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RESEARCH ARTICLE

Risk regulation and precaution in Europe and the United States: the case of bioinvasion

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Abstract
The precautionary nature of risk regulation in the European Union (EU) and the United States (US) is an ongoing debate. Theoretical contentions over 'who is more precautionary' confirm that the degree of relative precaution may lead to different levels of protection, but also suggest that precaution needs to be evaluated against different parts of the regulatory process. This paper addresses a new case of transatlantic split which has occurred with the adoption of the EU regulation on alien invasive species. This regulation aims to drive important changes at the trade–environment nexus and reflects Europe's integrated policy approach to environmental, health, and safety risks. We have carried out a comparative analysis by examining parts of the regulatory process. We argue that differences in legal and policy frameworks, risk assessment, and risk management structures have left the EU and the US wide apart as to their risk governance ambitions. The EU exhibits more precautionary approach with regard to these parts, as compared to the US. Our finding suggests that policy divergence, as reflected in this case, is true for both stringency and regulatory process, expanding literature discussions on precaution in these systems. Yet, with the EU's regulation being relatively new, there are still implementation issues up for debate.

Keywords Risk regulation · Precautionary principle · European union · Transatlantic policy divergence · Invasive species · Trade–environment nexus

Introduction

The role of the precautionary principle (PP) in driving or understanding risk regulation in the EU and the US is an ongoing debate (e.g., Botos et al. 2018; Burgess 2013; Christoforou 2004; Lieberman and Zito 2012; Löfstedt 2004; Tosun 2013; Vogel 2012). At the heart of this debate is the contentions over 'who is more precautionary' in addressing

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environmental, health and safety (EHS) risks. A central claim is that there has been an overall shift from greater American to greater European relative precaution and stringency in risk regulation (Schreurs et al. 2009; Kelemen and Vogel 2003, 2010, 2012). A contradictory claim asserts that there is a complex mix of parity and particularity between Europe and US in their application of precaution (IRGC 2017; Wiener et al. 2011). In the discussions on the nature of their risk regulation, it has been argued that precaution needs to be evaluated against different parts of the regulatory processes. By breaking up the regulatory process into its distinct elements, one can more accurately study whether and how US and EU risk policies reflect (or don't) precaution (Wiener et al. 2013). In other words, regulatory risk policy is about making choices, but it is also necessary to describe the context in which choices are made, to identify which factors (e.g., risk analysis methods, degree of policy integration) participate in the process of policy decisions about risks, and to examine the formulation and implementation of regulatory policies.

With so much evidence in some domains (e.g., GMOs, chemicals), and the absence of empirical evidence for other, less politically salient topics, this analytical approach is useful to gain further insight into this issue. Moreover, the emergence of complex risk problems such as bioinvasion, which require deviation from traditional policies, revives the interest for discussion to promote understanding of current PP's use in policymaking (Tosun 2013: 1518).

In this paper, we examine a new case study that addresses the risk of invasive alien species (IAS or bioinvasion) associated with international trade. Globalization facilitates the spread of IAS as international commerce develops new trade routes, markets, and products. Many species that become invasive are introduced intentionally as pets, garden, or aquarium plants, for recreational fishing, and for biological control. Others arrive accidentally as a by-product of commerce, for instance, through ballast water discharge or agricultural commodities. As stated by bioinvasion researchers, 'correcting the imbalance between trade and precaution is one of the greatest challenges we face' (Reichard 2005). One aspect of this problem, which has frequently been seen as an obstacle, is the need for an appropriate legal framework (World Bank 2006).

The European Union (EU) adopted in 2014 legislation for the prevention and management of IAS (the 'Regulation').[1] From 2016, a list of IAS of 'Union concern' ('Union list') is banned from import into the EU territory, on the basis of risk assessment and available scientific evidence. The EU-wide ban makes it illegal to import, keep, sell, transport, reproduce, or release these species. At the US federal system, by contrast, there is no dedicated legislative act, nor regulatory reform of trade policy. Despite the fact that federal agencies have recognized the need for effective coordinated action, regulatory change is not included in federal management plans.

This article aims to examine current transatlantic differences in bioinvasion risk regulation. We ask whether and how precautionary approach impacts their regulatory policies. Analytically, we focus on three important parts of the regulatory process, namely the legal and policy framework, risk assessment, and risk management structures. We explore below whether the EU exhibits a more precautionary approach with regard to these components, as compared to the US.

The empirical analysis draws on review of key policy documents and professional reports, analysis of rulemaking and policy actions, as well as bioinvasion and risk

[1] Regulation (EU) 1143/2014 of the European Parliament and the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species. OJ L 317.

regulation literatures. Methodologically, we use comparative and process-tracing analyses. Process tracing is particularly useful for tracing the European regulatory process, identifying risk contexts which led to applying the PP and increased stringency.

The article proceeds as follows. The second section summarizes gaps in the available science predicting risk and impacts of bioinvasion. It then discusses the impact assessment conducted in Europe prior to the regulationin order to understand the role of the PP in policy discussions. The third section identifies and comments on the precautionary measures undertaken in the EU. Section four provides an overview of the regulatory approach adopted by the US. Building upon the previous two sections, section five contrasts the EU precautionary approach with that adopted by the US. Section six provides an analysis of challenges for implementation of the precautionary approach in the context of the EU and the World Trade Organization (WTO) rules. The final section concludes.

The science supporting policymaking on bioinvasion

Scientific research on IAS has many facets, but the questions directly related to policymaking are: (a) how severe are the damages caused by IAS? (b) what are the paths of invasion? (c) what species are potential invaders? (d) which ecosystems and under what conditions are most prone to invasion?

As the phenomenon of IAS has grown, policymakers have become concerned about the monetary value of their ecological and socioeconomic impacts. Yet, until recently little research has estimated their economic damages at regional scales. In fact, the first study to quantify the costs of IAS associated with ecosystem services in Europe was published only in 2009 (see Vilà et al. 2010). Part of the problem was the fragmentation of knowledge across Member States and sectors, and the absence of large-scale assessment of impacts across biogeographic regions (Hulme 2007). Another difficulty is the lack of clear criteria for interpreting what constitutes an impact. It represents a major shortcoming because the quantification of impact would allow for prioritizing actions against the most harmful IAS or with the highest potential of spreading.

Likewise, ecologists still lack the capacity to predict when and how quickly damage may emerge. The severe impact of IAS may not be manifested for decades after their introduction (the so called 'lag phase'). Therefore, the decision on whether or not to introduce it needs to be taken far in advance of the species becoming successfully invasive. For example, the potential impacts had not been assessed accurately before introducing the signal crayfish (*Pacifastacus leniusculus*) (mini-lobster) into Europe. When the Scandinavian fisheries of European crayfish (*Astacus astacus*) were damaged by a crayfish plague, signal crayfish, originating from North America, were introduced to Norway and Finland for recreational and commercial capture. It turned out that signal crayfish were not only the carriers of the crayfish disease, but also became invasive, threatening European crayfish as well as benthic fish and aquatic plants. The species nevertheless has beneficial effects for crayfish production, resulting in a conflict of interest between those who want to control it and those who want to breed it (Gherardi et al. 2011). This means that current risky activities in Europe may set in motion many future invasions. Clearly, a decision should have been taken long before allowing the introduction of this species.

A large volume of scientific research has aimed at identifying the major paths of bioinvasion. Although the magnitude of this problem can be attributed to more than just one factor, free trade, transportation, and travel have come under increasing scrutiny as key

drivers of bioinvasion (Jenkins 1996; IUCN 2000; Levine and D'Antonio 2003). With increased economic interdependence via world trade, the threat of IAS arriving to regions from which they were previously absent is expected to grow. Economic sectors not only act as a major source of IAS introductions, but also suffer impacts from IAS.

Among of the core research goals of invasion biology today, as relates to the third and fourth questions, is the identification of stressors that increase the risk of bioinvasion. Pressures of invasion to ecosystems are frequently attributed to interactions of various factors, including propagule pressure (i.e., introduction efforts), environmental conditions, and climate change. Studies also suggest that islands or geographically isolated areas are more prone to invasion. In these ecosystems, trade routes have played a key role in this process. For instance, North-eastern Europe was historically relatively isolated from the native range of ragweed seeds, but extensive imports of seed commodities from invaded parts of Europe has increased invasion pressure of this region (Chapman et al. 2016). However, current theories suggest that even if those stresses occur, the likelihood of invasion varies because of the complex interaction between species attributes and environmental conditions that is inherently difficult to predict (Lonsdale 1999; Mack et al. 2000). The result is significant uncertainty in cause-and-effect relationships.

Applied ecology today aims at advancing risk and impact assessments (e.g., Dahlstrom et al. 2011; Kumschick and Richardson 2013). However, risk analysis methods are still being developed for IAS, and the inherent complexity may preclude accurate results (Lodge et al. 2016). The fact that such a small percentage of introduced species actually become invasive (Williamson 1996) is also a major limitation for prediction (Smith et al. 1999).

The pan-european impact assessment

In 2002, the EC has recognized IAS as a regional threat, launching a non-binding strategyunder the Pan-European Bern Convention and in line with the International Convention on Biological Diversity ('CBD') (Genovesi and Shine 2004). It aimed to lead important changes in Member States'policies on IAS. In an action report from 2008 (EC 2008), serious delays in implementation were illustrated, by pointing out that:

> 'Only 3 Member States have specific national strategies on IAS, 7 MemberStates are developing strategies…and for 10 Member States national strategies have not been found.'

In January 2008, while bioinvasion was of low priority on the political agenda of many Member States, the EC mandated a first comprehensive study, led by the Institute of European Environmental Policy (IEEP), aimed at quantifying the aggregated environmental and socioeconomic impacts of IAS in Europe. In particular, it aimed to provide technical support and assessment with regard to (1) the number of most damaging IAS in Europe per country, (2) their damage and management costs, (3) the costs associated with EU-level policy action *vs* inaction, and (4) proposed priorities for action. The rationale for the assessment was 'to strike the right balance between invasive species risk management and freedom of movement and trade' (Shine et al. 2010:68).

In November 2010, the assessment team published its final report, in which it identified the rationale for an integrated policy framework. The report indicated a strong correlation between trade and the rate of introduction of new species both into and between different parts of the EU territory. It demonstrated that IAS are a growing cross-sectoral and transboundary

problem affecting the whole region, with severe impacts predicted to further increase in response to environmental pressures including climate change. Based on these findings, there is a clear case for addressing the problem through a coordinated action at the EU-level. In monetary terms, the assessment identified that lost output, health impacts, and expenditure to address IAS damages have already cost the EU at least €12.5 billion per year over the past 20 years, of which costs identified for key economic sectors have been estimated at over €6 billion per year (Kettunen et al. 2008). Since available data on monetary costs remain scarce for key sectors such as tourism and health, the report warned that in reality the costs for the EU economy are higher.

In light of the incomplete understanding of the ecological process of invasion, the team was able to make the case for prioritizing prevention. It stated (Shine et al. 2010):

> The development of an EU framework for risk assessment and a Europe-wide information and early warning system are seen as fundamental to effective action before biological invasions take hold, consistent with the precautionary principle and the EU's commitment to a high standard of environmental protection.

The report also emphasized the need to identify species of very high concern or priority for risk assessment, a preventive risk management approach that eventually was adopted in the Regulation.

In sum, while the study team was entrusted with the authority to conduct the risk and impact assessments, its opinion—due to the EC's Better Regulation agenda, was also expected to provide some sort of risk management advice. Indeed, the team—bases on technical and scientific studies, as well as consultation with stakeholders and experts, clearly concluded that the adoption of an extensive, legal framework at Union level is the most effective and cost-efficient policy option.

The team 's commitment toward ensuring an ambitious policy also emerged from its methodological approach. A quantitative assessment of costs and benefits associated with implementation clearly expresses the need to be aware of the real added value of precautionary framework because prevention is likely to cost less than long-term control. 'Prevention is better than cure' was the mantra, making precautionary measures more salient for Member States.

It seems that the team, in its own earlier scientific outputs, anticipated criticisms on the 'robustness' of the cost–benefit assessment of regulatory impacts, clarifying that (Shine et al. 2010):

> Given the data limitations, the costs presented should be treated as initial and indicative. Regardless of these limitations, however, the developed estimates are considered as a reasonably robust indication of the likely scale of costs associated with the future EU action on IAS.

By using the policy tools of cost–benefit analysis for the entire region, the scientific advice opened the door to a paradigmatic shift to precautionary policy, with significant influence on EU'sinternational economic relation (on the role of cost–benefits analysis in paving the way for precautionary regulation in the EU, see Vogel 2003).

The EU regulation

In September 2013, the Commission issued a proposal for a regulation of IAS restricting their use. In particular, it proposed a ban on the sale and use of prioritized 'species of concern,' established and having a negative impact in parts of the EU. The Commission noted in its explanatory memorandum that the assessment of the overall damage and thequantified forecast of the costs demonstrates the significance of this problem for the Union, as to further justify action. The Commission considered, based on the evaluation of alternative policy options, that the costs of leaving the status quo or other less ambitious policy options are likely to be significant higher than the costs of dedicated law. On this basis, the Commission concluded that the high risk from IAS justifies imposing trade restrictions. While the procedure for the impact assessment conforms with the standards laid down by the European Commission Impact Assessment Guidelines, this document and the accompanying consultation process provided the basis for determining the proportionality character of the proposal (EC 2013). Furthermore, the outbreak of the economic and financial crisis in 2008 incentivized the EU to expand the precautionary principle to the area of bioinvasion, so as to save enormous costs (Justo-Hanani and Dayan 2020).

On April 2014, the European Parliament and the European Council reached a consensus in a vote on this proposal (606 votes to 36, 4 abstentions). The regulation responded to the critics of the draft legislation by removing the numerical cap of 50 species of the Union list, and the number is currently unlimited. The main elements of the regulation are as follows:

- the core of the Regulation is a Union list (black list), which is to be kept updated regularly. It currently includes 66 species. The regulation restricts their use and placing on the market.[2]
- the list will be formulated together with Member States, and updated based on risk assessment, pursuant to the provisions of the WTO agreements on placing trade restriction on species (Articles 11,13)
- an independent scientific forum was established to provide an opinion on whether the risk assessment is robust and fit for purpose.
- the regulation provides for a regional 'three-stage hierarchy' of risk management: prevention, early detection, and long-term control, in line with Article 8(h) of the CBD.

The attempt of the Commission to base the Regulation on the precautionary approach is self-evident. The structure and the language adopted in the restrictive measures both witness the implicit invocation of this approach. The preventive-precautionary nature of the Regulation is characterized by a combination of the proactive and stringency of regulatory measures, as demonstrated below.

[2] It represents a precautionary approach because it applies to all the Union territory, including Member States that are not yet affected or are even unlikely to be affected (Article 10).

The US policy approach

Although the issue of IAS damages arose also in the US during the last decades, the federal regulatory response is more limited than in the EU. Executive Order (E.O. 13,112) established a National Invasive Species Council (NISC) in 1999 with the charge to coordinate a federal response to this problem.[3] The NISC is co-chaired by the Secretaries of the Interior, Agriculture, and Commerce. Its members include representatives from 13 federal departments and agencies of the US government. Since the formation of the NISC and the launch of the first (2001) and the updated (2008) Management Plans, federal authorities have invested considerable resources to better address bioinvasion and its drivers. Yet, there is no single, comprehensive federal law that deals with all types of IAS, and their pathways (at all stages of invasion). This is unlike other areas of US EHS law, such as air pollution, water pollution, and pesticides regulation (Williams 2017).

Despite an intensive level of research and management efforts, overall damage continues to grow. The current state of bioinvasion was detailed in the Management Planadopted on 2016 (NISC 2016). The plan includes strategic goals such as information exchange, prevention, early detection, and rapid response.[4]

While the federal management plan emphasizes the lack of comprehensive authority, or clarity of authority, necessary to effectively control IAS, it does not—unlike the EU's regulation—recognizes a specific role played by a dedicated federal legal instrument for regional cooperation (Burdyshaw 2011; NISC 2016; Miller 2011). Rather, the plan concludes that (NISC 2016):

> Nothing in this plan is intended to alter, or should be interpreted as altering, the existing authorities of any agency.

In other words, while prevention, early detection, and rapid response continue to be a high priority topic for the NISC, the current state of the legal capacity—as reflected in the plan, might not seem to require a new legal authority tailored to particular pathways of introduction, among them trade.

A transatlantic policy divergence

While the EU is already restricting the commercial use of species in the Union list in the name of the precautionary approach, the US authorities favor regulatory status quo. A similar pattern occurs regarding nanotechnology environmental, health, and safety risks. The EU exhibits precautionary approach, in terms of both regulatory process and stringency, as compared to the US (Justo-Hanani and Dayan 2016).

How to explain the different regulatory approaches between the EU and the US? The level of public pressure about bioinvasion was relatively low in both sides of the Atlantic (Miller 2011; EEA 2013). Therefore, there is a need to explore some other possible causes for divergence. We propose the following explanations: (1) differentiated levels of legal and policyframeworks, (2) the risk assessmentstructure, and (3) the risk management

[3] Amended by E.O. 13,751 (December 2016).

[4] In addition to federal laws, a number of states have laws restricting transport or possession of certain IAS. State laws are not described in this paper.

Table 1 Main differences between EU and US regulatory policies on IAS

	EU	US
Legal and policy framework	Single comprehensive law Dedicated instrument, specifically intended to deal with IAS + sectoral laws coordinated policy approach + Precautionary, regional trade restrictions, which include MS that are not yet affected (Still, there are implementation and policy integration challenges across MS)	Fragmented, inconsistent legal framework Sectoral laws, relating indirectly to IAS. A number of states have laws restricting transport and possession of certain IAS in the State (e.g., Minnesota) Lack of regulatory coordination among federal and state agencies
Risk assessment (RA) structure	Proactive, precautionary listing approach Large-scale RA: across biogeographic regions, sectors, large-scale event, introduction pathways Ongoing development of common RA process and methods Formal, mandatory criterial for RA	Reactive listing (e.g., IAS already established) Limited to specific geographical area or sectors RA poorly developed and parameterized Lack of common, agreed procedures or methods
Risk management structure	Transboundary approach: cross-sector and cross-border management Proactive approach: three-stages hierarchy (prevention, early detection, and rapid response)	Lack of border risk management for all taxa. rarely implemented Reactive approach: focus on early detection and rapid response

structure. The EU exhibits a more precautionary approach in terms of both stringency and scope of these aspects, as compared to the US (Table 1 summarizes our findings).

Different legal and policy frameworks

The concern regarding the introduction and use of IAS in Europe stemmed from the low political awareness for the problem among the Member States that caused the costs of bioinvasion to growth and weighon the Single Market (EEA 2013). Heterogeneity in policy approaches toward IAS among Member States also made the Single Market particularly vulnerable. Consistent action was needed to avoid distortion of the Single Market, and situations where action taken in one Member State is undermined by inaction in another (Article 18). This sort of 'market failure' inevitably prompted the EC reaction to correct it by choosing the policy instrument of EU-wide legislation on IAS to address the variety of paths by which they enter and spread in the Union, including harmonized trade restrictions. While doing so, the EC opts for a type of 'California Effect' (Vogel 1997, 2018) at both the EU and the international levels, imposing stringent regulation on IAS traded within Europe, and forcing it as a precondition for access to the Single Market (for discussions on how the EU's application of the precautionary principle affects its relationship with international trade partners, see Falkner 2007; Meunier and Nicolai'dis 2006; Smith 2010; Young and Peterson 2006; Zandler 2010).

The EU International trade restrictions based on the PP were also adopted as part of the EU commitment to the CBD. The US, which signed but has not ratified the CBD, refused to invoke the PPin consistence with the US federal government stance in other EHS policies, where it has strongly disagreed with the notion that the PP has become a rule of negotiations about international trade. In that regard, Cameron (2001) has noted that while the PP has informed regulatory approaches within jurisdictions inside the US, the US federal government has refused to invoke it in negotiations about international trade.

By taking into account the EU constitutional structure and the policy background inherent to the Single Market, the EU precautionary action to ban the trade of species of Union concern can be assessed and compared with the US approach. These circumstances contributed to making the EU more prone to take precautionary and harmonized legislative action at the regional level, than the US.

EU and the US also diverged in their judgment over the 'appropriateness' of their existing legal frameworks. The EU adopted a comprehensive legal regime for the region. By contrast, the US regulation is highly fragmented, with many different agencies implementing different statutes to address different risks, inhibiting effective control (Burdyshaw 2011; Miller 2011, 2015). The main problem is the particular purpose of the various laws and regulations that address IAS. These laws are often designed to protect a valued economic activity rather than to target IAS, many of which were considered valuable when first introduced. In 1993, the Office of Technology Assessment(OTA) report on the problemconcluded that (OTA 1993):

> Federal law is largely a patchwork of laws, regulation, policies and programs. Many only peripherally address IAS.

The general observations of OTA remain true. For instance, existing wildlife legislation (e.g., the Endangered Species Act) does not address the higher vulnerability to invasion of many American Islands. Some agricultural weeds are covered by plant pest legislation, but many potentially invasive plants are not. The Lacey Act adopts a 'black list' approach, but

unlike the EU regulation, the listing process is more reactive than proactive, and there is no emergency or rapid listing option. Lori Williams (2017), former executive director of the NISC at the Department of the Interior, argues that 'perhaps most problematic is that the Lacey Act black list approach guarantees that the large majority of vertebrates will never be screened for invasiveness prior to importation because the slow pace if listing.' Likewise, laws of environmental liability do not apply clearly to damaging activities related to IAS.

These legal gaps were expressly recognized in the Congressional Research Service (CRS) report, which stated that (CRS 2017):

> Despite efforts to achieve high-level interdepartmental coordination, comprehensive legislation on the treatment of invasive species has never been enacted, and no single law directs coordination among federal agencies. No laws focus on the broad problems of invasive species, their interception, prevention, and control across a variety of industries and habitats. Instead, the current legal framework is largely governed by a patchwork, inconsistent regulation, and policies.

Williams (2017) further illustrates the 'challenge of navigating the complex array of federal laws and regulations governing invasive species,' as well as 'the importance of timely coordination among federal and states agencies to address a potential crisis.'

All of these concerns are now addressed in the EU by a single, comprehensive legislative instrument, which makes an effort to coordinate with existing laws. Assuch, it addresses categories of species and trade pathwaysfalling outside existing sectoral laws, setting a coherent regime for risk assessment and quarantine measures (Articles13,32).

It should be noted that the new US–Mexico–Canada free trade agreement (USMCA) includes a commitment for parties to coordinate efforts on IAS (Article 24.16). As it allows discretion over the specific initiatives a party can prioritize, it remains to be seenwhether and how the US federal government will change its trade policy.

Different risk assessment frameworks

Looking at the risk assessmentprocess, its objectives, scope, and methods differ between the two systems. The EU regulation establishes a coordinated risk assessment framework, constantly evolving (e.g., Article 32). The decision to include a species in the list is based on the assessment of potential adverse effects across all Member States and outmost regions. In this respect, the risk assessment represents precautionary approach, because it covers all the Union territory toward imposing trade restrictions even on those Member States where there are significant uncertainties of cause-and-effect relationships.[5] In contrast, the US federal system to date has not taken a coordinated approach to the application of this tool, and there is no risk assessment frameworkfor the entire region. Risk assessments are conductedby national or federal authorities, e.g., the US Environmental Protection Agency (EPA), and the US Department of Agriculture (USDA) regarding their respectiveinterests, geographic areas, or specific taxonomic groups (CRS 2015, 2017). This was recently noted by a large group of scientists as an

[5] It should be noted that an even more precautionary listing approach would employ a 'white list', that is prohibiting the importation of a species unless it has been listed as allowed, or until the risk that it may become invasive has been evaluated (Simberloff 2006). A few nations, including New Zealand and Australia, have adopted this approach.

obstacle for successful monitoring and prevention of IAS in the US (e.g., Lodge et al. 2016).

Not only the legal context of risk analysis (regional trade-restrictive measures *vs* ongoing monitoring), but also the framework for collecting scientific data differs. The EU regulation departs from traditional approaches to risk assessment of IAS, which have focused primarily on qualitative analysis of the likelihood of entry into new locations, toward a quantitative evaluation predicting their potential biological and *economic impacts,* which is more robust and fit for purpose. Article 5(1) sets formal criteria for risk assessment, laying a long list of mandatory elements for Member States. Key features of precautionary risk appraisal which included in the regulation contain (following Farrow 2004; Stirling and Gee 2002): (a) predictions over the impacts of large-scale events across different countries (e.g., future effect of climate change), and (b) the potential adverse impact, as well as the positive and negative economic impact for multiple stakeholders (cost–benefit analysis).

The EU also moved to enhance implementation, by developing common elements of risk assessment, including methods and minimum standards, to improve efficiency andconsistent use of this tool by Member States (Commission Delegated Regulation (EU) 2018/968). As part of these efforts, the EC together with scientists are working continually to provide protocols for the use of the PP in risk assessment (e.g., Turbé et al. 2017). While their practical implementation faces many challenges (e.g., the need in further research and information), they play an important role in modernizing traditional risk assessment for IAS, reflecting policymakers' effort to stabilize the role of the PP. Moreover, implementation challenges can be seen, through interpretive lens, as a by-product of regulatory ambition, which requires adjustments as part of a learning-by-doing process (for the ongoing review of methods in view of accumulated experience, see Roy et al. 2019).

These developments mark a significant deviation from regulatory tools in the US, which has not yet established formal, harmonized procedures for risk assessment intended to be used by policymakers in various locales across the region (Vannijnatten and Stoett 2017). Risk assessment for IAS is carried out within states and agencies (e.g., Florida; EPA), but it is not mandatory within the regulatory process, and no legally binding criteria for assessment exist. Moreover, scientists remarked on the 'appropriateness' of the EPA's methodology, noting that the risk assessment framework it chooses is intended to deal with chemicals and physical stressors, while its applicability to biological stressors, such as IAS, is unclear (for critiques, see Simberloff 2005). Relatedly, risk assessments for introduced species have mostly targeted species as potential vectors for pathogens, rather than as potentially invasive themselves. Non-agricultural risks, like damage to natural areas, get little attention (Simberloff 2006). As of 2019, the Trump administration disbanded the external scientific advisory committee on IAS. The government is no longer funding the Interior Department's Invasive Species Advisory Committee to NISC, which was placed in an administrative inactive status (Green 2019).

In the discussion of the tensions between evidence-based risk assessment and precautionary approach, it is often argued that precautionary regulation tends to marginalize science in decisions. This case shows that this may not always be so. Bioinvasion appears to be a specific example for the interface between science and policy process (Richards 2019): science is applied in the EU regulation to learn whether the ignorance is indeed as great as feared to imposing precautionary trade restrictive measures (for general discussion on precautionary risk appraisal, see Klinke and Renn 2002).

Different risk management frameworks

Third, the regulation adopts a transboundary approach to risk management (Cabane and Lodge 2017). This strategy for risk management has been widely recognized by scholars for its precautionary nature, given that there is no certainty of the transition of the risk across borders, and it is estimated to increase the vulnerability of other sectors (risk-vs-risk tradeoffs) (Ansell et al. 2010; Linnerooth-Bayer et al. 2001). For the merit of cross-jurisdictional governance for biodiversity conservation, see Clement et al. (2015).

Precautionary rhetoricis used in the legislative text regarding all key actionsof reducing transboundary spread of IAS. First, it addresses the first line of defense against their movements across jurisdictional borders: banning their importin the first place. Higher priority is given to the listing of IAS that are not yet present in the Union (Article 15). This pragmatic shift toward prevention, which is clearly precautionary-oriented, adopted in administrative procedures. The Commission implementing regulation [(EU) 2016/1141] confirms that the list will includeboth new species for the region and species that are already established in certain Member States,[6] in order to prevent new introduction or spread, where they are not yet presented [Articles 6(a)]. The list is binding in its entirety and directly applicable in all Member States, with the precautionary logic that imports to one Member State may impact the others.

Second, the regulation applies the precautionary principle regarding the second line of defense against transboundary risk: early detection and rapid response. Article 20 states that:

> 'Emergency measures at Union level would equip the Union with a mechanism to act swiftly in case of presence or imminent danger of entry of a new invasive species in accordance with the precautionary principle.'

In addition, Member States are required to put in place a surveillance system for detecting potential invaders in their borders, taking into account the transboundary impact and features [Article 14 (d)].

Third, lack of scientific evidence shall not prevent authorities from taking any precautionary measures regarding foreseeable pathways for invasion. For example, with regard to the use of IAS for scientific research and medical purposes—common pathways for invasion, national competent authorities may withdraw or amend permits issued for these uses based on scientific grounds, and 'where scientific information is insufficient, on the grounds of the precautionary principle' (Article 8). As a result, the burden of proof on the Commission or national authorities seeking to validly withdraw or amend authorization of several uses is relativelylax.

At the US, by contrast, there is no mention of the term 'precaution'in federal management plan (NISC 2016), nor adherence to precautionary elements. Even though it recognizes prevention as the most effective mean in IAS risk management, it is not accompanied by regional proactive regulatory measures, which is a core element of a precautionary approach. According to Williams (2017), border risk management programs for vertebrates are rarely applied. Regulation is left to state management instead, which is inherently difficult, because most states lack any form of border protection against IAS. She further argues that the US weak border management reflects political and cultural preferences

[6] Amended by EU 2019/1262.

for unhindered commerce. The result is that introductions within the US are damaging as introductions from outside the US borders (Simberloff 2006).

Given the more holistic legal approach undertaken by the EU, as compared to that performed by the US, it does not come as a surprise that the latter focuses largely on early detection and quick response to imminent or actual harm in priority landscapes and water (NISC 2016; US DOI 2016) and does not consider wider implications for risk avoidance pertaining to the whole factors responsible to accelerating the problem. According to Wiener et al. (2011), increasing interconnectedness of risk poses new challenges for policymakers: first, to develop earlier warning and coordinated response, given that risks may spread more quickly across borders. Second, to innovate better policies and institutions to reduce overall risks, and to think comprehensively about systemic interactions. Third, to facilitate learning in risk management. All of these challenges are now addressed by an EU coordinated risk management, which makes an effort to think comprehensively about systemic risks.

Implementing precautionary policy

It currently seems that the implementation of the EU regulation is being challenged by both industry and national policymakers with regard to its preventive-precautionary approach on several grounds.

The proportionalityand subsidiarity principles

With regard to the proportionality principle as set up in article 12 of the Regulation,[7] economic interests will be taken into consideration before experts determine which species will be banned without comprising the Regulation objectives. Due to conflicting interests in balancing economy–ecology trade-offs, attempts to raise the 'risk–risk tradeoffs' arguments are part of national lobbying activities to keep some IAS out of the Union list. For instance, one of Europe's most destructive predatory import, the American mink (Neovison vison) was subject to intense lobbying by firms and politicians from Finland and Denmark, which produce over 14 million American mink furs per year. Denmark raised a 'negative cost–benefit' argument. It argued that 'banning the mink will enable the country to win "green brownie" points in the home market,' but it will have significant negative economic consequences for the state budget (EURACTIV 2013). Eventually, the economic argument has won, with the result that the American mink has not been included in the Union list.

As to the proportionality and solidarity principles, the Regulation should not go beyond what is necessary in order to achieve its objectives (Article 37). For example, the Regulation requires Member States to take eradication measures for species of the Union list. However, derogations are possible when these costs are exceptionally high and disproportionate to the specific circumstances of the Member State, based on cost–benefits analysis

[7] Proportionality means that measures based on the PP must be proportionate to the desired level of protection. In some cases, a total ban may not be a proportional response to a potential risk. In other cases, it may be the sole possible response to a potential risk (Communication from the Commission on the precautionary principle COM (2000) 1.).

(Article 16). In the context of subsidiarity,[8] while the risk assessment carried out for prioritizing species for the Union list is a matter of shared competence between the Commission and the Member States (Article 5.2), it seems that the insufficient EU financial support could serve as an argument by Member States for avoiding costly risk assessments. Therefore, there is a need forfurther support to increase the number of IAS in the Union list.

Nevertheless, there have already been successful implementation stories. For example, all North American signal crayfish have been eradicated from a quarry pond in Scotland, increasing local fish and amphibian populations (Highland Council 2015). Also, Malta already set a national strategy in 2017, making a progress in managing IAS (Environment and Resources Authority 2018). Moreover, in addition to 66 species on the union list, there are several risk assessments under review for inclusion of new species.

Overall, while the stringency of the regulation appears to satisfy the conditionsgoverning its invocation, including proportionality, subsidiarity, and cost-effectiveness assessment, there is a need for further support the move from successful design to effective implementation (see also Cabane and Lodge 2017).

The conformity of risk assessment with WTO rules

While the Regulation's main implementation tool is the Union list, it falls under the scope of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures for placing trade restrictions on species (the SPS Agreement 1995). The Regulation explicitly clarifies that the risk assessment will carried out in line with the applicable provisions of the relevant agreements of the WTO (Articles 11, 13, 20). The SPS Agreement provides that, while Members have the right to establish their own level of protections, restrictive measures are only allowed where they can be proved to be scientifically based, using risk assessment guidelines of WTO/SPS and or international standards where available (Articles 2.2. and 5.1).[9] Robust risk assessment methods are required to provide the foundation upon which to base measures that may affect imports into the EU and future agreements with trade partners without infringing the rules and disciplines of the WTO. Since international standards and agreements still do not cover several key pathways for IAS spread, the EU must substantiate scientifically the risk assessment for the Union list, which is to be validated under the SPS Agreement. However, due to gaps in information systems and capacity, the EU might invoke Article 5.7 of the SPS Agreement. This article does not use the term 'precaution,' but provides for provisional measures to be taken pending further assessment. It refers to cases where relevant scientific evidence is insufficient. In such cases Members may provisionally adopt sanitary or phytosanitary measures on the basis of 'available pertinent information,' and will seek to obtain additional information within

[8] Under the principle of Subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if the objectives of the proposed action cannot be sufficiently achieved by the Member States, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level (Art.5 of the Treaty of European Union).

[9] Besides the WTO/SPS, there are other international regulation and standard-setting organizations which might be relevant to risk assessment of bioinvasion by trade. Some of them include precaution in some form (explicitly or non-explicitly), such as the International Plant Protection Conventions (IPPC), and World Organization for Animal Health (OIE). However, there is a general lack of guidance on how precaution could be implemented into the risk assessment of biosecurity/bioinvasion. For a comprehensive discussion on inconsistent and insufficient guidance for incorporation of precaution in international instruments, see Dahlstrom et al. (2011).

a reasonable period of time. The WTO's Appellate Body has expressly acknowledged that the precautionary principle finds reflection in Article 5.7 of the SPS Agreement (WTO 1998). In the meantime, since prioritizing species for the list depends on thedevelopment of a robust risk assessment, the Scientific Forum on IAS and the Commission introduced a delegated act that establishes methodologies for risk assessment (EC 2018/968). This is expected to clarify the listing process, resulting in adding species to the Union list.

Conclusions

As demonstrated by the analysis herein, the differences between US and the EU, as reflected in this case, are not semantic. By dividing the analysis into parts of regulatory process and their components—risk assessment, risk management, and legal frameworks (with their rhetoric, methods, and degree of integration), we were able to appreciate the level of divergence between the two regulatory systems.

Our conclusion is thus that the precautionary approach can be considered once again as a way to assess transatlantic policy choices, in terms of both stringency and regulatory process. This should revive the interest in promoting discussion on regulatory use of the PP in handling new and emerging EHS risks.

Although the precautionary approach and its application still remains to be seen, it plays an important role in making the EU bioinvasion policy more stringent than the American one. It also makes the European agencies better able and willing to respond in a risk-averse manner than their American counterparts.

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