CETA Threatens EU and Member States' Ability to Effectively Regulate the **Dangers of Pesticides**



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I. Introduction

The EU-Canada Comprehensive Economic and Trade Agreement (CETA) is an agreement between the EU, its Member States, and Canada. The European Commission, Council of Ministers, and European Parliament have formally approved the agreement, and once Canada has ratified CETA according to its domestic procedures and notified the EU, most of the agreement will be provisionally applied. However, EU national parliaments must approve CETA before it can take full effect.

The main focus of CETA is to reduce differences in regulations, which are considered "trade irritants," by encouraging the EU and Canada to harmonize their regulations.¹ As the former Director-General of the World Trade Organization Pascal Lamy observed, "the real obstacles to trade and investment (between Canada and the EU) are differences in regulation."²

However, the EU and Canada regulate pesticides differently, and Canada has used trade mechanisms and instruments to lobby against EU pesticide regulations in the past. Regulatory convergence in pesticide regulation is therefore likely to lead to a lowering of EU standards.

CETA creates multiple forums for and imposes new obligations on EU and Canadian regulators to work towards regulatory convergence. CETA is also the first trade agreement formally approved by the EU that grants corporations the right to challenge EU policies and actions in private trade tribunals.³

Taken together, these provisions provide Canada and companies doing business in Canada a variety of new tools to challenge and influence EU and EU Member States' ability to regulate pesticides.

¹ Comprehensive Economic Trade Agreement, EU-Can., Oct. 30, 2016 [hereinafter CETA], arts. 21.3(b)(vi) (agreeing to avoid "avoid unnecessary regulatory differences"), 21.4(f)(i) (committing to "examine the possibilities for greater convergence on objective and scope of regulations"), 21.4(g) (committing to examine "opportunities to minimise unnecessary divergences"), 21.4(h) (committing to cooperate on international standards), 21.4(k) (agreeing to use same assumptions and methodologies), 21.4(n)(vi) (agreeing to "conduct cooperative research to minimize unnecessary differences"), 21.4(r) (committing to identify "the appropriate approach to reduce adverse effects of existing regulatory differences"), and 21.5 (agreeing to enhance "convergence and compatibility between the regulatory measures").

² Anne Wordsworth et al., *European and Canadian Environmental Law: Best Practices and Opportunities for Co-operation* iv (Ca. Envtl. Law Ass'n 2007).

³ Although individual Member States are party to bilateral investment treaties that include ISDS, the only EU agreement currently in force that includes ISDS is the Energy Charter Treaty. The EU is negotiating numerous other trade agreements that include ISDS, but the EU has not yet formally approved them.

This report demonstrates that the national parliaments of EU Member States should vote against CETA ratification in order to preserve EU and its Member States' ability to maintain strong pesticide management and to protect people and the environment from the harmful effects of pesticides.

This report begins by exploring trade rules and environmental health protections in EU food safety regulations in light of scientific uncertainty. Next, it examines the differences between EU and Canadian pesticide regulations, in particular regarding the approval of active substances in pesticides and the setting of Maximum Residue Limits (MRLs). The report then explores how regulatory cooperation under CETA could affect certain upcoming EU regulatory decisions. Finally, the report describes potential effects of CETA's specific investors' rights on EU regulatory processes that protect people and the environment from pesticides.

II. Protecting People & Environment in Light of Risk & Uncertainty

Scientific information about the safety of many chemicals, including pesticides, is often insufficient. Understanding the full range of adverse health outcomes, chronic effects, and the interactive impacts of exposure to multiple pesticide ingredients (i.e. the "cocktail effect") is particularly challenging.⁴ Decisions about whether to use pesticides in light of this uncertainty, as well as decisions about how much risk a society should bear in exchange for the potential benefits of using pesticides, are political questions. Applying the precautionary principle, which serves as the basis of EU environmental policy,⁵ the EU precludes the use of pesticides when there is inadequate information about their safety.

"Because it is often challenging to reach definitive conclusions about environmental impacts on human health, the application of the precautionary principle is critical in addressing uncertainty." David Boyd As explained by the European Commission (the Commission), the precautionary principle provides a basis for prohibiting products that are likely to be hazardous when scientific data does not provide a complete evaluation of the risk.⁶ The EU also places responsibility on companies to generate a certain amount of information

demonstrating the safety of pesticides before they are allowed on the market.⁷ In authorizing pesticides, the EU prioritizes protecting the environment and human and animal health over improving plant production.⁸

⁴ David R. Boyd, *Cleaner, Greener, Healthier: A Prescription for Stronger Canadian Environmental Laws and Policies* 145 (UBC Press, 2015).

⁵ Consolidated Version of the Treaty on the Functioning of the European Union art. 191, 2008 O.J. C 115/47, at 133 [hereinafter TFEU].

⁶ Communication from the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1 final [hereinafter Commission Communication on the Precautionary Principle].

⁷ *Id.* at 20.

⁸ Council Regulation 1107/2009/EC concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, recital 24, 2009 O.J. L309/1 [hereinafter Pesticides Regulation].

On the other hand, the World Trade Organization (WTO) requires food safety measures (including pesticide regulations) to be based on risk assessment and "sufficient scientific evidence" justifying the measures.⁹ To be considered sufficient, the information must demonstrate the existence of the risk that the food safety measure is designed to address¹⁰ and how the measure will address that risk.¹¹ In addition, food safety measures must be based on existing international standards, guidelines, or recommendations, such as the maximum pesticide residue levels determined under the auspices of the United Nations Food and Agriculture Organization (FAO) and the World Health Organizations (WHO) Codex Alimentarius Commission (Codex).¹² A party can decide to achieve a higher level of protection than provided by international standards, but the level of protection sought must be described with "sufficient precision."¹³ When uncertainty exists, only temporary food safety measures are permitted for a "reasonable amount of time."¹⁴

Under these trade rules, which are re-affirmed in CETA,¹⁵ Canada (together with the US) has successfully challenged the EU's decision to regulate the use of beef hormones and genetically modified organisms at the WTO. According to the WTO Appellate Body Panel, the requirements for a risk assessment and sufficient scientific evidence reflect the "delicate and carefully negotiated balance" the parties have agreed to in weighing "the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings."¹⁶ The Panel acknowledged the need for governments to proceed cautiously when the risks are unclear, but only insofar as they are "irreversible, e.g. life terminating, damage to human health are concerned."¹⁷

III. Differences Between EU and Canadian Pesticide Regulations

The EU and Canada regulate pesticides differently and have historically reached different conclusions about the risk of hazardous pesticides. Although both the EU and Canada endorse the precautionary principle, the impetus for implementation in both places has less to do with the degree to which the principle is embodied in law and policies and more with the overall political

⁹ Agreement on the Application of Sanitary and Phytosanitary Measures, arts. 2.2 and 5.1, Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

¹⁰ Panel Report, United States - Poultry (China), ¶ 7.200, WT/DS392/R (Sept. 29 2010) (noting that "the scientific evidence must be sufficient to demonstrate the existence of the risk which the measure is supposed to address").

¹¹ Appellate Body Report, *Japan — Agricultural Products II*, ¶ 73, WT/DS76/AB/R (Oct. 27 1998) (noting that sufficiency "requires the existence of a sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific evidence.")

¹² SPS Agreement, *supra* note 9, art 3.1. The Codex is a collection of standards, guidelines and codes of practice to protect consumer health and promote fair practices in food trade.

¹³ Appellate Body Report, Australia – Measures Affecting Importation of Salmon ¶ 207, WT/DS18/AB/R (Oct. 20 1998).

¹⁴ SPS Agreement, *supra* note 9, art. 5.7.

¹⁵ CETA, *supra* note 1, art. 5.4.

 ¹⁶ Appellate Body Report, *EC* — *Hormones*, ¶ 177, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998).
¹⁷ *Id*.

support for precautionary decision-making.¹⁸ Some examples of how the EU and Canada differ in their approach to pesticides include the approval of active substances (i.e., the operative ingredient in pesticides) and the setting of maximum residue limits (MRLs), as discussed in more detail below.

A. Approval of Active Substances

Active substances have general or specific effect on harmful organisms or on plants, parts of plants, or plant products. Under both EU¹⁹ and Canadian²⁰ law, the management of risks from active substances in pesticides begins with the identification of hazards. Depending on the nature and dimension of the hazards, as well as their exposure conditions, generic risk considerations or a specific risk assessment can lead to the development of risk management measures. However, the two entities differ in their approach to generic risk considerations and the conclusions they draw from risk assessments, resulting in different determinations for the approval of active substances. Thus, for example, the EU prohibits the use of a number of active substances in pesticides that are permitted in Canada. A 2015 review identified nearly 40 active substances that were approved for use in Canada but banned by the EU.²¹ Over one thousand registered pesticide products in Canada contain substances banned in the EU and other developed countries.²²

1. Hazard-Based Cutoffs

In the EU, the presence of persistent organic pollutants (POPs), persistent, bioaccumulative, and toxic substances (PBT), very persistent and very bioaccumulative substance (vPvB), and substances that are carcinogenic, mutagenic, or reprotoxic (CMR), or which have endocrine disrupting properties (EDs)²³ automatically triggers risk management measures without consideration of exposure. These are generally referred to as "hazard-based cutoff criteria." Recognizing the decades of evidence demonstrating that certain intrinsic hazards cannot be adequately predicted or controlled, no pesticide containing such substances is allowed on the EU market.

Canada takes a different approach to pesticide regulation. Although Canada also uses cutoff criteria for PBTs, it does not do so for other substances (such as CMRs or EDs).²⁴ For all substances but PBTs, Canada requires a specific risk assessment addressing dose response, exposure, and risk characterization.²⁵

¹⁸ Boyd, *supra* note 4, at 247 (noting that although commonly found in both federal and provincial environmental legislation and endorsed by the Supreme Court of Canada, implementation of the precautionary principle has not yet lived up to aspiration.)

¹⁹ Pesticides Regulation, *supra* note 8, Annex II, section 3.7.

²⁰ Health Canada, Science Policy Note: Technical Paper – A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency (Dec. 22, 2000).

²¹ Boyd, *supra* note 4, at 145-6.

²² *Id.* at 146-7.

²³ Pesticides Regulation, *supra* note 8, Annex II.

²⁴ Canada Environmental Protection Act §§65(3) & 77(3)(a), S.C., ch. 33 (1999).

²⁵ Health Canada, Science Policy Note: Technical Paper – A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency (Dec. 22, 2000).

2. Risk Assessments

In both the EU and Canada, substances that are not excluded by hazard-based cutoffs may still be banned if they fail the risk assessment. The two jurisdictions can differ in their decisions based on these full risk assessments, leading the EU to reject some substances while Canada approves them. For example, the EU banned atrazine and simazine because of potential drinking water contamination.²⁶ Canada continues to allow the use of these pesticides, with atrazine of the ten most heavily used pesticides in Canada by volume. However, because Canada's permissible limit for atrazine and simazine in groundwater is 50 times higher than the limit in the EU, these pesticides are authorized.²⁷

In another example, the EU banned chloropicrin due to health risks concerns for operators and groundwater, as well as aquatic, bird, and mammal species.²⁸ However, Canada determined that "…continuous subchronic and chronic exposure to birds and mammals is expected to be minimal and is not of concern."²⁹

Canada has also favored risk reduction measures over bans. For example, when the EU banned paraquat due to concerns about the risk to birds and mammals, Canada concluded that requiring the use of groundboom sprayers with drift-reducing shields would result in minimal residue on crops eaten by birds.³⁰

Canadian and EU risk assessment decisions can also differ based on the way that each handles incomplete information. Many EU decisions to ban active substances are based, at least in part, on a lack of sufficient information, including bans on dichlorvos, ³¹acephate, ³² atrazine, ³³ carbaryl, ³⁴ chloropicrin, ³⁵ diazinon, ³⁶ permethrin, ³⁷ and trichlorfon. ³⁸ The Pesticide Action Network (PAN)

²⁶ Commission Decision No. 2004/248/EC (Simazine), 2004 O.J. L 78/53.

²⁷ Pest Management Regulatory Agency, Re-evaluation Note REV2017-02, Special Review Decision: Simazine (Feb. 10, 2017).

²⁸ Commission Implementing Regulation (EU) No 1381/2011 (Chloropicrin), 2011 O.J. L 343/26.

²⁹ Pest Management Regulatory Agency Re-evaluation Note REV2017-04, Special Review Decision: Chloropicrin (Mar. 10, 2017).

³⁰ Pest Management Regulatory Agency, Re-evaluation Note REV2015-14, Special Review Decision: Paraquat (Dec. 23, 2015).

³¹ Commission Decision No. 2007/387/EC (Dichlorvos), 2007 O.J. L 82/40 (noting the "uncertainties of the genotoxic and carcinogenic properties of the substance also considering the overall poor quality of the dossier").

³² Commission Decision 2004/129/EC (Acephate), 2003 O.J. L 37/27 (noting insufficient information).

³³ Commission Decision No.2004/248/EC (Atrazine) 2004 O.J. L 78/53 (noting insufficient monitoring data regarding impacts to groundwater).

³⁴ Commission Decision No. 2007/355/EC (Carbaryl) 2007 O.J. L 133/40 (noting insufficient information about consumers exposure).

³⁵ Commission Implementing Regulation (EU) No. 1381/2001 (Chloropicrin) 2011 O.J. L 343/26 (noting missing data for groundwater and surface water assessment, sediment dwellers, bees, earthworms, and non-target plants).

³⁶ Commission Decision No. 2007/393/EC (Diazinon) 2007 O.J. L 148/9 (noting insufficient information on toxic impurities),

³⁷ Commission Decision No. 2000/817/EC (Permethrin) 2000 O.J. L 332/114 (noting insufficient information).

³⁸ Commission Decision No. 2007/356/EC (Trichlorfon) 2007. O.J. L 133/42 (noting significant lack of supporting

International identifies these substances as highly hazardous pesticides,³⁹ some of which PAN considers among the highest priority pesticides for phase out.⁴⁰ Conversely, Canada allows these substances based on risk assessments. These assessments must necessarily rely on assumptions and extrapolations where there are gaps in information.⁴¹

In 2016, a Canadian federal court ordered the its Pest Management Regulatory Agency (PMRA) to conduct a special review of pesticides that had been banned by member countries of the Organization for Economic Co-operation and Development (OECD) for environmental or health reasons, as required by Canadian law.⁴² As of June 2017, the PMRA had conducted ten of these reviews, reaffirming its approval of every one of those substances pursuant to its risk assessment.

B. Maximum Residue Levels

MRLs are the highest levels of residues legally allowed to be in or on food items. The EU generally has the strongest MRL standards in the world.⁴³ For many pesticides, Canada and Codex allow higher residue levels than the EU.⁴⁴ Canada also allows a higher default MRL, which is used when a MRL has not been determined. In the EU, the default limit is ten times lower than in Canada.⁴⁵

Canada's approach to hazard-based cutoffs, risk assessment, and MRLs reflects the political decisions the country has made with respect to balancing the risks and benefits of pesticides. The different risk tolerances for pesticides between the EU and Canada create a high potential for friction when they seek to reduce non-tariff trade barriers in agricultural products. This friction is most likely to result in threats to EU food safety through two mechanisms under CETA: regulatory cooperation and investor dispute resolution.

IV. CETA's Regulatory Cooperation Threatens EU Food Safety

Trade pressures have threatened to undermine the strong pesticide regulations in the EU well before CETA was ratified, but the pressure is likely to increase and its impact worsen under CETA's regulatory cooperation provisions. These provisions provide an avenue for Canada to

studies).

- ⁴¹ Mark Eliot Shere, The Myth of Meaningful Environmental Risk Assessment, 19 Harv. Envt'l L. Rev 409, 413 (1995).
- ⁴² Equiterre and David Suzuki Foundation v. Minister of Health, 2016 FC 554 (CanLII) (May 17, 2016).
- ⁴³ Caroline Handford, et al., A review of the global pesticide legislation and the scale of challenge in reaching the global harmonization of food safety standards: Global Harmonization of Legislation, 11 Integrated Envtl Assessment and Mgmt 525, 528 (2015).
- ⁴⁴ See Boyd, supra note 4 at 150 (noting that "in a head-to-head comparison with the European Union, Canada has a weaker MRL in thirty-four out of thirty-eight cases.)
- ⁴⁵ Compare art. 18, Commission Regulation No. 396/2005/EC (MRLs) 2005 O.J. L 70/1 (setting default at 0.01 mg/kg) with Canadian Food and Drug Regulation (C.R.C., c. 870), § B.15.002(1) (setting default MRL at 0.1 mg/kg).

³⁹ PAN International, List of Highly Hazardous Pesticides (December 2016) http://www.pangermany.org/download/PAN_HHP_List_161212_F.pdf.

⁴⁰ Pesticides Action Network and IPEN, *52 priority endocrine disrupting pesticides for phase out* (identifying atrazine, carbaryl, and trichlorfon) http://ipen.org/sites/default/files/documents/hhps-edcs-postcard-back-v1_2a.pdf.

influence EU regulations by questioning their scientific and economic justification and by undermining their application through harmonization and mutual recognition. Although regulatory cooperation on any particular activity is not required, the "voluntary" nature of these provisions does not diminish the potential for Canada to sway EU decision-making.

Pursuant to CETA, the EU has agreed to meet with Canada in three different regulatory forums to consult on issues related to pesticides. CETA also provides for additional specific consultation where a Party can present its concerns about food safety measures and technical regulations, including pesticides.⁴⁶ These forums are explicitly designed for the parties to influence each other's laws.⁴⁷

Scrutiny and questioning of the sufficiency of scientific evidence justifying food safety measures is a primary avenue of influence. CETA's committees are specifically charged with facilitating discussions related to the scientific basis of regulations, including risk and hazard assessments.⁴⁸ Upon Canada's request, the EU must provide a risk analysis, scientific opinions, relevant information, studies, and data supporting its proposed regulations.⁴⁹ These discussions provide an opportunity for Canada to promote industry data, as it has at the WTO.⁵⁰

Regulatory cooperation provides an opportunity for Canadian regulators to question not only the sufficiency of scientific justifications, but also the economic rationale for EU laws. For example, CETA encourages regulators to exchange views on the costs and benefits of enacting protective measures and the "economic practicability" of those measures in relation to their objective.⁵¹ Yet a consideration of the economic impacts of restrictions on pesticides runs contrary to the EU's clear prioritization of human health and environmental protection.⁵²

The elimination of regulatory differences is a central aspect of regulatory cooperation. As the European Parliament recognized in the context of the Transatlantic Trade and Investment Partnership,⁵³ regulatory convergence and mutual recognition could align standards to the lowest level.⁵⁴ For example, CETA promotes deregulation through its mutual recognition provisions. CETA requires the EU to accept Canada's food safety regulations as equivalent to its own if

⁴⁶ CETA, *supra* note 1, arts. 4.7, 5.12, 5.14 & 21.6.

⁴⁷ *Id.*, art. 21.4(d) (stating purpose of cooperation is "so that comments and proposals for amendments may be taken into account.")

 $^{^{\}rm 48}$ Id., arts. 4.7(1)(c) & 5.14(2)(f).

⁴⁹ Id., arts. 4.4 & 5.11(2).

⁵⁰ WTO Committee on Technical Barriers to Trade, Minutes of the Meeting of 9 Nov. 2007, G/TBT/M/43 (Jan. 21, 2008), ¶ 95 (noting Canada complaint that the EU did not avail itself of industry's "offer to provide detailed data to assist in a scientific assessment" of nickel-based substances).

⁵¹ CETA, *supra* note 1, art. 21.4(f)(ii) ("a comparison of the potential cost-effectiveness of the regulatory proposal to that of major alternative regulatory requirements or approaches considered"); *see also*, art. 21.4(a)(iv) ("exchange experiences with regulatory tools and instruments, including regulatory impact assessments").

⁵² See, e.g., Pesticides Regulation, supra note 8, recitals 8 & 10.

⁵³ The Transatlantic Trade and Investment Partnership is an agreement between the EU and the EU, similar to CETA. The agreement has not been finalized.

⁵⁴ European Parliament, Directorate-General for Internal Policies, Risks and Opportunities for the EU Agri-Food Sector in a Possible EU-US Trade Agreement 12 (2014) [hereinafter Risks and Opportunities].

Canada "objectively demonstrates" to the EU that its measure achieves the EU's "appropriate level" of protection.⁵⁵ The criteria to measure how Canada would successfully demonstrate that its regulation of a food safety measure is equivalent will be measured against principles and guidelines to determine, recognize, and maintain equivalence that are yet to be drafted.⁵⁶ Because the Annex that governs equivalence has not yet been drafted, it is unclear how equivalence will be determined, and it is also unclear how "appropriate level" of protection will be defined. Thus, the Parties have agreed to recognize each other's food safety laws under a process that will be created without democratic input and that could leave little ability for the EU to maintain its own level of protection.

It is clear that in specifying the process to establish equivalence, the CETA commitment will be more proscriptive than what both parties have agreed to under the WTO.

CETA imposes no obligations of transparency or public participation in these forums, although it allows for consultations with "private entities." The parties are not required to consult with stakeholders, and CETA provides no guidance for how voluntary consultations should occur.⁵⁷ Thus, significant policy making efforts will take place outside of public oversight.

The EU's obligations to cooperate with Canada apply to a wide range of food safety related issues, including active substance approvals and the determination of MRLs.

A. Active substances

The Commission's decisions regarding active substances will be subject to regulatory cooperation. Many of these are highly contentious, including the pesticide regulation refit, criteria, and guidance on EDs, and a decision on whether to allow the continued use of glyphosate.

1. Evaluation and Fitness Check of the Pesticide Regulation

The Commission's pending evaluation and fitness check of the pesticide regulation will be subject to regulatory cooperation rules. One of the issues the Commission has identified for this evaluation is the use of hazard-based cutoff criteria.⁵⁸ Within Europe, the pesticide industry has lobbied for revisions to the regulations that would eliminate hazard-based cutoffs altogether.⁵⁹ The EU and US pesticide industry has stated that the elimination of hazard-based criteria is a necessary pre-condition to achieving regulatory convergence.⁶⁰ Canada has already complained about the

⁵⁵ CETA, *supra* note 1, art. 5.6(1).

⁵⁶ *Id.*, art. 5.6(2), Annex 5-D.

⁵⁷ Id., art. 21(8).

⁵⁸ Roadmap for the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues 5 (Nov. 17, 2016).

⁵⁹ Position on the future revision of Regulations 1107/2009 and 396/2005 (European Crop Protection Association) July 13, 2015, <u>http://www.ecpa.eu/sites/default/files/22085-ECPA_position_on_future_revision_of_Regs_1107and396-Updated_0.pdf</u>.

⁶⁰ Proposal on US-EU Regulatory Cooperation (European Crop Protection Association and CropLife America) March

EU's hazard-based cutoffs through the WTO⁶¹ and EU public consultations.⁶²

Given Canada's use of risk assessment for most pesticide hazards, Canada will presumably use the regulatory cooperation provisions of CETA to continue its efforts to undermine the cutoffs by arguing that generic risk assessment (i.e. hazard-based cutoffs) for any substances that are not PBTs are "trade irritants."

2. Endocrine Disrupting Chemicals

The Canadian government has been particularly vocal in its opposition to the EU's approach to regulating endocrine disruptors (EDs), arguing that the proposed ED criteria "have the potential to significantly disrupt Canadian and global exports of agriculture and agri-food products to the EU" and would violate trade rules.⁶³ In particular, Canada argued that trade rules require the EU to consider additional factors of risk when defining ED criteria, such as "the degree of potential exposure to these substances."⁶⁴ Many Canadian companies also argued that the ED criteria are unnecessary barriers to trade and violate the requirement for a risk assessment.⁶⁵

Canada is poised to continue its tactic of using regulatory cooperation to pressure the EU to incorporate more aspects of risk assessment in the regulation of EDs, a contradiction to legislation democratically adopted by the EU. Because CETA provides multiple one-on-one forums for Canada and the EU, outside public scrutiny, this pressure on the EU is likely to be much greater.

In each of these forums, Canada is likely to rely on CETA's regulatory cooperation provisions relating to the assessments of risk and hazard⁶⁶ to continue arguing against the EU's proposed

⁶³ Public consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and the biocidal products regulation, 26.09.2014 to 16.01.2015, Submission by Government of Canada <u>http://ec.europa.eu/dgs/health_food-</u> <u>safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm#CD [hereinafter Canada</u> 2015 submission].

^{7, 2014,} at 1. [hereinafter ECPA/CLA Proposal],

https://corporateeurope.org/sites/default/files/attachments/ecpa-cla_ttip_position__paper_10-03-14.pdf. See also id. at 6 (noting "we have particular concern about the EU's hazard-based cut off criteria").

⁶¹ See, e.g., WTO Committee on Technical Barriers to Trade, Minutes of the Meeting of 9-10 March 2016, G/TBT/M/68 (May 12, 2016) ¶ 2.143 (arguing that the EU's hazard based approach "contravened the fundamental principle of the WTO SPS agreement, which was to base measures on scientific risk assessments and to not maintain them without scientific justification") [hereinafter TBT Committee Minutes of March 2016].

⁶² Commission Regulation .../... setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009 (draft), Feedback of Government of Canada, 28 July, 2016 [hereinafter Canada 2016 Feedback].

⁶⁴ Canada 2016 Feedback, supra note 62.

⁶⁵ See, e.g., Commission Regulation .../... setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009 (draft), Feedback of Canada Grains Council, Canadian Seed Trade Association, Canola Council of Canada, Croplife, Grand Growers of Canada, Ontario Agriculture Business Association, Soy Canada, and Western Canadian Wheat Growers Association, 28 July, 2016.

⁶⁶ CETA, *supra* note 1, arts. 4.7(1)(c) & 5.14(2)(f).

criteria as an unnecessary barrier to trade insufficiently supported by science.⁶⁷ The pesticide industry, notably opposed to the regulation of EDs, has specifically identified the "opportunity" in CETA to harmonize the scientific and risk assessment procedures related to EDs in pesticides.⁶⁸

CETA also provides Canada with an opportunity to slow the implementation of the criteria once adopted – an issue Canada has already inquired into at the WTO. Although the criteria are supposed to go into effect immediately upon their entry into force, Canada can request that their effective date be delayed, and under CETA, the EU must "give positive consideration" to this request.⁶⁹

The Commission has already revised the ED criteria proposal in an apparent attempt to address trade concerns, and in light of the likely increase in pressure from Canada under CETA, the Commission is likely to continue to cave to Canadian pressure in the finalization of the criteria, the promulgation of a guidance document, and future actions to regulate EDs.

How do trade threats influence the Commission?

The EU's trade obligations appear to have influenced the Commission's work on developing ED criteria. In July 2016, a Commission official acknowledged to ambassadors from the United States, Canada, and other countries that the Commission proposed to establish maximum residue levels for pesticides containing EDs in an effort to "address the concerns" of the ambassadors.⁷⁰ In so doing, the Commission's proposal included an amendment that would allow the use of ED pesticides on products from Canada even though they are banned in the EU, as long as the residues from those pesticides did not exceed specified levels (to be determined in the future).⁷¹

Other aspects of the ED proposal also seem responsive to trade related pressures. The Commission proposed an exception to the ban on EDs in pesticides if the risk of exposure is negligible.⁷² The introduction of risk assessment may better meet WTO and CETA rules, although it undermines the EU law's intent to prohibit endocrine disrupting pesticides. In addition, the proposal does not distinguish between known, presumed, and suspected EDs, which "deprives the legislator of the flexibility to adjust regulatory responses depending on the level of evidence."⁷³

⁶⁷ See, e.g., TBT Committee Minutes of March 2016, *supra* note 61, ¶ 2.143 (arguing that the EU's hazard based approach "contravened the fundamental principle of the WTO SPS agreement, which was to base measures on scientific risk assessments and to not maintain them without scientific justification.")

⁶⁸ ECPA/CLA Proposal, *supra* note 60 at 10.

⁶⁹ CETA, supra note 1, art. 4.6(7).

⁷⁰ Memo re BTO meeting Commissioner Andriukaitis with Ambassadors, 13 July 2016. http://www.stephanehorel.fr/wpcontent/uploads/2016/11/11_BTO_Meeting_Andriukaitis_Ambassadors_2016.pdf

⁷¹ Commission Regulation (EU) .../... setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009, Ref. Ares(2016)3071834 - 29/06/2016, draft annex. [hereinafter Draft ED Criteria].

⁷² Id.

⁷³Giulia Carlini et al., Disrupted Criteria: The Criteria To Identify Endocrine Disruptors: Implications Beyond Pesticides And Biocides 9 (CIEL and ClientEarth 2017), <u>http://www.ciel.org/wp-content/uploads/2017/02/Disrupted-Criteria_EDCs_Final_14feb2017.pdf</u>.

3. Glyphosate

Depending on when CETA is provisionally applied, the EU's upcoming review of glyphosate, a potential carcinogen, would also be subject to regulatory cooperation under CETA.

At the time of writing, the Commission has extended the active substance approval for glyphosate while the substance undergoes a prolonged and contentious review. The review should be completed after the European Chemical Agency's opinion is due at the end of 2017.⁷⁴ A European Citizen's Initiative proposes a ban on glyphosate, and the Commission is required to give it serious consideration.

The Commission's review of glyphosate is particularly contentious, not only because of the dispute between the WHO and the Commission about the scientific evidence of harm caused by this pesticide,⁷⁵ but also because of the importance of the product to Canadian agriculture.⁷⁶ Canada's involvement in EU decision-making processes through regulatory cooperation under CETA will only make it more difficult for the Commission to strictly regulate glyphosate.

Given Canada's overt opposition to the EU's use of hazard-based cutoffs, the country is likely to challenge and attempt to influence a wide range of future decisions related to substances of very high concern, such as those that are carcinogenic, mutagenic, reprotoxic, or EDs. Canada is also likely to question the scientific basis and economic rationale of EU decision-making for other substances that undergo a full risk assessment. The regulatory cooperation provisions of CETA therefore pose a serious health risk to EU workers, consumers, and communities.

B. Maximum Residue Levels

Regulatory cooperation under CETA will also create ways for Canada to advocate for higher levels of toxic pesticides permitted on foods exported to the EU. Regulatory convergence in the area of MRLs is particularly important to the Canadian pesticide industry because it would dramatically simplify regulatory approval of its products.⁷⁷ In addition, the industry seeks to establish MRLs for pesticides that are not approved in the EU. In this way, Canadian products with residues of EU-banned pesticides can be sold in the EU, as long as the residues do not exceed the established MRLs.⁷⁸

⁷⁴ Commission Implementing Regulation (EU) 2016/1056 (Glyphosate) 2016 O.J. L 173/52.

⁷⁵ See, e.g., European Food Safety Authority Press Release (Jan. 13, 2016), <u>http://www.efsa.europa.eu/en/press/news/160113.</u>

⁷⁶ Pest Management Regulatory Agency, Proposed Re-evaluation Decision PRVD2015-01: Glyphosate (Apr. 13 2015) (noting "Glyphosate is the most widely used herbicide in several major crops grown in Canada such as canola, soybean, field corn and wheat.")

⁷⁷ Croplife Maximum Residue Limit for Pesticides Overview, Jan. 19 2016 (stating "Our ultimate aspiration is one truly Global residue GAP that can be submitted simultaneously in all countries to ensure MRL harmonization") [hereinafter Croplife MRL Overview], <u>http://www1.agric.gov.ab.ca/\$Department/deptdocs.nsf/all/crop15631/\$FILE/carolsaunders.pdf</u>.

⁷⁸ ECPA/CLA Proposal, *supra* note 60 at 6.

The Commission has already weakened its stance with respect to MRLs that are below Codex levels in response to trade pressures.⁷⁹ For example, wheat is the most important agricultural commodity that Canada exports to the EU,⁸⁰ and the Canadian pesticide industry specifically identified MRLs for chlormequat in wheat as a "challenge" for Canadian growers.⁸¹ After CETA negotiations began, the European Food Safety Authority (EFSA) recommended an increase of the MRL for chlormequat in wheat, which would be the same as the Codex and Canadian MRLs.⁸² Regulatory cooperation under CETA is only likely to further influence the Commission's decisions to increase MRLs in the future.

MRLs are reviewed regularly, and in 2017, the EU will begin reviewing the MRLs⁸³ for nearly 25% of the pesticides identified as having endocrine disrupting properties.⁸⁴ The Commission has already suggested that Canada will be able to avoid the ban on ED pesticides as long as its products meet MRL requirements.⁸⁵ How high those MRLs are set will likely depend on the pressure Canada continues to put on the Commission. The case of chlormequat MRL on wheat sets a worrying precedent.

Under CETA, Canada will be able to use regulatory cooperation to advocate for residue limits that match its own, including by questioning the EFSA's scientific opinions and supplying contrary scientific studies commissioned by the companies that use these active substances in their pesticides. For example, whether or not the EU decides to continue allowing glyphosate, Canada is likely to pressure the EU through regulatory cooperation to adopt a higher MRL for this substance. Canada has specifically raised its concerns at the WTO about the failure of countries to apply the Codex MRL for glyphosate.⁸⁶

⁷⁹ European Parliament, Opinion of the Committee on the Environment, Public Health And Food Safety for the Committee on International Trade ¶ U (Apr. 16, 2015), in *Report containing the European Parliament's recommendations to the European Commission on the negotiations for the Transatlantic Trade and Investment Partnership (TTIP)* A8-0175/2015 (June 1, 2015) (noting that trade obligations are likely to result in the Commission overriding EFSA's traditionally strong stance in favor of lower MRLs).

⁸⁰ Eurostat, EU trade since 1988 by HS2-HS4 (DS-016894), http://ec.europa.eu/eurostat/data/database.

⁸¹Croplife MRL Overview, *supra* note 77.

⁸² European Food Safety Authority, Review of the existing maximum residue levels for chlormequat according to Article 12 of Regulation (EC) No 396/2005 19, table 4 (Mar. 7, 2016,), http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4422/full.

⁸³ WTO Committee on Sanitary and Phytosanitary Measures, Communication from the EU, On-Going Review of Maximum Residue Levels of Pesticides in the European Union 7, table 2, G/SPS/GEN/1494 (June 17, 2016).

⁸⁴ Pesticide Action Network Europe, Impact Assessment of the Criteria for Endocrine Disrupting Pesticides 11 (n.d.) (identifying active substances will be reviewed in the "future process" beginning in the second quarter of 2017), <u>http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pan-report-impact-endocrine-criteria-2016.pdf</u>.

⁸⁵ Memo re BTO meeting Commissioner Andriukaitis with Ambassadors, 13 July 2016, http://www.stephanehorel.fr/wpcontent/uploads/2016/11/11_BTO_Meeting_Andriukaitis_Ambassadors_2016.pdf

⁸⁶ WTO Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 27-28 October, 2016 ¶4.28, G/SPS/R/84 (Dec. 22, 2016), ; WTO Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting of 30 June – 1 July, 2016 ¶¶12.5 & 12.6, G/SPS/R/83 (Aug. 9, 2016).

Beyond influencing the EU's specific MRLs, Canada is also likely to seek mutual recognition or harmonization for setting, maintaining, revising, and enforcing MRLs generally.⁸⁷ Thus, under CETA's regulatory cooperation provisions, the Commission will be under significant pressure to facilitate trade in agricultural products by accepting Canadian products with higher levels of pesticide residues, by raising its own acceptable levels, and by aligning its overall approach to establishing and regulating MRLs with that of Canada, resulting in a higher consumption of toxic pesticides by EU residents.

In sum, the effect of regulatory cooperation on EU decision-making is uncertain, but it is most likely that harmonization will occur downwards to the lower level of protection.⁸⁸ Even where regulatory cooperation does not lead to the weakening of EU standards, the process can be burdensome and costly, and slow the EU's ability to enact protective measures on a timely basis. The time and effort involved will detract from the goal of protecting people and the environment.

V. Disputes

In addition to the effects of regulatory cooperation, CETA's dispute resolution provisions are most likely to result in threats to EU food safety and environmental health.

A. State-to-State Dispute Resolution Under CETA

Under CETA's state-to-state dispute resolution procedure, Canada could challenge a variety of EU laws and future decisions. Many of these could also be brought to the WTO, but those related to new government obligations imposed by CETA would be enforceable only under CETA, such as the requirements to: recognize food safety regulations as equivalent;⁸⁹ provide a rational legal basis and objectives for a proposed regulation; and provide sufficient time for comments on technical regulations.⁹⁰ Canada could also challenge Member State and local regulations, such as local government restrictions on the use of glyphosate. As compared to the WTO, CETA places a heightened burden on the EU to ensure compliance with CETA *at all levels of government.*⁹¹ Canada has demonstrated its willingness to employ state-to-state dispute resolution to promote industrial interests over health and environmental concerns, as demonstrated by its WTO challenge to a French ban on asbestos.

⁸⁷ ECPA/CLA Proposal, *supra* note 60 at 6.

⁸⁸ See, generally, Kenneth Harr et al., Dangerous Regulatory Duet 20-26 (Corporate Europe Observatory 2016), https://corporateeurope.org/sites/default/files/attachments/regulatoryduet_en021.pdf

⁸⁹ CETA, *supra* note 1, art. 5(6).

⁹⁰ Id. art. 4.6.

⁹¹ Id. art. 1.8(2).

B. Investor Disputes Under CETA

The investor rights and investor-state dispute settlement procedures under CETA are even more concerning. These provisions subject the EU to significant liability and reduce the EU's ability to adequately protect human health and the environment from the risks of pesticides.

Under CETA, an investor can submit a claim that either Party has violated its rights to a private trade tribunal created under the agreement.⁹² The tribunal will consist of fifteen members chosen by the CETA joint committee for a five-year term, renewable once.⁹³ Three members of the tribunal, of whom one shall be a national of a Member State of the European Union, one a national of Canada, and one a national of a third country, will be selected to hear each case.⁹⁴ The tribunal is empowered to make a final award of monetary damages or property restitution against the EU, a Member State, or Canada, which is binding on the Parties.⁹⁵ On the other hand, the tribunal is not empowered to hear claims against or impose penalties on investors.

The primary investor right that the tribunal can enforce is the right to "fair and equitable treatment."⁹⁶ This includes protection against an act that constitutes "manifest arbitrariness" or a "fundamental breach of due process," as well as a breach of any obligation to be defined in the future by the CETA Committee on Services and Investment, as affirmed by the Joint Committee.⁹⁷ To interpret this standard, tribunals can take into account a "specific representation" that creates a "legitimate expectation."⁹⁸ This provision has previously been interpreted to create a right to a stable regulatory environment,⁹⁹ and it provides companies with "a powerful weapon to fight regulatory changes, even if implemented in light of new knowledge and democratic choice."¹⁰⁰

CETA also grants investors the right to compensation for indirect expropriation.¹⁰¹ Companies have successfully used similar provision to win compensation when a country enacts measures to protect the environment and public health.¹⁰² An annex in CETA attempts to provide additional guidance for defining an indirect expropriation but leaves much to the interpretation of the tribunal.¹⁰³

¹⁰⁰ Pia Eberhardt, The Zombie ISDS 6 (Katharine Ainger, ed., 2016),

https://corporateeurope.org/sites/default/files/attachments/the_zombie_isds_0.pdf.

¹⁰¹ CETA, *supra* note 1, art. 8.12.

⁹² Id. arts. 8.18 & 8.23.

⁹³ Id. art. 8.27(2), 8.27(5).

⁹⁴ Id. art. 8.27(6).

⁹⁵ Id. arts. 8.39 & 8.41.

⁹⁶ Id. art. 8.10(1).

⁹⁷ Id. art. 8.10(2)(b)-(c) & 8.10(3).

⁹⁸ Id. art. 8.10(4). For a discussion of how these standards are interpreted, see, generally, Rethinking Bilateral Investment Treaties: Critical Issues and Policy Choices 164 (Kavaljit Singh And Burghard Ilge, eds, 2016).

⁹⁹ See, e.g., Pia Eberhardt et al., *Trading Away Democracy* 14 (Scott Harris and Katharine Ainger, eds., 2016), https://www.tni.org/files/publication-downloads/ceta-trading_away_democracy-2016en.pdf.

¹⁰² See, e.g., Eberhardt, supra note 100, at 20 (discussing Metlaclad Corp. v. Mexico).

¹⁰³ Indirect expropriation excludes non-discriminatory measures that protect "legitimate" public welfare objectives that do not "appear manifestly excessive." CETA, *supra* note 1, Annex 8-A.

As the EU's Sustainability Impact Assessment for CETA explained, "CETA will allow Canadian and certain other investors a wider mandate to sue the EU over the policies of its [Member States]."¹⁰⁴ Not only will Canadian companies be able to use this provision, but also multinational companies with Canadian subsidiaries. For example, four out of five US-owned firms operating in EU Member States would potentially be able to use the provisions in CETA to challenge EU and Member State laws.¹⁰⁵

Thus, EU decisions with respect to the approval of active substances, such as glyphosate, and setting specific MRLs, such as those for endocrine distrupting pesticides, could be subject to challenge by the producers of pesticides containing these substances, provided they have related investments in the EU. Companies could argue that the decisions constitute manifest arbitrariness and therefore violate fair and equitable treatment, pointing to a lack of scientific justification or adequate risk assessment to support their argument. The companies could also argue that tighter regulation or bans on its substances constitutes an indirect expropriation.

Similar challenges have been brought in the past, under different – but similar – investor agreements. For example, a challenge under NAFTA's investor state dispute system, brought by Dow Chemicals in response to the province of Quebec's ban on 2,4-Dichlorophenoxyacetic acid (2,4-D), resulted in a settlement whereby the Quebec government agreed that products containing 2,4-D did not pose an unacceptable risk to human health or the environment, provided that the instructions on the label are followed.¹⁰⁶ Yet EFSA has noted that 2,4-D presents a "high risk to aquatic organisms,"¹⁰⁷ and the WHO has identified the substance as a possible carcinogen to humans.¹⁰⁸

Under CETA, there are no limits to the amount of compensation that a tribunal can award an investor, and the EU could therefore be liable for extensive sums as a result of its pesticide regulations. The threat of such an outcome alone could have a serious chilling effect on protective regulations.

¹⁰⁴European Commission, A Trade SIA Relating to the Negotiation of a Comprehensive Economic and Trade Agreement 369, Trade 10/B3/B06 (June 2011).

¹⁰⁵ Public Citizen, Tens of Thousands of U.S. Firms Would Obtain New Powers to Launch Investor-State Attacks against European Policies via CETA and TTIP (2014), http://www.citizen.org/documents/EU-ISDS-liability.pdf

¹⁰⁶ Settlement Agreement between Dow Agrosciences and Canada, In the matter of an arbitration under chapter 11 of the north American Free Trade Agreement and the UNCITRAL arbitration rules (May 25, 2011).

¹⁰⁷ European Food Safety Authority, 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D, EFSA Journal12(9): 3812 (2014).

¹⁰⁸ World Health Organization press release, IARC Monographs evaluate DDT, lindane, and 2,4-D (June 23, 2015).

VI. Conclusion

Trade agreements should support protection of the environment, human health, and sustainable development. The European Parliament has outlined a list of fundamental principles for trade, and at a minimum, Member States should judge CETA by these standards.¹⁰⁹ It is not in the interest of the EU or its Member States to participate in regulatory cooperation in areas where the EU is more protective, such as the regulation of pesticides. Member States should therefore reject ratification of CETA.

¹⁰⁹ The EP identified these standards in conjunction with TTIP. *See, e.g.*, CIEL and HEAL, A Compliance Check of the European Parliament's TTIP Resolution: Public health, environment and democracy at risk (July 2016),

http://www.ciel.org/wp-content/uploads/2016/07/TTIP-Resolution-Compliance-Check.pdf. Although the EP consented to CETA without establishing a similar set of standards, the TTIP standards should be equally applicable to CETA.