FAQ—REGULATORY COOPERATION, HARMONIZATION AND "GOOD REGULATORY PRACTICES" IN USMCA

Q: Are regulatory cooperation and regulatory harmonization the same thing?

A: Regulatory cooperation is a broad term that includes many activities, including consultations between regulators from different countries to discuss ways to eliminate differences between their countries' regulations—in other words, to discuss regulatory harmonization. Another end-product of regulatory cooperation could be an equivalency agreement, whereby two countries agree to accept each other's regulations and enforcement as "equivalent" even though the systems may be very different in practice. Regulatory cooperation can be informal and voluntary, or it can be a structured activity required by an international agreement. For example, the U.S. has created a US-Canada Regulatory Cooperation Council with detailed workplans and timetables for action covering many areas of government, and the New NAFTA (USMCA) requires U.S., Canadian and Mexican regulators to engage in regulatory cooperation in order to eliminate differences in workplace safety communication rules.

Q: Do regulatory cooperation and regulatory harmonization already exist? Or are these plans new?

A: While World Trade Organization standard-setting committees have existed for some time, we are seeing new and more comprehensive cooperation initiatives both within and outside of recent international agreements. These require countries to share information at the earliest stages of the rulemaking process, to give other countries' governments and regulated industries a seat at the table, and for regulators to meet in a formal process to systematically identify and eliminate differences in regulations—all in the interest of facilitating trade. After the original NAFTA went into effect, the U.S., Canada and Mexico established working groups to discuss harmonizing pesticide regulation and labeling, among other policy areas. In 2010-11 under the Obama administration, this process was formalized by executive action in the U.S.-Canada Regulatory Cooperation Council (RCC) and the U.S.-Mexico High Level Regulatory Cooperation Council. The RCC in particular developed extensive workplans in 23 different policy areas, including chemical safety risk assessment, meat inspection, aquaculture and transport of hazardous materials. In June 2018, the Trump administration and the Trudeau administration signed a Memorandum of Understanding that renewed the RCC and established guidance for its activities. Canada is also currently involved in an extensive regulatory cooperation process with the European Union pursuant to their recent bilateral trade agreement, CETA.

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Q: What about "Good Regulatory Practices"? How does that relate to regulatory cooperation or regulatory harmonization?

A: "Good Regulatory Practices" (GRP) is a chapter in New NAFTA that includes provisions defining what information and studies may be used to develop domestic regulations, how other countries should be involved in the rulemaking process, and procedures for adopting, reviewing and repealing regulations. These provisions also have the goal or effect of limiting precautionary approaches to regulating by preferring "risk-based" standard-setting and defining "science" in ways that can shield corporate information needed to regulate effectively. Confusingly, the GRP chapter also includes many provisions promoting regulatory cooperation and harmonization.

Q: These sound like positive things. I'm all for cooperation and harmonization. What's the problem?

A: In theory, getting together across international borders to develop standards that both protect the public interest and smooth the way for compliance by industry should benefit everyone. Unfortunately, past experience has shown that regulatory cooperation activities most often take place behind closed doors, with a corporate-directed deregulatory agenda, and with minimal participation by civil society or stakeholders outside of the regulated industries. Not even U.S. state governments may be consulted, including when they are the primary regulators. Often, the goal of harmonization is to adopt international standards. These international standards are rarely the most protective, and they are developed with strong industry participation and sometimes, by private industry standard-setting organizations instead of by public agencies. As a result, there is strong pressure to harmonize standards down to the lowest common denominator, resulting in a standard that becomes a regulatory ceiling preventing policy responses to new information, emerging technologies or changed conditions.

Q: Is there any chance that regulatory cooperation and harmonization will lead to health and safety problems?

A: Yes, because both can lead to preventing regulation in the first place or modifying protective standards to be less burdensome on industry while, at the same time, less protective of the public, workers, and the environment. There is a strong focus in New NAFTA and in the U.S.-Canada Regulatory Cooperation Council on engaging in regulatory cooperation and harmonization activities at the earliest opportunity, before regulations are initially developed in each country. There is also a push to adopt voluntary and non-regulatory mechanisms first, and then seeing whether they provide adequate protection. This approach has led to significant harm to public health and safety in the past. New and emerging policy areas that currently lack comprehensive regulation, such as gene editing, nano-scale technology, and digital agriculture, are specifically targeted for attention. This could short-circuit the usual regulatory process and leave the public and environment unprotected, for example, from increased exposure to toxins, manipulated genes in food and the environment, or corporate control of data.

Q: How would regulatory cooperation and harmonization affect the safety of my food?

A: Worsening food safety could result from these cooperation activities. The U.S. is already facing significant public health threats from foodborne disease, manifested most recently in pre-Thanksgiving warnings to avoid eating turkey from many processors and romaine lettuce from any source whatsoever because of contamination by deadly strains of E. coli and salmonella. Regulatory cooperation, regulatory harmonization, or declaring food systems mutually equivalent could lead to even worse problems by preventing the adoption of stricter food safety standards and allowing food to be sold that doesn't meet even existing inadequate standards. Also, while food systems may appear equivalent on paper, how regulations are implemented—including whether there are enough inspectors, the extent to which inspections have been privatized, and whether violations are penalized—can differ widely from one country to the next.

Q: Where is this stuff spelled out? Or at least, where does it exist? Is it just part of trade agreements, or are there other places it is hiding that I don't know about?

A: The June 2018 Memorandum of Understanding renewing the U.S.-Canada Regulatory Cooperation Council is posted online. The prior RCC workplans are publicly available through the Commerce Department's International Trade Commission website, but many details of the council's activities, including the membership and actions of the committees, are not readily available. The RCC's activities are not dependent on the existence of a trade agreement; it is taking place as an initiative of the executive branch. However, if New NAFTA goes into effect as written, these activities would be expanded and made more permanent, and could be enforced through dispute settlement. In fact, regulatory cooperation and harmonization shows up throughout the NAFTA 2.0 agreement, including extensive provisions in Chapter 28, "Good Regulatory Practices"; five "sectoral annexes" to Chapter 12, Technical Barriers to Trade, (covering chemicals, cosmetics, communication technology, energy performance standards, pharmaceuticals, and medical devices); and Chapter 9 on food safety.

Other regulatory cooperation initiatives are also underway. The U.S. Trade Representative has announced that it has existing authority to engage in regulatory cooperation discussions with the European Union on several issues, including pharmaceuticals, even without entering into a trade agreement with the bloc, and the U.S. Department of Agriculture has already entered into numerous equivalency agreements on food safety including with countries that the U.S. does not have a trade agreement with, such as an agreement with China on poultry.

Q: You mentioned that the regulatory provisions would be enforceable through dispute settlement. Could you be more specific?

A: The Chapter 28, "Good Regulatory Practices", is enforceable through state-to-state dispute settlement. In other words, through an enforcement action brought by one of the three NAFTA countries against another. Trade sanctions, as in other dispute settlement cases, could be imposed. As in prior free trade agreements, New NAFTA's state-to-state dispute settlement is an arbitration process. With respect to the GRP chapter, article 28.20 states that dispute settlement applies within one year of entry into force of the overall agreement and "for a matter arising under this Chapter," only "to address a sustained and recurring course of action or inaction that is inconsistent with a provision of this Chapter." Other NAFTA 2.0 chapters, such as Technical Barriers to Trade (Chapter 12) and its sectoral annexes, are also subject to dispute settlement.

Q: Could these regulatory cooperation and harmonization provisions cause the repeal of a regulation that is good for food safety or other public interest standards?

A: There are many ways that these provisions could undercut the effectiveness of U.S. protections and even result in the repeal of existing regulations. Some examples:

- One of the provisions in New NAFTA (Chapter 28, GRP) requires the U.S. to establish and maintain a procedure where businesses could petition an agency to repeal or modify a regulation that "has become more burdensome than necessary to achieve its objective." This provision opens the door to repealing effective food safety and other regulations that agribusiness and other corporate interests would rather not comply with.

- An agreement to recognize another country's food safety system as equivalent would allow food from that country to be sold in the U.S. even if it did not meet U.S. standards. While this wouldn't directly repeal any food safety laws, consumers could be exposed to substandard food and, at the same time, if the imported food is cheaper, there would be pressure to repeal the stronger (and more costly) domestic standard.

- Some New NAFTA provisions require harmonization of standards, for example for chemical safety information in the workplace. If regulators agreed to a lower harmonized standard, the stronger existing standard would be proposed for repeal. If it was not repealed, this could be a factor in a legal challenge brought by affected industries in domestic courts, or it could be subject to a state-to-state challenge by Canada or Mexico. The remedy wouldn't be automatic repeal, but the U.S. could be hit with retaliatory tariffs if it didn't change the regulation.

Q: What if we discover that something we thought was safe turns out not to be, and we need new laws to regulate it? Will regulatory cooperation and harmonization make that impossible, or unlikely? Who would decide?

A: Regulatory cooperation and harmonization, as well as the rules about science and risk assessment in the GRP chapter, will make it harder to regulate when new hazards are identified. If U.S. regulators need to get advance Canadian and Mexican support when new regulations are adopted, or at the very least engage in serious discussions, delay is likely. Moreover, many of the provisions in the GRP chapter and the Technical Barriers to Trade annexes would delay regulation of new and emerging technologies by requiring voluntary and non-regulatory measures to be tried first. Other provisions prioritize marketing products even if safety studies are incomplete. U.S. regulators could always decide to go ahead with regulation anyway without complying with all of these provisions, but the new rules could be vulnerable to legal challenge both in domestic courts and a trade-based dispute resolution forum. One of the biggest dangers is that regulators will be discouraged from pursuing regulations to address new safety concerns because they are worried that they will face legal challenges if they do—the "chilling effect."

Q: Europe has stronger food and chemical health and safety regulations than the U.S. does right now. Would regulatory cooperation and harmonization mean that instead of the U.S. raising our standards and level of protection, the EU would have to lower its standards and Europeans would be at higher risk?

A: There is certainly the potential that lower standards could result from regulatory cooperation initiatives. Even if the EU refused to change its standards, consumers would be vulnerable if there was an agreement to allow U.S.-produced food to be sold even if it did not meet EU standards, for example pork grown with the chemical additive ractopamine or chicken processed with various antimicrobial washes currently banned in the EU. A mutual equivalence agreement would undermine high EU standards and create pressure to lower those standards so that EU producers wouldn't be disadvantaged by higher production costs than for the U.S. imports. The United Kingdom may be even more vulnerable to reduced food standards resulting from harmonization with the U.S., especially if the Brexit process leads to a no-deal "crash out" of the European Union.

Q: To what extent does the regulatory chapter undo some of the gains in the ISDS chapter by forcing nations to tailor their regulations to NAFTA restrictions and corporate "rights"?

A: There has been an increasing corporate focus on stronger regulatory cooperation measures in recent trade negotiations. Many corporations, including the chemical and pesticide industries, are recognizing that preventing a regulation in the first place, rather than waiting to challenge it after the fact, is far more effective in reducing their costs. Now that ISDS has become widely reviled in the public sphere, even in government, this strategy is becoming a necessity. New NAFTA eliminates ISDS between the U.S. and Canada after three years and narrows the scope of corporate ISDS challenges between the U.S. and Mexico. New NAFTA's beefed-up regulatory cooperation and harmonization provisions, its language providing for petitions to repeal regulations, and the information limitations and requirements that undermine the precautionary approach to protecting the public, do indeed offset the ISDS gains. These provisions will make it harder to protect the public and environment in the future.

Q: With the ongoing turmoil of the Trump administration, and building opposition to the New NAFTA in Congress, how likely is it that what was negotiated will actually end up law?

A: Regardless of whether Congress agrees to New NAFTA, many of its regulatory cooperation and deregulation initiatives will continue. The U.S.-Canada Regulatory Cooperation Council was recently reaffirmed by the two countries and is being implemented without public awareness and oversight, but with extensive corporate participation. The deregulatory Office of Management and Budget oversees the RCC and views it as an opportunity to implement Trump directives such as the Executive Order requiring repeal of two regulations for every one that is adopted. We cannot expect Canada to be a brake on this activity, since Canada continues to be an enthusiastic supporter of similar measures and was a strong proponent of regulatory cooperation in New NAFTA. While these provisions were controversial in

the context of the Trans-Pacific Partnership, which included several countries considered to have low standards, such concerns are unlikely to be raised with long-term trading partners Canada and Mexico, or with the EU which is generally viewed as having higher standards than the U.S. In fact, the U.S. and the EU have announced that they have already initiated regulatory cooperation negotiations outside of any potential trade deal.