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The difficult harmonisation of EU policies: insights into the implementation of EU pesticide policy in Italy

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Abstract

The EU pesticide policy is informed by a one-fits-all logic: scientific guidelines as well as procedural norms have been harmonised and centralised at EU level. Yet member states have adopted very different institutional models to contribute to implementation. The paper provides an analysis of the institutional model in place in Italy and advances two main arguments. First, some of the features of the Italian model prevent national experts from fully contributing to EU common procedures; second, because of the harmonised nature of EU pesticide policy, inefficiencies at national level have the potential to directly affect the overall capacity of the EU to achieve policy results. The paper concludes by suggesting some potential directions for the reform of the Italian system.

1. Introduction

Scholars working on multilevel governance (MLG) have observed that the dispersion of policy making across territorial levels can be an effective arrangement for a polity as diverse as the European Union (EU) (Piattoni, 2010). They also observe that the EU strongly endorses this principle by requiring the decentralisation of policy competence in a number of sectors (Newig & Koontz, 2014). The Water Framework Directive, Cohesion policy, and Air Quality Directive are relevant examples in this respect. Notably, a push for a re-scaling of policy competence has been observed in the supranational sector *par excellence*: the Common Agricultural Policy (Garzon, 2006; Greer, 2005). Increasingly, EU policies have been adopted with a built-in specified multilevel governance architecture: provisions require cooperation at vertical and horizontal levels from a variety of institutional, civic and social actors. On a less positive note, scholars also observe that, while desirable in principle, 'it cannot be taken for granted that operational designs based on MLG bring necessarily to the desired improvements in implementation performance' at national level (Domorenok, 2017, p. 667) and point out that a variety of multi-level institutional arrangements with different degrees of efficiency have been adopted across Europe.

This paper builds on these insights from MLG literature on the variety and performance of institutional arrangements for policy implementation to expand the analysis to fully centralised and harmonised EU policies. It takes as a starting point the observation that the trend towards decentralisation is likely predominant but not ubiquitous. A push for centralisation and harmonisation at EU level can also be observed: REACH, food safety and pesticide policy are cases in point. These are areas largely characterised

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by a 'one-fits-all' logic, intended to define common regulatory standards that are valid across all Member States (MSs) and implement them according to uniform procedures. The EU also prescribes a specific governance architecture for these areas, requiring strong convergence in institutional arrangements and procedural norms (Knill, 2005). Yet research shows that harmonised EU policy might be characterised by relevant differences in national institutional arrangements and that, as in decentralised policies, institutional arrangements have different implementation performances (Bozzini, 2017). This paper argues that, unlike in decentralised sectors, in the case of a one-fits-all EU policy, inefficiencies at national level do have *direct* consequences for other MSs and for EU institutions, affecting the overall regulatory regime and its capacity to fully achieve policy results.

To illustrate the argument, the paper provides an in-depth analysis of the model adopted in Italy to deliver EU pesticide policy. Pesticide regulation[1] in particular is a good example in the context of centralised, one-fits-all sectors. To list but a few features included in Regulation (EC) 1107/2009: chemical substances to be employed in the production of pesticides receive a single 'pan-European' approval; the assessments are jointly carried out by authorities from all 28 MSs and the European Food Safety Authority (EFSA) in a common procedure; shared protocols and guidelines prescribe in fine detail how scientific information must be gathered, evaluated, reported, and discussed in hazard and risk assessments. To some extent the allocation of workload across MSs is decided by the European Commission (EC), which also dictates the timing and content of assessments. Regulation 1107/2009 also foresees a specific governance arrangement at national level: each MS must designate a Competent Authority (CA) to contribute 'with one voice' to EU processes at EFSA and the Directorate-General for Health and Food Safety of the EC (DG Sante).

The paper describes the complex institutional arrangement in Italy and discusses the advantages and disadvantages in relation to EU harmonised goals. It argues that some of the institutional features of the Italian system prevent an effective contribution to common regulatory goals and, because of the one-fits-all logic of pesticide policy, have the potential to negatively affect EU procedures and policy results. The argument of the paper is structured as follows. The first section sets the context and illustrates the main defining goals of EU pesticide policy. The second section describes policy outputs and the contribution of Italian authorities to these, providing empirical evidence to show that Italy has had a low degree of involvement in common EU procedures. The third section focuses on Italian institutional arrangements in the sector as the main explanatory factor for the limited input to EU processes. The final section provides some concluding remarks on the potential implications of the Italian institutional model for the overall EU regulatory regime and suggests some directions for reform.[2]

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[2] The empirical base for the analysis was collected in the context of two research projects carried out by the author in the period 2015-2018: 'Law, science and interests in European policy-making' (LASI) funded by the ERC and the evaluation of implementation of Regulation 1107/2009 carried out on behalf of the European Parliament Research Service (Bozzini 2018). The research design involved semi-structured interviews with CAs across 28 MSs, EFSA and EU Commission officials. In addition, an extensive documentary analysis was performed. Specifically, the empirical documentary research for this paper

2. Features of the EU pesticide regulation

In the EU the first common pesticide policy was introduced in 1991 (European Union, 1991) and later reformed in 2009 (European Union, 2009). Since its inception the EU pesticide legislation has had a clear harmonisation character: main goals are to define shared, uniform scientific criteria and common regulatory procedures for the evaluation and approval of active substances that can be put safely in use in all 28 MSs (Bozzini, 2017).[3]

There are strong arguments to favour harmonisation in pesticide policy: to avoid market fragmentation and remove possible obstacles to trade are among the most important ones. Further, it is widely recognised that health and environmental protection goals are best served by the application of a 'one-fits-all' logic (Frank & Ottoboni, 2011). In particular the assessment of the safety of active substances is informed by the principle 'one substance, one assessment' (United Nations, 2017). It means that the inherent properties of a chemical are assessed once at EU level and are valid across all 28 EU MSs. From a toxicological point of view, this approach makes sense because the – let's say – carcinogenicity potential of a substance does not vary according to the national origins of individuals.[4] A similar point can be made for the environmental fate of chemicals or for ecotoxicology: if a substance is persistent in the environment or if it threatens the health of bees, this is because of the intrinsic characteristics of the chemical that do not change depending on the location. Last but not least, shared ethical norms require the minimal use of laboratory animals (Joint Research Centre, 2016), and therefore there is a need to avoid unnecessary repetitions of testing across MSs (Annys et al., 2014; Scholz et al., 2013).

The EU goals proved very ambitious, requiring the assessment of a wide range of hazards and risks according to stringent criteria.[5] As the EC observed 'in many instances, the risk assessment methodologies required for the evaluations did not exist and had to be developed. It was necessary to develop new science, and then to ensure agreement on its application' (European Commission, 2001, p. 4). The criteria for carrying out assessments have been harmonised (Hardy, Bopp, & Egsmose, 2012): over the years EU and national experts have adopted guidelines to establish what laboratory tests need to be taken into consideration for the evaluation of, for example, mutagenicity or genotoxicity, the protocols for their study design as well as quality criteria for the validation of testing (Brooks, Koch, Wathen, & Valley, 2015).[6]

Further, similarly to scientific guidelines, procedural rules have gone through a process of harmonisation (Bozzini, 2018). Regulation (EC) 1107/2009 prescribes that 'in the interest of predictability, efficiency and consistency, a detailed procedure should be laid

includes interviews with five officers at the Ministry of Health and experts based at two certified research centres, an elaboration of data gathered from the EU Pesticide Database and an analysis of dossiers published in the EFSA Register of Pesticide Dossiers.

[3] It goes beyond the scope of this paper, but it is worth mentioning that commercial formulations containing one or more active substances approved at EU level must obtain a second 'zonal' authorization. The entire EU territory is divided into three zones, North, Central and South. Italy is included in the South zone together with Bulgaria, Greece, Spain, France, Cyprus, Malta, Portugal, and Croatia.

[4] Indeed, the UN advocate a global, harmonised system of hazard assessment.

[5] The EU legislation on pesticides is usually considered the most stringent and restrictive one. See (Pelaez, 2013).

[6] For a more informed overview of progress in the harmonisation of scientific guidelines see (Bozzini, 2018). It should be noted that regulators must (try to) keep pace with advances in scientific understandings; therefore, guidelines are always 'in progress' and their adequacy is often a matter of discussion.

down for assessing whether an active substance can be approved' (Regulation (EC) 1107/2009 preamble 12). The assessment of hazards and risks associated with active substances to be used in the production of pesticides is therefore centralised at EFSA, with the fundamental involvement of designated experts from all MSs who are required to contribute to the common EU assessments. Today there are guidelines that regulate all the different steps in the process, like the format of evaluation reports, the timing of procedures, how to organise the expert discussion for the interpretation of results, how to make information available to the general public. All these and other aspects have been painstakingly defined over the years by scientists and regulators at EFSA, DG Sante and MSs.

As mentioned, the procedure relies on the joint cooperation between EFSA and national CAs that are required to take part in common EU procedure. Specifically, the procedure for the assessment of an active substance starts at the national level: a manufacturer who want to market its pesticide in the EU submits an application to the MS of its choice or, if the substance is already on EU markets and its approval must be renewed, to an MS indicated by the EC.[7] The chosen MS becomes the Rapporteur Member State (RMS) for that specific active substance. It works on behalf of EFSA to perform a first evaluation of data and produce a Draft Assessment Report (DAR) on the active substance. This is arguably one of the most demanding tasks for CAs: legal requirements prescribe the analysis of data gathered from over 400 different tests in areas as diverse as chemistry and toxicology (Kaltenhauser, Kneuer, & Marx-Stoelting, 2017), and the DAR can total thousands of pages. The DAR, therefore, is resource-intensive: it entails the involvement of experts from different scientific backgrounds and specifically trained on regulatory issues.[8] Further, according to Regulation (EC) 1107/2009, the DAR must be finalised by national CAs within a specified time-limit: 12 months, possibly extended to 18 if additional data are needed to further clarify the risk profile of the chemical under evaluation. The existence of precise time limits is an extremely important point: deadlines make the procedure predictable to interested manufacturers as well as to other CAs who need to plan their activities in advance. Indeed, after this first evaluation on the part of one MS, the DAR, as well as the raw data, are made available to EFSA and to the other 27 CAs, who are required to step in and contribute to the assessment.

This second stage in the evaluation takes place at EFSA, which organises the so-called 'peer-review procedure' on the dossier. In this context, the peers who are required to review the DAR are mainly experts from the other CAs.[9] They have two months to read and send comments to the various part of the assessment report, according to a specified format, to double check the interpretation of evidence advanced by the RMS and assess the preliminary conclusions on the hazards and risks associated with the substance under discussion. In a third stage all the comments are subsequently discussed in common meetings at EFSA in Parma. The discussion between experts from 28 MSs and EFSA must be finalised within four months and terminate with the delivery of the document

[7] Approvals of active substances are temporary. After 10 years, manufacturers must submit a request for renewal updating the existing dossier. See Regulation (EC) 844/2012.

[8] Space limitations prevent a discussion on this important point. Suffice to note that one thing is to have expertise in toxicology, another is being knowledgeable in the EU version of regulatory toxicology.

[9] A so-called 'sanitized' version of the dossier – clear of confidential information relevant to patent rights – is made available to external experts, stakeholders and the general public for comment. As might be expected, public participation is de facto non-existent on these highly technical dossiers.

reporting EFSA conclusions on the active substance. The publication of the 'EFSA conclusion' is the final act in the scientific assessment of risks associated with a specific chemical and reflects the shared expert opinion as developed in the context of the EU procedure.[10] Finally, it is important to note that to ensure transparency and traceability, all documents relative to an active substance are subsequently made available to the public in the EFSA Register of Questions and in the EU Pesticide Database run by DG Sante.[11] The latter represents the unique, pan-EU list of approved active substances which, as mentioned above, has always been the ultimate policy output in the context of pesticide regulation. At the time of writing (January 2019) the EU Pesticide Database collects the scientific and legal documents published over the years on the safety of around 1400 chemicals. Of these, 490 have been considered safe and are therefore included in the list of active substances approved for use; those remaining are banned from the EU pesticide market.

To sum up, strong efforts have been sustained over the years to achieve ambitious policy goals in terms of harmonisation and in so doing, ensure timely, transparent and scientifically accurate assessments.[12] Harmonisation requires the contribution of all MSs to joint evaluation processes carried out according to common rules and procedures as well as specific deadlines. The next section illustrates to what extent the Italian authorities have contributed to such policy efforts.

3. The Italian involvement towards common policy outputs in EU pesticide regulation

As noted in the preceding section, the most relevant – and demanding – tasks for national CAs in the implementation of EU pesticide legislation are the delivery of the DARs and participation in EFSA peer-review processes. In this section I illustrate the involvement of Italian authorities in these two tasks.

To start with, it is important to stress that MSs have, as might be expected, different interest in the pesticide sector. This is evident if we consider that not all 490 approved active substances are in use in all EU countries. MSs have different agronomic and climatic conditions as well as agricultural productions and are therefore differentiated in terms of their crop protection needs. **Error! Reference source not found.** shows in the second column the number of active substances in use in each of the 28 MSs, to provide evidence of the variation in terms of range of pesticides needed in each EU country. Of interest in the context of this paper is the fact that Italy, with 335 different chemicals in use, is first in this specific ranking. The high number of pesticides required by Italian farmers reflects the highly diversified agricultural production of the country, as well as its peculiar climatic conditions that make crops highly vulnerable to, for example,

[10] The EFSA conclusions are then sent to DG Sante, and findings are discussed in the context of the comitology committee SCoPAFF. A final decision on risk management is taken by a qualified majority and adopted in the form of an Implementing Regulation.

[11] See the document available online: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

[12] The effective capacity of the EU regulatory system to meet its ambition is a matter of debate. See (European Parliament Research Service, 2018; Scientific Advice Mechanism, 2018).

bacteria and fungi. In short, Italy has a strong interest in the EU pesticide regulation and the importance of this sector for the country cannot be underestimated.

Table 1. Number of active substances in use, number of dossiers processed by each EU country, and the ratio between these two measures.

Country	Number of active substances[a]	Total number of dossiers[a]	Ratio
UK	275	152	1.8
SE	142	61	2.3
AT	266	103	2.6
DE	265	98	2.7
NL	266	98	2.7
FR	317	115	2.8
ES	304	70	4.3
IT	335	74	4.5
BE	287	57	5.0
EL	287	57	5.0
FI	148	29	5.1
IE	215	42	5.1
DK	153	26	5.9
PL	257	33	7.8
HU	266	25	10.6
CZ	261	22	11.9
PT	254	18	14.1
EE	149	9	16.6
LV	149	9	16.6
SI	204	10	20.4
SK	221	7	31.6
HR	197	4	49.3
BG	204	4	51.0
LT	162	2	81.0
RO	224	1	224.0
CY	189	0	
LU	219	0	
MT	54	0	
Total		**1126**	

[a] Source: Own elaboration from EU Pesticide Database

The third column of Table 1 provides information on the division of workload among CAs, in terms of the number of DARs delivered. Data show that out of a total of 1126 dossiers processed, Italy has been in charge of 74. The fourth column of the table synthetizes the data between national demands for pesticides and level of involvement in the regulatory effort. Specifically, the table reports the ratio between the number of active substances in use in a country and the number of dossiers processed by that same country. Data show that the ratio for Italy is 4.5, meaning that for each dossier delivered, Italian authorities 'receive' 4.5 in return. In other words, without the common EU regime Italian authorities would have to process 4.5 more dossiers to have the same number of 335 authorised chemicals in the country as they have today. In this sense the

ratio provides an indication of the added value of the EU regulatory regimes for each MSs: the higher the ratio, the greater the advantage for the country. This means that in relation to the national demand for active substances, Italy commits itself to a low number of evaluations.

In terms of participation in EFSA peer-review procedures, data show that the contribution of the Italian CA is extremely limited. The analysis of documents relative to the 49 procedures finalised at EFSA in 2016 and 2017 reveals that Italy wrote comments on two substances only: one for which it was RMS and one for which it acted as co-RMS, meaning that it cooperated with the official RMS in the drafting of the DAR.[13] On all other occasions the Italian authority sent no written contributions to comment on draft evaluations. This represents a serious limit, since – as noted – the peer-review procedure at EFSA is essential to achieve a shared, consistent assessment of the hazards poses by a chemical.

It seems safe to argue that Italy has had an overall low level of involvement in common EU pesticide regulation: it takes advantage of the input of other MSs in a significant measure while it provides a partial contribution, both in terms of DARs and participation in EFSA processes.

This paper suggests that Italy's low performance in contributing to the common pesticide regulatory effort is due to the features of the institutional model in place in the country, as illustrated in the next section.

4. The Italian institutional model

Article 75 of Regulation (EC) 1107/2009 establishes that each MS must designate a CA to deal with the obligations laid down by the legislation in terms of approvals of active substances and authorization of PPPs. All MSs are obliged to observe this requirement, and it is therefore possible to identify who is responsible for the implementation of Regulation (EC) 1107/2009 in each of the 28 EU countries plus Norway. Each country can adopt its own institutional arrangements and previous research indicates that there is significant variation between MSs in this respect (Bozzini, 2018).

As far as Italy is concerned, it adopts an institutional model that foresees the cooperation between a governmental body and external research institutes and universities. Assessments are outsourced to research centres which are in charge of evaluations of part of the dossier according to their competence. This means that the system is based on a vast network of institutional and research actors that have to coordinate to deliver pesticide policy.

To start with the governmental body, the institution officially identified as CA for the country is an administrative structure established in the context of the Ministry of Health and more specifically within the 'Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e della Nutrizione' (DgSan). DgSan is therefore formally responsible for pesticide policy. More specifically, the 'Ufficio 7' within DgSan deals with all matters related to plant protection products, having responsibility for all EU legislation that covers the entire 'pesticide chain', from authorizations to factories, to market authorizations

[13] Italy was RMS for the active substance Linuron, a herbicide. It was co-RMS for Iprovalicarb, a fungicide.

and labelling, to controls of residues on food. Officials from Ufficio 7 also participate in comitology procedures in Brussels.

As far as the scientific assessment of active substances is concerned, it is of note that officials at Ufficio 7 mainly guarantee administrative support and do not deal with the merits of evaluations, which are outsourced to certified research institutes. Specifically, eleven different centres and/or universities replied to a public procedure last launched by DgSan in 2014 and have been selected to provide scientific advice and perform evaluation on behalf of the Italian CA.[14] Centres meet a wide range of requirements; in particular they must possess expertise in all the disciplines included in the EU assessment of pesticides (chemistry, toxicology, ecotoxicology, endocrinology, environmental fate, etc.) as well as being familiar with EU regulatory guidelines and procedures.

Every year the centres sign a financial agreement, 'Convenzione', with DgSan and when an application is delivered to Italy, Ufficio 7 allocates it to one of the centres.

The allocation of dossiers depends on the availability and competence of the selected centres. For example, the Scuola Superiore Sant'Anna and the Fondazione Mach have specific expertise on biopesticides, while the others are generally in charge of the assessment of conventional chemicals. There is no official information available on the allocation of dossiers; as a consequence, it is not possible to track with certainty the process for each active substance and reconstruct 'who did what'. According to interviewees, most evaluations are carried out by the University of Milan, ICPS and ISS. Further on this point, it is of note that research centres can also decide not to carry out the evaluation in-house but, for example, to recruit ad-hoc external personnel to perform these tasks. Finally, it is important to note that DgSan allocates to external centres only dossiers for which Italy is RMS and for which it receives a fee from manufacturers, while there are no procedures in place (or resources) to identify experts who can contribute to EFSA peer-review processes.

Once the centre has the DAR ready, it is sent to the 'Commissione Consultiva Prodotti Fitosanitari' (CCPF). The CCPF is one of the five sub-committees dealing with food safety and was created in its current form in 2013.[15] It comprises representatives from four different ministries that have a policy interest in the authorization of pesticides: Health, Environment, Agriculture and Economic Development. Members are both public servants employed at the Ministries and experts appointed by each Ministry, for a total of 32. The CCPF has a wide variety of different functions, reflecting the complexity of tasks related to pesticide policy. It is of interest here to note that it should review assessment reports delivered by external centres to double-check conclusions. However, there are no indications of the CCPF's systematic involvement on this front. First, it might be noted that internal procedural rules at DgSan prescribe very tight deadlines for this particular task: CCPF members have 10 days to submit comments on the

[14] The list was revised and confirmed in 2018. It includes: Istituto zooprofilattico sperimentale della Lombardia ed Emilia Romagna; Centro internazionale per gli antiparassitari e la prevenzione sanitaria (ICPS); Università Cattolica Sacro Cuore di Piacenza; ARPA Emilia Romagna; Istituto Superiore di Sanità (ISS); Scuola Superiore Sant'Anna; Fondazione Mach; Dipartimento di Scienze farmacologiche e biomolecolari dell'Università di Milano; Istituto zooprofilattico sperimentale del Lazio e Toscana; Università di Milano Bicocca; Istituto zooprofilattico sperimentale dell'Abruzzo e del Molise 'G. Caporale'.
[15] DPR 28 March 2013, n. 44, 'Regolamento recante il riordino degli organi collegiali ed altri organismi operanti presso il Ministero della salute, ai sensi dell'articolo 2, comma 4, della legge 4 novembre 2010, n. 183'.

draft assessment which, as noted, includes the analysis of hundreds of laboratory tests. Second, the remit of the CCPF is very broad and includes urgent tasks like the management of emergencies resulting from pest outbreaks.[16] As a result, CCPF mainly focuses on 'national' issues, leaving EU procedures at the margin.

5. Discussion and conclusion

The data illustrated in the preceding sections suggest two main considerations with regard to Italy. First, the regulation of pesticides is of relevant national interest for a country with strong and variegated agricultural production and where the use of pesticides is among the highest in Europe in terms of number of active substances needed by farmers. Second, the involvement of Italian authorities in EU assessments, measured in terms of number of dossiers and contributions to EFSA procedures, is significantly limited. My argument is that the reason for Italy's low involvement is to be found in the peculiar institutional arrangement for the delivery of assessments that prevents a greater contribution of the Italian CA to EU procedures.

The implications of this argument are that the Italian institutional arrangement presents relevant shortcomings that have an impact beyond the domestic arena; because of the one-fits-all logic of pesticide policy that requires common procedures as well as deadlines, such shortcomings have the potential to affect the workings of the EU system. In fact, Italy delivers dossiers on behalf of the entire EU. If Italy has an opaque procedure and does not send contributions to the EFSA peer-review procedure, this works to the detriment of the entire EU process of evaluation. This concluding section points out some of the most relevant consequences for the overall policy goals in the sector, focusing on the transparency, timing and consistency of EU evaluation procedures.

As noted, in Italy there is a fundamental lack of transparency in the pesticide system, since it is not possible to identify with precision who has performed the scientific assessment of a specific active substance. It might be argued that this lack of transparency on actual assessors is not an issue, since the final responsibility for the content of the DAR lies with the Ministry of Health which is formally accountable as CA for the country. However, two considerations emerge. First, lack of information on who is in charge of evaluations discourages manufacturers to apply to Italy, since this increases the overall uncertainty of a process that, as noted above, is very demanding and time consuming. Second, it should be noted that transparency and traceability are fundamental principles for EFSA. The EU authority publishes in the dedicated 'Register of Questions' the working material on each active substance, to make it possible for external interested parties to trace the entire process and the role of each actor in it, including minority opinions on specific aspects of the evaluations. In this sense, the opacity that characterises Italian assessment negatively affects the level of publicity sought at EU level.

The need for a public procedure to allocate the drafting of assessment reports is time-consuming and might have the effect of slowing down the substantial evaluation. Delays in the delivery of DARs to EFSA and to other CAs are not uncommon, and by no means limited to Italy. However, it is relevant to note that delays on the part of one MS

[16] The most dramatic and known emergency is that of xylella in Apulia. However, in Italy there are dozens of smaller, less damaging outbreaks that need emergency legislation. See http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1110&area=fitosanitari&menu=autorizzazioni.

affect the entire EU regulatory regime because the smooth implementation of a one-fits-all pesticide policy requires the careful planning of activities at the national level. In particular, national CAs have to schedule well in advance their assignments in EFSA written peer-review procedures that involve reading and commenting on DARs from other countries. Delays 'disrupt' such planning and therefore result in inefficiencies at EU level.

The Italian system also discourages the participation of Italian authorities in the EFSA written peer-review procedure which, as noted above, is one of the most crucial processes to achieve a EU-wide validation of scientific assessment. Ufficio 7 firstly allocates to external centres dossiers for which Italy is the RMS, but there is no identification of experts in charge of the review of DARs that are delivered by other countries. As a result, the Italian CA intervenes on a very limited number of active substances under discussion at EFSA. This holds back the valuable contribution of Italian experts to the common EU evaluations and potentially negatively affects the consistency and the strength of the EFSA procedures that rely on inputs from, ideally, all MSs to properly assure multidisciplinarity and pluralism.

Italian officers understandably tend to defend the system in place. Yet the analysis presented in this paper suggests that Italy is performing at a level lower than should be expected based on the relevance of the pesticide sector and the range of expertise possessed by the country. The analysis also reveals that improvements are possible, and that institutional reforms could be useful to achieve a better implementation performance. In this regard, it seems safe to argue that some of the shortcomings in the system could be easily solved. In particular, the lack of transparency and the low participation in EU procedures could be addressed in a relatively straightforward way, without substantial institutional reforms. The mandatory publication of information on risk assessors would allow stakeholders and interested parties to trace procedures. A specific provision to systematically identify experts who could participate in EFSA procedures could also be decided at DgSan. A more radical innovation could be the creation of an independent regulatory agency to conduct evaluations in-house. This could be an important – albeit expensive – improvement in the risk assessment of pesticides and more broadly in evaluations in 'cognate' sectors like biocides, cosmetics, and all the chemicals under REACH.

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