kingdom should:

- **Diverge from the BPR.** Owing to its recent exit from the EU, the U.K. is still, for practical purposes, participating in the BPR. There are benefits to U.K. labs maintaining the ability to test to EU standards, even if those standards are driven by bureaucracy, not science. It enables those labs—in the absence of mutual recognition of testing—to serve U.K. exporters. But there are no benefits for U.K. consumers or producers, or to the U.K. as a whole, by sticking with the BPR.¹²

The U.K. should immediately diverge from the BPR. It should reject a one-size-fits-all model for biocides and should instead adopt an approach that allows suppliers to use existing, open scientific literature in licensing procedures that recognize that higher levels of scrutiny should be applied to new products and substances—while lower levels are appropriate for well-tested approaches.¹³

Conclusion

The EU’s Biocidal Products Regulation illustrates why many EU member states have low economic growth. The BPR does not just burden foreign suppliers: It burdens EU suppliers, too. It raises prices for consumers, imposes unnecessary costs on producers, and makes it harder for the EU

to innovate. The bureaucracy imposed by the BPR adds nothing to safety, but each BPR-like measure is another brick in the EU wall preventing higher productivity and greater prosperity.

The ultimate price of the EU's many BPR-like policies, taken together, is the steady relative decline in the EU's share of the world economy. Such an outcome diminishes the influence of the Western democracies relative to China. The fact that the EU seeks to respond to the constraints it imposes on its own consumers and producers by encouraging other democracies to adopt its job- and growth-killing rules only makes the problem worse.

Working together, the U.S. and the U.K. should press the EU to amend the BPR to eliminate the non-tariff trade barriers it creates. The U.K. should diverge from the BPR.

Above all, both nations should oppose the broader EU model driving the BPR that prioritizes bureaucratic process over growth, jobs, consumer choice, and common sense.

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Endnotes

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