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Effects of the EU chemicals regulation REACH in a globalized internal market: *FCD and FMB*

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Case C-106/14, *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB)* v. *Ministre de l'Écologie, du Développement durable et de l'Énergie*, Judgment of the Court (Third Chamber) of 10 September 2015, EU:C:2015:57.

1. Introduction

The place of EU law in a global world is a topic undergoing intense study by EU law scholars. Only during the course of a few years, the literature on the EU as a global actor and the effects of EU law beyond Union borders has grown enormously.1 Several recent judgments of the Court of Justice of the EU dealing with the external implications of EU legal order have further enhanced and consolidated this focus on the global reach of EU law. The greatest waves were caused by the *Air Transport* judgment handed down in 2011 by the Court of Justice.2 The challenge raised by the appellants, and subsequently dismissed by the ECJ, argued that the European Emission Trading System (ETS) was illegal under international law because it required foreign airlines operating out of European airports to pay for emissions produced during the entire flight, including those emitted outside EU airspace. The recently delivered *Inuit* rulings of the General Court and the Court of Justice,3 which dealt with the EU import ban for seal products,

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1. Evans and Koutrakos (Eds.), *Beyond the Established Legal Orders: Policy Interconnections between the EU and the Rest of the World* (Hart Publishing, 2011); Jørgensen and Laatikainen (Eds.), *Routledge Handbook on the European Union and International Institutions: Performance, Policy, Power* (Routledge, 2013); Van Vooren et al. (Eds.), *The EU's Role in Global Governance. The Legal Dimension* (OUP, 2013); Kochenov and Amtenbrink (Eds.), *The European Union's Shaping of the International Legal Order* (CUP, 2014); Zeitlin (Ed.), *Extending Experimentalist Governance? The European Union and Transnational Regulation* (OUP, 2015).
2. Case C-366/10, *Air Transport Association of America and Others*, EU:C:2011:864.
3. Case T-18/10, *Inuit Tapiriit Kanatami and Others* v. *Parliament and Council*, EU:T:2011:419; Case C-583/11 P, *Inuit Tapiriit Kanatami and Others*, EU:C:2013:625 as well as Case T-526/10, *Inuit Tapiriit Kanatami and others* v. *Commission*, EU:T:2013:215 and Case C-398/13 P, *Inuit Tapiriit Kanatami and others* v. *Commision*, EU:C:2015:535. Following the decision of the WTO dispute settlement appellate body in June 2014, the EU adopted a new proposal that took into account the WTO decision. See COM(2015)45 final, Commission Proposal for a Regulation to amend Regulation 1007/2009 on trade in seal products. *Common Market Law Review* **53**: 763–778, 2016.
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and the *Cattle transport* case4 where the ECJ ruled that EU rules concerning protection of animals during transportation apply also to the part of journey that takes place in the territory of the third

country, highlight a new orientation within EU law associated with the extension of effects deriving from Union law to third countries and the subsequent blurring of a traditional internal-external distinction.

The decision that forms the focus of the present commentary joins this emerging case law on the external effects of EU law. **The judgment in this case concerns the interpretation of Articles 7(2) and 33 of the EU,s Chemicals Regulation REACH.5**

These articles lay down notification and communication obligations in relation to articles containing substances of very high concern (SVHCs) in a concentration above 0.1% weight by weight. **Member States and the Commission disagreed on how the concentration threshold is determined in situations where an article consists of several components which are themselves articles.** The disagreement did not arise from the lack of definitions, for REACH uses the term "article" to define an object that is determined by the functions it could be used for, not just by its chemical composition. The problem lay in the fact that REACH provides no guidance for situations where an article consists of several objects each with a particular function. **According to the ruling, notification and communication obligations also apply to articles which are present in complex products (i.e., products composed of several articles) as long as these articles keep a special shape, surface or design, or as long as they do not become waste. For those operators whose commercial activities are regulated by the REACH Regulation, this means that it is not sufficient that information on the presence of hazardous chemicals is produced and communicated at the level of the entire article (e.g. shoe) but must be provided for each individual component (shoe laces, insole, and so on) that make up the entire article**.

Given that the REACH Regulation applies both to substances manufactured in Europe as well as to those imported into the Union,6 **the judgment was eagerly awaited outside the EU**. And, indeed, it marked an end to long-drawn debates at the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Committee and elsewhere concerning difficulties that uncertainties about the definition of an "article" created for third country

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4. Case C-424/13, *Zuchtvieh-Export GmbH* v. *Stadt Kempten*, EU:C:2015:259.
5. Reg. (EC) 1907/2006, O.J. 2006, L 396/1.
6. Note that although REACH requirements apply both to products produced within the EU as well as those manufactured elsewhere but imported into the EU, companies established outside the EU do not directly incur obligations under REACH, and the responsibility for fulfilling the requirements of REACH falls on the importer established in the EU or on the "only representative" of a non-EU manufacturer.

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operators.7 However, **this case is of crucial relevance also to those not in the chemicals business or interested in the intricacies of chemicals regulation. The ruling raises a more general question of how to conceptualize the internal market in situations where "virtually all internal market policies carry to some degree an international dimension",**8 ***and whether such a dimension and, more broadly, the effects of EU law on parties outside the EU should be reflected in the adoption or interpretation of EU law***. The above-mentioned cases provide very different contexts in which to ask and answer such questions. In the *Air Transport* case, the EU legislature tested the outer limits of its law-making authority in a situation where no global agreement was in place and where the EU could, in the absence of a global action, perceive itself

to be bound (or at least morally justified) to proceed on its own.9 The limits to EU action and ramifications on non-EU parties need to be assessed in this particular context. However, in the three other cases (including the present case) the context is conspicuously different. **These cases demonstrate – in very concrete terms – the external market-building dimension of the internal market. In other words, not only EU laws, such as the REACH Regulation, regulate the functioning of the internal market, but also, and increasingly more often, they create a market that is no longer internal to the EU but global in its effects, suggesting a certain insufficiency or limitedness in the traditional ways of understanding the meaning of an 'internal' market**.

In addition to the external implications of the judgment, it was long-awaited internally as well since it authoritatively resolved a dispute concerning the interpretation of "article" between the Commission, the European Chemicals Agency (ECHA), and Member States. **Advocate General Kokott and the ECJ sided with the minority of Member States (France, Belgium, Denmark, Germany and Sweden as well as Norway) and concluded that the provisions of REACH need to be applied to ensure that maximum information is available both for the ECHA to take regulatory action and consumers to make informed choices about risks**.

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7. The question about the definition of "article" in the Regulation was repeated several times at the TBT Committee meetings in the past years, suggesting that the Members were not satisfied with the explanations proffered by the EU. See Minutes of meetings of the Committee on Technical Barriers to Trade, <www.wto.org/english/tratop_e/tbt_e/tbt_e.htm> (last visited 11 March 2016). Furthermore, the Asia-Pacific Economic Cooperation (APEC) forum sent a formal letter to the Executive Director of the ECHA, <www.nikkakyo.org/reach/_userdata/V1/_documents/APEC%20letter%20to%20ECHA%2012_cdsg1_003.pdf> last visited 11 March 2016).

8. DG Internal Market, Industry, Entrepreneurship and SMEs (DG Growth), "Management Plan 2015", 10 Sept. 2015, 31. See also COM(2010)2020, "Europe 2020: A strategy for smart, sustainable and inclusive growth", 22; SEC(2010) 114, "Lisbon Strategy Evaluation Report", 7. 9. Opinion of A.G. Kokott in Case C-366/10, *Air Transport,* EU:C:2011:637, paras. 202 et seq.

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5.2. *External effects*

The same feelings of disappointment may apply externally. Stabilizing the interpretation of what constitutes an "article", the ruling, of course, mitigates the uncertainties felt by EU and non-EU businesses on how to produce and import articles involving substances of concern to the EU. **However, this ruling, as well as the others referred to in the introduction, clearly demonstrate that even when actors outside the EU are affected by EU measures, *the interests of non-EU parties are not given much of a role in the interpretation of EU law***. This is most apparent from the fact that no proportionality analysis is undertaken in relation to duties involving operators established in non-EU countries. It is acknowledged that a particular rule interpretation may cause difficulties for EU-based operators who rely on information from non-EU parties (subsequently complicating the position of non-EU parties, as well), but, as the Court put it, this does not affect

the interpretation of the law. Instead, the capability of a certain interpretation to disseminate EU rules beyond Union borders is a factor to be taken into account and, to my knowledge, it is the first time that the judicial dialogue openly admits that an interpretative position may be favoured over another on the grounds that it helps spreading EU standards further afield.41

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39. TBT Committee, "Minutes of the meeting of 20 March 2008", G/TBT/M/44, 10 June 2008, point 38.
40. E.g. TBT Committee, "Minutes of the meeting of 23–24 June 2010", G/TBT/M/51, 1 Oct. 2010 or TBT Committee, "Minutes of the meeting of 3–4 November 2010", G/TBT/M/52, 10 March 2011.
41. Opinion, para 83

Theoretically the issue is with the globalization of the internal market. Space precludes a full discussion, but a few general remarks are offered here. The external dimension to the internal market is, of course, an old idea and much debated in scholarship.42 Yet this strand of literature is concerned with external economic policy and does not address the question about the global reach of internal market legislation and whether external effects should be articulated and accounted for in the adoption or application of EU rules. No formal description of the aims or instruments for the externalization of the internal market exists in the Treaties either. Article 21(3) TEU makes an explicit link between internal and external principles in the pursuit of the EU,s global role. However, the same linkage does not occur in internal market Articles 26 TFEU or 114 TFEU,43 and there is no guidance in the Treaties on how these rules or provisions laid down in relevant secondary legislation are to be applied in the new socio-political contexts of the internal market.

The EU,s Merger Regulation, which gives the EU the power to control mergers between foreign firms when concentrations have an EU (the 2004 text speaks of "Community") dimension, i.e., have an impact on the internal market, is a much discussed example of problems arising in connection with the external application of internal market rules.44 Whether or not the concentration has an EU dimension is determined in the Regulation by references to the combined aggregate worldwide and EU turnovers of the undertakings in question. The application of EU merger control outside EU borders, especially in cases where the Commission blocked the measure already approved by the US competition authorities (e.g. Boeing/McDonnell or GE/Honeywell) resulted in strained transatlantic relations. Aware of the potential to cause long-term injury to international relations, the EU court developed standards to limit the global reach of EU merger control in the international sphere. In the *Gencor* case, the GC argued that the extraterritorial application of the Merger Regulation is justified under public international law if it is foreseeable that a proposed concentration will have an immediate and substantial effect in the EU. Furthermore, the Court required that the exercise of jurisdiction does not violate the principle of

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42. E.g. Cremona, "The external dimension of the single market. Building on the foundations", in Barnard and Scott (Eds.), *The Law of the Single EU Market. Unpacking the Premises* (Hart Publishing, 2001); Eeckhout, "The external dimension of the EC Internal Market: A portrait" 15 World Comp. (1991) 5–23; Eeckhout, *The European Internal Market and International Trade*. *A Legal Analysis* (OUP, 1994).
43. Fahey, *Global Reach of EU Law* (Ashgate, 2016, forthcoming), Ch. 2.

44. Reg. (EC) No 139/2004 O.J. 2004, L 24. For a new literature on extraterritoriality see Scott, "Extraterritoriality and territorial extension in EU law", 62 AJCL (2014), 87–125; Scott, "The new EU extraterritoriality", 51 CML Rev. (2014), 1343–1380.

non-interference or proportionality.45 Besides defusing the transatlantic tension, the emphasis on effects in the EU as well as consideration of the proportionality principle were intended to ensure that the interests of third country undertakings are taken into account.46

In much the same vein, despite the fact that as a policy REACH has an external dimension and its effects outside the EU are considerable, it is an internal measure and its external application outside EU territory is triggered by a territorial connection with the EU affecting anyone wishing to export to the internal market. **What about its justification under public international law? On a general level, the argument can be made that the effects of REACH on third country operators are taken care of at the level of public international law, more specifically at the level of WTO.47 It is clear that the existing WTO obligations, in particular those enshrined in the TBT Agreement, had an impact on the drafting of the REACH Regulation.48 Since the formal WTO notification of the REACH Regulation in January 2004,49 numerous WTO Members, including developing countries, have continued to express trade concerns about REACH, mostly pertaining to its registration/data gathering and notification obligations.50 Between 2004 and 2015, the REACH Regulation was discussed at 32 meetings, and as recently as in June 2014.51 The subject matter of the annotated ruling has featured prominently in**

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45. T-102/96, *Gencor Ltd* v. *Commission*, EU:T:1999:65, paras. 90–92. See Ezrachi, "Limitations on the extraterritorial reach of the European Merger Regulation", 22 ECLR (2001), 137–146; Wagner von Papp, "Competition law and extraterritoriality", in Ezrachi (Ed.), *Research Handbook on International Competition Law* (Edward Elgar, 2012), pp. 21–59; Whish and Bailey, *Competition Law*, 7th ed. (OUP, 2012), p. 500.
46. In recent years, both authorities have worked together to increase regulatory convergence. The hard work has yielded results, for now US and EU authorities "usually agree on U.S. mergers". See Verdy, "The European Commission,s extraterritorial jurisdiction over U.S. mergers and acquisitions: Closing the gap between Brussels and D.C.", 48 *Cornell International Law Journal* (2015), 117.
47. REACH was also discussed in other international forums, such as the Organization for Economic Cooperation and Development (OECD) or the International Organization for Standardization (ISO). Discussions on chemicals management are also conducted within Free Trade Agreement negotiations, now especially within the negotiations over the Transatlantic Trade and Investment Partnership (TTIP) Agreement. Finally, the Commission holds (bilateral) dialogues with important trade partners such as Japan to exchange information about legislation relating to chemicals.
48. One of the political objectives of the proposed REACH Regulation was to ensure the
conformity with EU,s international obligations under WTO law. See COM(2001) 88 final, "White paper – Strategy for a future chemicals policy", 7.
49. Reference G/TBT/N/EEC/52.
50. Gruszczynski, "The REACH Regulation and the TBT agreement: The role of the TBT Committee in regulatory processes", in Trebilcock and Epps (Eds.), *Handbook on the TBT Agreement* (Edward Elgar, 2013).
51. Given that the TBT Committee convenes three times a year, this means that REACH was discussed in every meeting held between the years 2004 and 2013. The year 2014 was the

Members, lists of concern, too. Despite a high level of concerns submitted to the TBT Committee, REACH has not been formally challenged.52

Whilst mechanisms put in place by public international law, such as the TBT Committee, have provided a platform for information exchange between WTO Members and facilitated mutual engagement in the process of elaboration of norms,53 the role of public international law is restricted as regards the wider questions posed by the ruling. This is because debates in various committees and working groups are conducted in the framework of the (in)compatibility of particular EU measures with obligations arising under public international law, framing the discussion in the terms of what is, for instance, forbidden under the TBT Agreement.54 Public international law does not contain any specific guidance to deal with new issues arising out of extension of effects of EU law to third countries. Is it acceptable or desirable to endorse the EU,s regulatory prominence through judicial means? Do the external effects of EU law on third countries justify or necessitate a heightened sense of awareness of these effects in the interpretation of EU law even if a particular measure is deemed WTO compliant? Given the international dimension of many of its internal market policies, can the EU be required to assess the costs of its decisions for operators from third countries?55 […]

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first time that REACH was discussed only in 2 out of 3 annual meetings. Minutes of the TBT Committee are available at the WTO website.

52. The EU,s exemplary engagement of other Members, concerns in the TBT Committee is believed to be a major reason. See Bergkamp, *The European Union REACH Regulation for Chemicals: Law and Practice* (OUP, 2013). See Kogan who has recently suggested that REACH,s registration and data gathering and notification rules are discriminatory, Kogan, "*REACH revisited: A framework for evaluating whether a non-tariff measure has matured into an actionable non-tariff barrier to trade*", 28 *American University International Law Review* (2013), 489–668.

53. In Gruszczynski,s view, the system has not been as effective as could have been hoped. See Gruszczynski, op. cit. *supra* note 50. Note also that REACH provides platforms for continued discussion outside WTO. One such platform is Competent Authorities for REACH and CLP (CARACAL). This expert group advises the Commission and ECHA on the implementation of REACH and CLP. The group is composed of representatives of national Competent Authorities for REACH and CLP, representatives of Competent Authorities of the EEA-EFTA countries, as well as a number of observers from non-EU countries, stakeholders from industry and trade associations, NGOs, trade unions, and international organizations.

54. The TBT Agreement forbids discrimination between domestic and like imported products and requires that the proposed measure constitutes the least trade restrictive alternative to achieve the desired regulatory objectives. See Gruszczynski, op. cit. *supra* note 50.

55. A.G. Maduro raised the question in passing and answered in the negative in the context of compliance with the WTO agreements, see Opinion of A.G. Maduro in Joined Cases C-120 & 121/06 P, *FIAMM and FIAMM Technologies* v. *Council and Commission*, EU:C:2008:98, para 68