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The role of science in the EU plant health regime: insights from the *Xylella fastidiosa* outbreak.

Pietro Mattioli*

Abstract

This paper examines the interplay between scientific knowledge and policy implementation in the EU plant health regime. It aims to demonstrate how science has become more deeply embedded in EU policies, particularly in plant health management. For that purpose, it employs an interdisciplinary approach that integrates a legal analysis with Actor-Network Theory (ANT). The legal analysis first identifies the shortcomings of the initial regulatory framework, Directive 2000/29/EC. Next, it examines how Regulation 2016/2031 on protective measures against plant pests and Regulation 2017/625 on official controls have addressed these deficiencies, highlighting the shift towards a more science-based enforcement approach. Subsequently, this paper applies an ANT methodology to analyse the *Xylella fastidios*a outbreak. This approach illustrates how the role of scientific actors can evolve to take on pivotal roles in policy implementation and emergency response. In this context, a key finding is the emergence of the European Food Safety Authority (EFSA) as an influential player in plant health governance.

Keywords:

EU plant health law, *Xylella fastidiosa* outbreak, EFSA, enforcement, interdisciplinary approach, Actor-Network Theory.

I. Introduction

The outbreak of *Xylella fastidiosa* has emerged as one of the most significant challenges destabilising the EU plant health regime in recent years. It has particularly highlighted the limitations of the Council Directive 2000/29/EC (Plant Health Directive),[1] which was the regulatory framework governing plant health when the

* Pietro Mattioli is a Ph.D. researcher at the University of Liège, within the framework of the ERC Starting Grant EUDAIMONIA (GA: 948473). He is currently a visiting researcher at the Amsterdam Centre for Transformative Private Law (ACT).

pathogen was first detected in the Apulia region of Italy in 2013. This legal framework was designed to prevent the introduction and manage the presence of non-native, harmful organisms, such as *Xylella*, within the EU territory.[2] However, significant failures in the implementation of Directive 2000/29 underscored the regime's inadequacy in effectively controlling the entry and spread of new invasive plant pests.[3]

In response, the EU has progressively developed a new plant health legislation, primarily embodied in Regulation (EU) 2016/2031 (Plant Health Regulation),[4] and partially in Regulation (EU) 2017/625 (Official Controls Regulation).[5] This framework surpasses Directive 2000/29 by establishing an enforcement system, which, among the other things, is strongly influenced by science.[6] This contribution argues that this feature of the new EU plant health regime represents an effort to stabilise a new regulatory network to better manage phytosanitary risks and emergencies across Europe. Within this network, scientific expertise, particularly the European Food Safety Authority (EFSA), holds a prominent position. To develop this argument, this paper intends to answer the following questions: how has the role of scientific knowledge evolved in the EU plant health regime? What are the potential challenges and limitations of relying heavily on scientific expertise in plant health enforcement?

Two chapters follow this introduction. Initially, chapter II provides a legal analysis of the EU plant health legislation. At first, it uses the *Xylella* outbreak as a concrete example to illustrate the limits of Directive 2000/29. Subsequently, it outlines how Regulation 2016/2031 and Regulation 2017/625 address these shortcomings by establishing a science-based enforcement framework.[7]

To complement this legal analysis, the paper proposes an Actor-Network Theory (ANT) study of the *Xylella* outbreak.[8] ANT provides a theoretical framework that examines the interactions between both human and non-human entities—referred to as actants—within a sociotechnical network. It employs concepts such as enrolment, mobilisation, and translation to describe these interactions.[9]

From an ANT perspective, the *Xylella* outbreak can be viewed as a disruptive actant that has significantly contributed to destabilising the framework established by Directive 2000/29. In that view, chapter III follows the series of interactions of the team of scientists who initially detected the presence of *Xylella* in the diseased olive trees in Apulia. First, it highlights how the researchers brought a local phytosanitary emergency to the attention of various actants, framing the presence of the bacterium as a significant threat. Subsequently, this chapter outlines how these researchers positioned themselves as obligatory passage points (OPPs) within the

[1] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [2000] OJ L 169/1.
[2] Ibid, recital 7-8.
[3] Commission staff working document executive summary of the impact assessment accompanying the document proposal for a Regulation of the European Parliament and of the Council on protective measures against pests of plants, SWD/2013/0168 final.
[4] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants [2016] OJ L 317/4.
[5] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation) [2017] OJ L 95/1. Previously, Directive 2000/29/EC established distinct control regulations for plant health. As a result, these specific controls were not governed by Regulation 882/2004, which dealt with official controls in other areas. Now, Regulation 2017/625 encompasses a comprehensive set of rules for official controls, which notably includes provisions for plant health.
[6] F Montanari and D Traon, 'Modernising EU Policy against Phytosanitary Risks – The New EU Plant Health Law' (2017) 12 European Food and Feed Law Review 131; and H Schebesta and K Purnhagen, *EU Food Law* (Oxford Academic, 2024), 142-144.
[7] F Blanc and M Faure, 'Smart enforcement in the EU, (2020) 23 Journal of Risk Research 1405, 1411-1412.
[8] E Cloatre, 'Actor-network theory and the empirical critique of environmental law: unpacking the bioprospecting debates' in A Philippopoulos-Mihalopoulos and V Brooks (eds), *Research Methods in Environmental Law* (Edward Elgar Publishing, 2017), 101-102.
[9] M Callon, 'Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay, (1984) 32 The Sociological Review 196; M Callon, The Sociology of an Actor-Network. (Macmillan Publishing, 1986); B Latour, Science in Action. How to Follow Scientists and Engineers through Society, (Harvard University Press, 1988); and J Bois, 'Taking the law seriously while acknowledging its social embeddedness: an Actor-Network Theory approach of EU law.' (2024) ORBi-University of Liège https://hdl.handle.net/2268/317536, accessed 1 September 2024.

network, influencing the collective response to the crisis.[10] This role allowed them to translate their scientific findings into legal frameworks, prompting the adoption of various measures that required action from multiple stakeholders. At the same time, this analysis also addresses the complexities of enforcing these legal responses, showing that these measures were subject to ongoing scrutiny regarding their effectiveness and scientific basis. As the key role of the research team came under question, the ANT study concludes by illustrating how EFSA has emerged as a new key actor in the response to the outbreak.

In sum, this ANT analysis has the objective of illustrating the influence of scientific knowledge on the development and implementation of EU legislation. By looking at the evolution of the interactions between various actants within the *Xylella* outbreak, it reveals how EFSA has been capable of establishing itself as a key actor for the governance of plant health. Finally, in support of the legal analysis of chapter II, an ANT perspective reveals how the EU's revision of the plant health regime reflects an attempt to legally stabilise network's dynamics that had already materialised in practice. This revision essentially formalises existing interactions and processes that had organically developed among stakeholders in response to plant health challenges.

II. Reforming the EU plant health legislation: the *Xylella* outbreak and regulatory modernisation.

Xylella fastidiosa is a bacterial plant pathogen with the ability to infect a diverse range of plants, leading to significant diseases.[11] In the American continent, it is associated with Pierce's disease, which commonly causes the obstruction of water-carrying vessels of the infected plants, ultimately leading to their death.[12] In October 2013, a similar phenomenon was observed in the province of Lecce in the Apulia region of Italy, where scientists confirmed the presence of *Xylella fastidiosa* on some olive plants. The detection of this plant pathogen drew further attention to the existing plant health regime, and its ability to effectively prevent and manage phytosanitary threats.

This chapter will first illustrate how the *Xylella* emergency underscored the already-known limitations of Directive 2000/29, prompting the establishment of a new regulatory framework. It continues with an analysis of Regulation 2016/2031 and Regulation 2017/625, illustrating how these legislations address the limitations exposed by the *Xylella* emergency and introduce new approaches to plant health management in the EU.

a. The *Xylella* outbreak: a key test for the EU plant health regime.

The *Xylella* plant pathogen had not previously been spotted in the EU territory. Nevertheless, an EU regulatory framework already existed for the prevention and management of the phytosanitary concerns that organisms such as *Xylella fastidiosa* might pose to the EU agriculture and ecosystem. Directive 2000/29 classified *Xylella fastidiosa* as a harmful organism that is 'not known to occur in any part of the community and relevant for the entire community'.[13] In that regard, it established a series of specific preventive and emergency measures aimed at safeguarding plants from this and other organisms. It provided that if the preventive measures to stop the introduction of these organisms have not succeeded, such as inspections and controls on certain plants, the central plant health authority of the affected EU country must take specific measures to control and eradicate the outbreak, notify the European Commission and the other Member States.[14] The Commission is then empowered to adopt necessary emergency measures to contain or eradicate the organism, and these measures

[10] This contribution employs the term 'obligatory passage point' to refer to an actor that becomes essential for all other actors in a network to achieve their goals. In more detail, Callon, 'Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay' (n 9), 205-206.
[11] EFSA, 'Statement of EFSA on host plants, entry and spread pathways and risk reduction options for *Xylella fastidiosa* Wells et al.' (2013) EFSA Journal, 5 https://doi.org/10.2903/j.efsa.2013.3468, accessed 1 September 2024.
[12] D Hopkins and A Purcell, '*Xylella fastidiosa*: cause of Pierce's disease of grapevine and other emergent diseases' (2002) Plant Disease, 86, 1056-1066.
[13] Directive 2000/29/EC (n 1), Annex I, Part A, Section I.
[14] Ibid, art. 16.

take precedence over national ones.[15] However, despite the framework of Directive 2000/29 in place, the *Xylella* pathogen reached Italy, and the situation shortly escalated into an EU phytosanitary emergency.[16]

Prior to this crisis, it had already been noticed that the Plant Health Directive was unable to effectively prevent the flux of new pests, while the risk of introducing such pests within the EU grew alongside the increase in global trade between EU Member States and non-EU countries.[17] Moreover, the creation of EFSA in 2002,[18] and the importance of scientific expertise and pest risk analysis as foundations for phytosanitary measures were regarded as other significant reasons for the revision of Directive 2000/29. An issue was also the unchanging status of harmful organisms contained in the Annexes of Directive 2000/29, which was still based of historical priorities of the Member States.[19]

Additionally, the 2010 *ex-post* evaluation of the EU plant health regime highlighted the inadequate implementation of existing policies. This assessment outlined two critical issues regarding Directive 2000/29. Firstly, there was a noticeable gap in the full implementation of the Plant Health Directive across Member States. Secondly, the evaluation uncovered a lack of consistency in how different countries applied the Directive's requirements.[20] In that regard, it can be noticed that the enforcement system of Directive 2000/29 was strongly decentralised.[21] The national phytosanitary authorities were responsible for conducting health inspections on certain plants and plant products within the EU, checking certain plants coming from non-EU countries,[22] notifying each other and the Commission when any harmful organism was detected and taking all necessary measures to eliminate them.[23] In this context, the Commission's supervisory role was also limited. Furthermore, while other agri-food regulations moved towards a science-based approach, the Plant Health Directive did not adapt accordingly.[24]

Against this background, the *Xylella* outbreak significantly weighs on the modernisation process of the EU plant health regime, uncovering many of the above concerns.[25] Several elements of this emergency highlight the overall failure of national competent authorities to implement the EU plant health regime. At first, the presence of *Xylella* within the EU territory exposed the ineffectiveness of the controls on plants imported from third countries.[26] In addition, the final report of an audit conducted by the department for health and food audits

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[15] Ibid, art. 16(3).

[16] The pathogen has progressively reached other EU countries. For instance, in 2015, it was detected in France. In 2016, Spain notified the presence of *Xylella*. In 2018, the bacterium reached Portugal. European Commission, 'Latest Developments of Xylella fastidiosa in the EU territory' https://food.ec.europa.eu/plants/plant-health-and-biosecurity/legislation/control-measures/xylella-fastidiosa/latest-developments-xylella-fastidiosa-eu-territory_en.

[17] Proposal for a Regulation of the European Parliament and of the Council on protective measures against pests of plants, COM/2013/0267 final - 2013/0141 (COD).

[18] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1.

[19] European Commission, 'Final Report: Evaluation of the Community Plant Health Regime' (2010), 6.

[20] Ibid, 278. Moreover, audits conducted by the Food and Veterinary Office (FVO) of the European Commission's DG SANTE revealed inconsistencies in the implementation of EU plant health legislation across Member States prior to the *Xylella fastidiosa* outbreak. For instance, European Commission, 'Final report of an audit carried out in Italy from 11 to 21 June 2013 in order to evaluate the system of import controls for plant health' DG(SANTE) 2023-7665.

[21] More generally, on the enforcement of EU law, see A de Moor-van Vugt and R Widdershoven, 'Administrative Enforcement' in J Jans, S Prechal and R Widdershoven (eds), *Europeanisation of Public Law* (Europa Law Publishing 2015); and M Scholten, M Luchtman and E Schmidt, 'The Proliferation of EU enforcement authorities: a new development in law enforcement in the EU' in M. Scholten and M. Luchtmann (eds), *Law Enforcement by EU Authorities* (Edward Elgar Publishing, 2017).

[22] Directive 2000/29/EC (n 1), art. 6.

[23] Ibid, art. 16(1).

[24] A risk-based enforcement model was already adopted by Regulation 178/2002.

[25] For instance, the statement of the former EU Commissioner for Health and Food Safety, Vytenis Povilas Andriukaitis, explicitly refers *to Xylella fastidiosa* as one of the plant pests that the new Regulation (EU) 2016/2031 aims to better protect the EU against the entry and spread of. European Commission, 'Statement by Commissioner Andriukaitis on the entry into force of the new Plant Health Regulation' (2016) https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_16_4309.

[26] A Sicard et al, 'Introduction and adaptation of an emerging pathogen to olive trees in Italy' (2021) 7 Microbial Genomics. In summary, this study highlights the genetic similarity between the Apulian and Costa Rican strain of *Xylella fastidiosa*. The evidence supports the hypothesis that the *Xylella* outbreak originated from a plant imported to Apulia from South America.

and analysis (at that time, the Food and Veterinary Office (FVO)) of DG SANTE of the European Commission in Italy in February 2014 concluded that the survey activities necessary to delineate the spread of the disease and to define infected and buffer zones were not fully carried out, and no eradication or containment measures were taken. As well, it raised concerns about the reliability of the ELISA test used to check for the presence of the virus on certain plants.[27] Under these circumstances, it is not surprising that the pathogen managed to reach other EU countries (France, Spain, Portugal), hence outlining the ineffectiveness of the checks on the movement of plants among EU countries.

Moreover, the case law of the Court of Justice of the European Union (Court of Justice or CJEU) also highlights the difficulties encountered in enforcing the emergency measures implemented at the EU, national, and regional levels during the *Xylella* outbreak. In *Commission v Italy*, the Commission accused Italy of non-compliance due to its failure to fully implement Directive 2000/29 and Implementing Decision 2015/789.[28] It argued that Italy had not adequately implemented the required containment and eradication measures, contributing to the further spread of the disease. At the same time, in *Giovanni Pesce*, the Court of Justice was called to evaluate the legitimacy of the measures implemented by Italy to address the spread of *Xylella*. This case arose from a national case before the Lazio Regional Administrative Court where certain Italian landowners opposed the decision to remove olive trees affected by the pathogen. [29]

The *Xylella* outbreak accelerated the push for a comprehensive overhaul of the EU's plant health legislation. It exposed the significant weaknesses in the existing regulatory framework, particularly in terms of prevention, detection, and containment of plant pathogens. The following sub-chapter will examine this modernisation process by looking at Regulation 2016/2031 on protective measures against pests of plants and Regulation 2017/625 on official controls.

b. Science at the core of the new EU plant health framework.

The new legislative framework for plant health–Regulation (EU) 2016/2031 and Regulation (EU) 2017/625–introduces some key innovations.[30] At first, it can be noticed that this framework is distinguished by a more robust EU role, although national competent authorities maintain a crucial responsibility in terms of enforcement.[31] However, within this new regulatory setup, prominent is the shift towards a science-oriented, risk-based enforcement approach.[32]

The new EU plant health regime places a strong emphasis on scientific knowledge to inform policy decisions and implementation strategies.

This regime relies on EFSA's scientific and technical expertise for conducting risk assessments used to implement protective measures against plant pests and design effective surveillance programs. Since its establishment, EFSA has been assisting the Commission, particularly through its Scientific Panel on Plant Health (PLH Panel), in matters related to plant health.[33] The new plant health regime enhances this role. In the

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[27] European Commission, 'Final report of an audit carried out in Italy from 10 to 14 February 2014 in order to evaluate the situation and official controls for *Xylella fastidiosa*' DG(SANCO) 2014-7260,18-19.

[28] Case C-443/18, *European Commission v Italian Republic* [2019] C:2019:676. In this ruling, the Court of Justice concluded that Italy had failed to fulfil its obligations under both Directive and the implementing decision.

[29] Case C-78/16, *Giovanni Pesce and Others v Presidenza del Consiglio dei Ministri - Dipartimento della Protezione Civile and Others* [2016] C:2016:428.

[30] For an overview of the new features of the Plant Health Regulation, see F Montanari and D Traon (n 6), 131–41.

[31] For instance, Regulation 2017/625 (n 5), arts. 116 and 119. As regards official controls, the Commission Directorate F (previously, FVO) can perform controls, including audits, in each Member State to verify compliance, assess national control systems, including the performance of the competent authorities, and gather information. In that regard, Member States have an obligation to 'take appropriate follow-up measures to remedy any specific or systemic shortcomings identified through the controls performed by the Commission experts'. In literature, M Scholten, 'Mind the trend! Enforcement of EU law has been moving to 'Brussels; (2017) 24 Journal of European Public Policy 1348.

[32] M Everson and E Vos, 'The Scientification of Politics and the Politicisation of Science' in M Everson and E Vos (eds), *Uncertain Risks Regulated* (Routledge/Cavendish Publishing, 2009) 1–17; Blanc and Faure (n 7); and M Scholten, *Research Handbook on the Enforcement of EU Law* (Edward Elgar Publishing, 2023), 8-9

[33] The Commission can request EFSA to provide scientific opinions on the risks posed by specific organisms. See, Regulation 178/2002 (n 18), art. 29.

context of Regulation 2016/2031, EFSA carries out risk assessments of plant pests that inform the Commission's management decisions regarding the list of Union quarantine pests, protected zone quarantine pests (including priority pests), and Union regulated non-quarantine pests.[34] Furthermore, on the basis of a preliminary assessment conducted by EFSA, the Commission lays down a list of high risk plants, plant products and other objects.[35] This preliminary assessment is then followed by a risk assessment conducted by third countries to evaluate whether the organism will remain prohibited.[36] EFSA is then called to provide scientific opinions on the dossiers presented by third countries for high-risk plants.[37]

Regulation 2016/2031 also introduces the concept of 'technical justification' as a key requirement for national risk management measures against plant pests. This concept mandates that any action taken to manage or eradicate pests must be based on conclusions drawn from appropriate risk analysis or comparable evaluations of available scientific data.[38] Therefore, EFSA's assessments might become a foundation for decision-making across Member States.

EFSA's scientific expertise also serves as a crucial tool for aligning and standardising plant health enforcement practices across Member States. Through its scientific committees and networks, EFSA helps develop harmonised standards, practices, and methodologies. For instance, within the Emerging Risks Exchange Network (EREN), it exchanges data and methodologies on emerging risks with Member States. Similarly, the Scientific Network on Plant Pest Surveillance provides support to the Member States for the development of effective risk-based surveys for quarantine pests.

In this view, Regulation 2017/625 also streamlines the processes involved in official controls applying a risk-based, precautionary logic in this field.[39] It affirms that the national authorities competent to perform official controls in the field of plant health need to adopt a risk-based approach identifying the risk, the information indicating a likelihood that consumers may be misled, operators' past record of compliance, reliability of controls performed by the operator themselves, and any information that might indicate non-compliance.[40] In addition, this Regulation refers to EU Reference Laboratories (EURLs), which are specialised scientific laboratories established by the Commission within the Member States to promote uniform practices and ensure the reliability of methods for analysis, testing, and diagnosis across Member States.[41]

To conclude, the new EU plant health regime establishes a science-based enforcement framework by making scientific expertise the foundation for decision-making. By recurring to science, this approach also aligns national enforcement practices, paving the way for a more uniform application of EU plant health legislation across Member States.

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[34] Under Regulation 2016/2031, the European Commission needs to establish and constantly update a list of Union quarantine pests, protected zone quarantine pests (including priority pests), and Union regulated non-quarantine pests. These pests are listed in Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants [2019] OJ L 319/1, Annex II, III, and IV.

[35] Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation [2018] C/2018/8877, OJ L 323/10.

[36] Regulation (EU) 2016/2031, art. 42(4). In that regard, on request of the Commission, EFSA has provided a document standardising the information requirements for technical dossiers to support demands (from third countries) for import of high-risk plants, plant products and other objects as specified in Regulation 2016/2031. EFSA, 'Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031' (2018) 15 EFSA supporting publication 1492.

[37] Commission Implementing Regulation (EU) 2018/2018 of 18 December 2018 laying down specific rules concerning the procedure to be followed in order to carry out the risk assessment of high risk plants, plant products and other objects within the meaning of Article 42(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council [2018] C/2018/8876, OJ L 323/7, art. 5.

[38] Regulation 2016/2031 (n 4), Annex II, Section 2, art. 1(5).

[39] F Blanc and L Megale, 'Food law' in Miroslava Scholten, Research Handbook on the Enforcement of EU Law (Edward Elgar Publishing, 2023), 340-341.

[40] Regulation 2017/625 (n 5), arts 4(1) and 9(1). These provisions state that for each of the areas governed by this Regulation, Member States need to designate the competent authority or authorities on which they confer the responsibility to organise or perform official controls. These controls need to be performed on 'risk basis'.

[41] Ibid, art. 91.

III. An ANT narrative of the *Xylella* outbreak.

The revised EU rules for plant health represent an effort to create a more effective enforcement framework for preventing and managing phytosanitary risks and emergencies across Europe. This chapter will conduct an ANT analysis of the *Xylella* outbreak to help gain a better understanding of the new EU's approach to plant health. By tracing the interactions among plant health actors, ANT exposes the implementing challenges of the framework of Directive 2000/29. Additionally, it concretely illustrates the evolution towards integrating scientific input into plant health and especially, the evolving role of EFSA. In this view, this analysis shows how the new regulatory framework formalised pre-existing network dynamics. Finally, an ANT analysis exposes hidden complexities, such as the potential challenges of integrating scientific expertise into the enforcement systems.

This chapter begins by examining the interactions of the team of researchers who claimed that *Xylella* was responsible for infecting olive trees in southern Italy, leading to olive quick decline syndrome. Following ANT principles, it describes the act of problematisation and the subsequent enrolment of different actants. In this context, this chapter emphasises how the researchers successfully positioned themselves as obligatory passage points within the network. It continues with a description of how various actants reacted to the act of mobilisation through law and how frictions within the network eventually undermined the scientists' position, affecting the effectiveness of the measures in place. As the emergency unfolded, EFSA has emerged as a new indispensable actant in the *Xylella* narrative.

a. The decline of olive trees in Apulia: how a team of scientists framed the emergency.

The narrative begins with a team of researchers discovering the presence of *Xylella fastidiosa* on some olive trees in Apulia. The presence of *Xylella* acted as a trigger for change in the existing network dynamics.

A local farmer from the town of Taviano in the province of Lecce, coincidentally a relative of Donato Boccia, a member of the National Research Council – Institute for Sustainable Plant Protection (CNR-ISPP), brought to the researcher's attention the desiccation of some olive trees. The hypothesis that the decline could be linked to the presence of the plant pathogen *Xylella* was then conceived by Giovanni Martelli who had extensively researched the Pierce's disease in California.[42] The laboratory analyses carried out by a team of researchers, including Boccia and Saponari who were members of the CNR-ISPP, confirmed the presence of *Xylella fastidiosa*.[43] The analysis also identified other elements that could have contributed to the rapid decline of olive trees, such as lignicole fungi, which is also known for causing the limitation of the lymphatic circulation of the plants.

Through an informative note,[44] the scientific institutions responsible for the discovery, namely the CNR-IPSP, Di.S.S.P.A., and the Network of Public Research Laboratories (SELGE) of the University of Bari, publicly communicated the results of their discovery. In the note, one can read that the researchers acknowledge that multiple factors might have contributed to the symptoms observed in olive trees. Nevertheless, they emphasised that the *Xylella* pathogen should be considered the primary cause of the disease. Once established a connection between *Xylella* and the unusual desiccation of olive trees in the province of Lecce, the researchers also recommended immediate actions, such as eradication of the infected plants, identification of infected areas, and intensified controls.

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[42] Giovanni Paolo Martelli, who was then an emeritus professor at the University of Bari – Department of Soil Sciences of Plants and Food (Di.S.S.P.A.), recognised similarities with the Pierce's disease of the California vineyards and consequently, recommended conducting laboratory analyses to explore the possibility of the *Xylella* pathogen as the cause of the olive tree desiccation in Apulia.

[43] R Bassi, G Morelli, and F Salamini, 'Rapporto *Xylella*' (2016) https://www.lincei.it/it/article/rapporto-xylella.

[44] Regional Council of the Apulia Region, 'Deliberazione della Giunta regionale 29 ottobre 2013, n. 2023: Misure di emergenza per la prevenzione, il controllo e la eradicazione del batterio da quarantena Xylella fastidiosa associato al "Complesso del disseccamento rapido dell'olivo' (2013) Bollettino Ufficiale della Regione Puglia - n. 153 del 22-11-2013, Annex II.

At this stage, the scientists had the complex task of convincing the other relevant actors of the validity of their claim.

The pathogen's ability to possibly infect a wide range of high-value plants, including grapevines and olive trees, and cause the progressive death of infected plants, made it an extremely dangerous threat. Without any cure for the diseases it triggers, this pathogen could result in massive environmental and agricultural damages in the Apulia region, having a devastating impact on local economies that rely heavily on olive oil production. Given these circumstances, it didn't take long for the team of researchers to convince the local communities of the gravity of the situation and the urgent need for specific measures to be implemented promptly.[45]

To capture the attention of political institutions, the team of researchers promptly engaged the Regional Plant Health Services (RPS) of the Apulia region through an informative note. The involvement of this authority proved crucial. RPSs serve as the official regional bodies responsible for implementing plant health legislations within their respective regions in Italy, as mandated by Article 2(1)(g) of Directive 2000/29.[46] Situated within the Agriculture Department of each region, the RPSs are also part of the Italian Central Plant Health Service, which is the MiPAAF in Italy, designated as Single Authority under Article 1(4) of Directive 2000/29.[47] Leveraging its strategic position within the public administration, the enrolment of the RPS of the Apulia region facilitated the team of researchers in communicating their position to political authorities.

Therefore, the Apulian phytosanitary authority promptly informed MiPAFF.[48] A week later, on October 22, 2013, during a National Plant Health Committee (NPHC) meeting chaired by MiPAFF, the Directors of the Apulia RPS and of the National Research Council-Institute of Plant Virology's (CNR-IVV) jointly presented information about *Xylella*'s presence and spread.[49] This strategic move enabled the team of researchers to directly engage with a significant body involved in national policymaking. Notably, this Committee is consulted on legislative proposals before they are presented to the State-Region Conference, facilitating the exchange of information on various plant health-related topics.[50]
The researchers' influence was further strengthened when Boccia, Saponari, and others were appointed to the Scientific-Technical Committee for *Xylella fastidiosa*. This committee, established by MiPAFF, was tasked with supporting the NPHC's activities related to *Xylella fastidiosa*.[51]

Moreover, it did not take long before the involvement of the European Commission. In view of the obligation listed in Article 16 of Directive 2000/29,[52] the Italian national authorities formally notified the Commission, which soon asked EFSA to provide urgent scientific and technical assistance. The Commission relies on EFSA's technical and scientific assistance on specific matters. On this occasion, recurring to Article 31 of Regulation 178/2002, it asked EFSA to review the known host plants and insect vectors of *Xylella*, identify potential pathways for the entry and spread of the bacterium, and evaluate possible preventative measures and risk reduction options.[53] Initially, EFSA's position seemed to be aligned with that of the researchers. However, its intervention was limited in scope by the Commission's request, which was specifically centred on understanding the nature of the bacterium. In this context, EFSA confirmed the risks associated with the presence of *Xylella*, and alternative explanations for the desiccation of olive trees in the Apulia region were not considered, yet.

Under these circumstances, the team of researchers managed to make themselves an obligatory passage point. After justifying the rapid decline of olive trees due to the *Xylella* plant pathogen and convincing other actants

[45] This pathogen was not totally unknown to the political sphere. It was listed in both Annex I, Part A, Section I to the Council Directive 2000/29/EC as a harmful organism whose introduction into and spread within all Member States is banned and in the European and Mediterranean Plant Protection Organization's (EPPO) A1 List of pests recommended for regulation as quarantine pests.
[46] Directive 2000/29/EC (n 1), art. 2(1).
[47] Ibid, art. 1(4).
[48] Note of the Phytosanitary Observatory Office prot. 0086998 dated 15 October 2013.
[49] Regional Council of the Apulia Region, 'Deliberazione della Giunta regionale 29 ottobre 2013, n. 2023 (n 43), 38707.
[50] For more information on the role of the Committee, see https://www.protezionedellepiante.it/cfn/.
[51] See, Ministerial Decree of 12 September 2014 establishing a Technical and Scientific Committee with the task of investigating the aspects related to the management of the phytosanitary emergency caused by *Xylella fastidiosa*
[52] Directive 2000/29/EC (n 1), art. 16(1).
[53] EFSA, 'Statement of EFSA on host plants, entry and spread pathways and risk reduction options for Xylella fastidiosa Wells et al.' (2013) 11 EFSA Journal https://doi.org/10.2903/j.efsa.2013.3468 accessed 1 September 2024.

of this claim, the expertise of the researchers from Apulia became indispensable. Not only they were the first to find a possible cause for the disease, but they also advanced with scientific research on the pest.[54] The team emphasised the key problem and necessary solutions for effectively managing the emergency, while trying to preclude the possibility of disputing the idea that the pathogen was the sole responsible for the desiccation of the olive trees. Established this connection and found the support of other actants, especially the EU and Italian institutions, the scientists were in a position to present their proposed solutions as inevitable.

However, in encountering this obligatory passage point, actants took divergent positions. The following sub-chapter will illustrate how some actants supported the scientists' position, while others opposed it.

b. Mobilisation through law: actants' engagement.

By successfully enrolling policymakers at various levels of governance, the scientists were in the position of directly influencing decision-making processes and hence, seeing their scientific expertise be effectively translated into policy outcomes. Therefore, the scientists created a network where their knowledge became an essential component in shaping the policy responses to the *Xylella* outbreak.

The Regional Council of the Apulia Region endorsed the hypothesis proposed by the researchers from the outset. Building on the assumption that *Xylella* was the major cause of the quick decline of olive trees, it adopted some measures for the prevention, control, and eradication of the quarantine bacterium on 22 November 2013. These measures included the delimitation of different areas (infected and buffet zone), the eradication of infected plants in outbreak areas, insecticide treatments of host plants, and practices to limit the spread of infection.[55] For the enforcement of these measures, local farmers and authorities, and the regional RPS were mobilised.

The Commission took the first emergency measures through Implementing Decision 2014/87/EU,[56] which was soon repealed by Implementing Decision 2014/497/EU in July 2014.[57] These initial emergency measures were enacted under the authority granted by Article 16(3) of Directive 2000/29, which allowed the Commission to take action when harmful organisms were detected within an EU Member State.[58] These decisions altered in part the existing restrictions already in place in Apulia, which were introduced by the Regional Council of the Apulia Region. They included requirements for establishing demarcated areas where the organism was detected,[59] specific control measures to be implemented within these demarcated areas,[60] obligations for Member States to conduct surveys and report findings,[61] and restrictions on the introduction and movement of specified plants that could potentially host the organism.[62]

Moreover, the Italian political institutions were successfully mobilised. In that sense, for instance, to facilitate the implementation of the EU emergency measures at the national and regional level, a special Commissioner delegated at the emergency *Xylella*, the Commander of the Forestry Commission of Apulia, Giuseppe Silletti, was appointed in February 2015.[63]

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[54] In 2013, there was no dedicated research program studying the Xylella fastidiosa plant pathogen in Europe and thus, specific investigations were necessary to understand the specific epidemiological traits of the outbreaks in Europe.
[55] Regional Council of the Apulia Region, 'Deliberazione della Giunta regionale 29 ottobre 2013', n. 2023 (n 43), Annex I.
[56] Commission Implementing Decision 2014/87/EU of 13 February 2014 as regards measures to prevent the spread within the Union of Xylella fastidiosa (Well and Raju) [2014] OJ L 45/29.
[57] Commission Implementing Decision 2014/497/EU of 23 July 2014 as regards measures to prevent the introduction into and the spread within the Union of Xylella fastidiosa (Well and Raju) [2014] OJ L 219/56.
[58] Directive 2000/29/EC (n 1), art. 16(3).
[59] Commission Implementing Decision of 23 July 2014 (n 57), art. 7 and annex III, section 1.
[60] Ibid, annex III, section 2.
[61] Ibid, art. 4.
[62] Ibid, arts. 2 and 3, and Annex I.
[63] Prime Minister Office, 'Ordinanza n. 225: primi interventi urgenti per fronteggiare il rischio fitosanitario connesso alla diffusione della Xylella fastidiosa in Puglia' (20 February 2015) 42 Gazzetta Ufficiale https://www.protezionecivile.gov.it/it/normativa/ocdpc-n--225-dell-11-febbraio-2015--primi-interventi-urgenti-per-fronteggiare-il-rischio-fitosanitario-connesso-alla-diffusione-della-xylella-fastidio/.

However, as the situation evolved, the position of obligatory passage points of the researchers started to erode. New and old actants, drawn into the network through these legal measures, began to question the researchers' central role. The strict measures, which were founded on the initial perception of the threat, faced increasing scrutiny. Consequently, both the scientific basis for the legal actions and the severity of the emergency measures became subjects of debate and disagreement.

c. Actants' resistance, friction within the network, and the establishment of a new OPP.

Despite these measures being in place, the disease continued to spread further throughout Apulia. Researchers who had advocated for the removal of both infected olive trees and those in close proximity as a means to stop the spread of *Xylella*, which was believed to be the main primary cause of the olive quick decline syndrome, found their stance challenged. Three main factors contributed to undermining their status of OPPs: friction in the network, the emergence of alternative theories and consequent loss of credibility, and the establishment of a new OPP.

As the situation further unfolded, frictions among actants within the network progressively emerged. Doubts were raised regarding the accuracy and validity of the initial theories on the desiccation of olive trees. Olive growers, in particular, voiced concerns about the economic burden imposed by the eradication strategy, which focused on removing both infected and healthy trees in close proximity.[64] Scepticism found the support of additional stakeholders, such as environmental and agricultural organisations, and of public opinion and media, which entered the network as new actants.[65] The contrasts between the eradication strategy and the concerns of olive growers became more pronounced as farmers began to challenge the measures in regional administrative tribunals in Italy.[66]

Moreover, two audits conducted by the FVO of DG SANTE (now, department for health and food audits and analysis) in the Apulian region in February and November 2014 proved that most of the emergency measures were not implemented. The latest audit reports that eradication measures as required by Implementing Decision 2014/497/EU were not enforced.[67] In addition, there were not sufficient guarantees that host plants in demarcated areas were kept within the areas. Official controls were insufficient and not all floriculture centres in the demarcated area were identified. In other words, the Commission's desire to see its policies on *Xylella* achieving their objective was hindered by the lack of enforcement by the Apulia RPS and local farmers. Under these circumstances, the Commission sent to the Italian authorities a letter of formal notice in December 2015, followed by another in July 2016, asking Italy to fully implement the Commission's implementing decisions to stop the progression of *Xylella*.

The researchers' position as OPPs was further eroded by shifting perspectives. During the early stages of the crisis, the Commission's understanding of the outbreak was heavily influenced by that specific part of the scientific community who believed that *Xylella* was the primary cause of olive tree desiccation. As a result, the Commission initially focused on drastic solutions to combat the bacterium. This narrow approach overlooked other factors or alternative explanations for the widespread decline of olive trees. In light of the unsuccessful eradication attempts, the Commission started to distance itself from the researchers' initial position. This shift marked a turning point in how the emergency was being addressed. Therefore, in 2015, the Commission requested a scientific and technical advice from EFSA to evaluate the various perspectives and approaches to the emergency.[68]

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[64] Commission Implementing Decision 2014/497/EU (n 57), Annex III, section 1.

[65] G Tipaldo, F Bruno and S Rocutto, 'Hands off the olive trees!»: the epistemic war in the Xylella fastidiosa epidemic in Italy. A Computer-Assisted Text Analysis of User-generated content on social media'(2022) 11 Cambio. Rivista sulle Trasformazioni Sociali 131 https://hdl.handle.net/2318/1864541.

[66] For instance, on 27 March 2015, the Regional Administrative Court of Lecce upheld a precautionary appeal against the eradication of olive trees infected with Xylella fastidiosa, suspending felling procedures until 9 April 2015. Additionally, multiple farmers and landowners appealed to the Lazio Regional Administrative Court, obtaining a suspension of the Italian Commissioner's plan.

[67] Commission (n 27); and European Commission, 'Final report of an audit carried out in Italy from 18 to 25 November 2014 in order to evaluate the situation and official controls for Xylella fastidiosa' DG(SANCO) 2014-7327.

[68] EFSA, 'Scientific Opinion on the risks to plant health posed by Xylella fastidiosa in the EU territory, with the identification and evaluation of risk reduction options' (2015) 13 EFSA Journal https://doi.org/10.2903/j.efsa.2015.3989, accessed 1 September 2024. In more detail, the Commission asked to deliver a scientific opinion on the pest risk posed

At the same time, alternative scientific opinions that downplayed the severity of the *Xylella* pathogen entered the scene. The team of scientists who attributed the symptoms of desiccation to *Xylella* found the resistance of another part of the scientific community. This new research strand was composed by the Institute of National Research Centre – Sciences of Food Production (CNR-ISPA) of the University of Lecce and more generally by researchers of the Universities of Lecce, Matera, and Foggia. They argued that the olive tree disease in Apulia could be associated with various factors, such as fungi, insects, and inadequate agronomic practices commonly used on olive trees in the south of the Apulia region. In fact, these elements were also detected within the infected plants.

This alternative scientific position found the support of environmental and trade associations as well as some political forces. These actors raised concerns about the polarised scientific foundation influencing policy decisions and thus, the necessity of specific emergency measures. In that sense, for instance, Peacelink, an Italian non-governmental organisation (NGO), claimed that the olive trees decline in the province of Lecce could be attributed to different causes, including but not exclusively to *Xylella*. In this scenario, it suggested that possibilities for treatment exist.[69] Similarly, the European Parliament issued a motion for a resolution on the *Xylella* emergency in May 2015 calling for broadening the scientific base that is used to lay down policies. In that sense, it underlines the need to adopt prevention measures to stop the spread of the bacterium rather than eradication measures. It also demands to be more cautious on insecticides due to environmental concerns.[70]

As the position of OPPs of the researchers who first discovered the *Xylella* bacterium started to erode, EFSA managed to position itself as a central actor in the network. Other actants progressively started to rely exclusively on EFSA's expertise and guidance. The next chapter will analyse the position of EFSA as an OPP in the context of the *Xylella* emergency.

IV. EFSA as OPP.

The discovery of *Xylella fastidiosa* by a team of researchers in Apulia was not only a scientific finding but also an act of problematisation. They brought to the attention of different actants the risks of the plant pathogen for agriculture and biodiversity, hence framing *Xylella* as a significant threat. Nevertheless, they failed to preserve the trust of the other actants. Soon, they faced resistance of part of the public, political, and scientific community. In this context, ahead of the many uncertainties still surrounding the emergency, EFSA quickly transformed itself into an obligatory passage point. Various elements might help in understanding how EFSA has managed to mobilise other actors (European Commission, Member States, and scientific community), and translate its scientific advice into legal measures, essentially positioning itself as OPP.

The status and operational model of EFSA within the EU system is a key factor for understanding the central position this agency has obtained within the network.

EFSA embodies the EU's broader trend of 'agencification' that began in the 1970s and accelerated in the 1990s.[71] This process saw the establishment of multiple specialised agencies to address specific technical challenges. The establishment of EFSA in 2002, in particular, was a direct response to the need to address the low expertise and credibility of the EU's food safety regulation system. The Bovine Spongiform Encephalopathy (BSE) crisis exposed significant weaknesses, especially in terms of governance of uncertain risks. The creation of EFSA reflected the EU's commitment to restoring public confidence in its food safety regulation. For this reason, this agency's institutional design focuses on concentrating scientific expertise in a

by *Xylella fastidiosa* for the EU territory and especially, to provide an opinion on the effectiveness of the current EU requirements against *Xylell*a in reducing the risk of introduction and spread of this pest

[69] EFSA, 'Response to scientific and technical information provided by an NGO on *Xylella fastidiosa*' (2015) 13 EFSA Journal 4082 https://doi.org/10.2903/j.efsa.2015.4082, accessed 1 September 2024.

[70] European Parliament, 'European Parliament resolution on the outbreak of *Xylella fastidiosa* affecting olive trees' (2015) 2015/2652(RSP).

[71] M Chamon, *EU agencies: legal and political limits to the transformation of the EU administration* (Oxford University Press, 2016); and E Chiti, 'Decentralized Implementation: European Agencies', in R Schütze, and T Tridimas (eds), *Oxford Principles Of European Union Law: The European Union Legal Order* (Oxford Academic, 2018) 748.

distinct entity, separate from the Commission, to ensure a clear separation between scientific advice and decision-making. This approach aims to guarantee the independence, transparency, and expertise necessary to provide reliable scientific guidance. Moreover, the specific internal structure of EFSA is organised in a way that allows this agency to operate in collaboration with national competent authorities – as another attempt of 'Europeanization' of science.[72]

Moreover, according to Regulation 178/2002, EFSA provides scientific and technical advice to the Commission on matters related to food safety and plant health. This process enables the Commission to develop science-based policies. This advisory function has been particularly significant in addressing the *Xylella* emergency. For instance, in 2015, EFSA delivered a risk assessment on *Xylella* that informed the Commission Implementing Decision 2015/789.[73] As well, the EFSA's 2019 update of the Scientific Opinion on the risks to plant health posed by *Xylella fastidiosa* also preceded the adoption of the Commission Implementing Regulation (EU) 2020/1201 (repealing Commission Implementing Decision (EU) 2015/789).[74] In this capacity, EFSA could actively shape how other actors perceived the emergency. For instance, by outlining the gravity of the situation, it determined the urgency of the response. By screening potential preventive measures, it guided the development of practical strategies to combat the spread of *Xylella*.

Keeping this in mind, additional elements should be considered to understand the processes of enrolment and translation of other actants by EFSA. Actants' mobilisation could be explained considering that the distribution of *Xylella* has undergone significant changes since its initial outbreak in the Apulia region. In 2015, the pest was detected in the Corse and Provence-Alpes-Côte d'Azur regions of France. In 2016, Spain notified the presence of *Xylella* in the Balearic Islands, in the province of Alicante, and in the Autonomous Region of Madrid. In 2018, the bacterium reached Portugal. This escalation placed the Commission at the forefront of the emergency, prompting it to rely on EFSA for scientific guidance and support. It also pushed the Member States to rely on EFSA's scientific assessments as basis for coordinated control strategies.

Additionally, EFSA's role as an obligatory passage point is evident in its ability to convene diverse scientific actors, becoming an authoritative source of knowledge for the entire scientific community. Its risk assessments are prepared by working groups composed of scientists having different backgrounds (for instance, risk assessment methodologies, plant pathology and disease epidemiology) and coming from different Member States.[75] By organising conferences and workshops, EFSA is also capable of shaping future research agendas, directing scientists toward areas requiring further investigation.[76]

The success of EFSA in shaping policy decisions is not without its consequences. From an ANT perspective, EFSA's expertise is an example of 'black box'.[77] In that regard, externally, EFSA's scientific opinions may appear unquestionable, particularly to the Commission, which relies heavily on EFSA's advice to inform its policies. This perception fails to recognise the shortcomings of this process.[78] For instance, to produce these outcomes, EFSA relies on a network of actors. The interactions among these actors are often hidden, as the outcomes are presented in a way that emphasises the scientific consensus rather than the complex processes involved. In fact, EFSA's scientific opinions, as published in the EFSA journal, show the agreed-upon conclusions. However, EFSA's risk assessments are adopted by majority, potentially obscuring dissenting views. Furthermore, EFSA employs specific criteria for data selection and methodologies for risk assessments which can significantly influence the final conclusions. In other words, EFSA's assessments need to translate complex scientific information into a language that can be used by multiple actors. Such accessible knowledge

[72] M vanAsselt and E Vos, 'EU risk regulation: the role of science in political and judicial decision-making' in HW Micklitz and T. Trimidas (eds.), *Risk and EU law* (Edward Elgar Publishing, 2015). 120-121; and E Vos, 'EU agencies on the move: challenges ahead' (2018) 1 SIEPS.
[73] EFSA (n 66).
[74] EFSA, 'Update of the Scientific Opinion on the risks to plant health posed by Xylella fastidiosa in the EU territory' (2019) 17 EFSA Journal https://doi.org/10.2903/j.efsa.2019.5665 accessed 1 September 2024; and Commission Implementing Regulation (EU) 2020/1201 of 14 August 2020 as regards measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* (Wells et al.) C/2020/5520 [2020], OJ L 269/2.
[75] For more information, https://www.efsa.europa.eu/en/careers/experts.
[76] For instance, EFSA has organised various conferences on *Xylella fastidiosa* over the years. These conferences serve as important platforms for discussing research advances and coordinating efforts to address *Xylella*.
[77] In ANT scholarship, the term 'black box' is employed to describe how some complex systems within a network might become opaque and overlooked by external observers due to their technical nature. See, Latour (n 9).
[78] Bois (n 9), 5.

might come at the expense of the minoritarian and less influential scientific perspectives. If these internal power dynamics are not adequately addressed, it is likely that the public trust in EFSA's expertise will progressively erode.

V. Conclusions.

The *Xylella fastidiosa* outbreak has significantly challenged the EU's plant health regime, exposing the limitations of the regulatory framework originally established by Directive 2000/29/EC. To create a more effective framework for managing phytosanitary risks and emergencies, the EU has progressively updated its legislation adopting Regulation 2016/2031 and Regulation 2017/625.

The new EU plant health regime establishes a science-based enforcement system. In this system, EFSA has emerged as a key player. Its scientific opinions are instrumental in informing risk management decisions at the EU and national levels. However, this paper highlights how this reliance on EFSA's expertise is not without its complexities. From an ANT perspective, this element can be viewed as a 'black box'. Its expertise may appear unquestionable externally. However, this overlooks the intricate network of actors contributing to its expertise, including scientists' backgrounds, data and methodologies, and institutional processes, which can potentially lead to the marginalisation of dissenting views and erosion of public trust if not adequately addressed.

In conclusion, by combining legal analysis with sociological perspectives, this contribution provides an in-depth understanding of how scientific expertise has become deeply embedded in EU plant health policy implementation. It demonstrates the increasing importance of science-based approaches in ensuring effective plant health management and highlights the evolving roles of various actors, particularly EFSA, in shaping and executing the EU's plant health strategy. In this context, however, it is also important to reflect on the shortcomings of this new enforcement framework and how to make the best use of science.