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Management of links of interest in European Union expertise authorities dealing with plant protection products: comparative analysis and recommendations

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Abstract

Background To ensure a high level of public health and environmental protection, authorities that deliver scientific expertise to inform decision-makers and the public at large need to be independent from external stakeholders and free of conflicts of interest. This independence requires effective rules for managing links of interest (LoIs) and a high level of transparency, including publication of declarations of interest (DoIs) where appropriate. In the particular case of plant protection products (PPPs) within the European Union, these requirements should apply to all Competent Authorities contributing to the marketing authorization processes.

Methods A comparative analysis of LoIs management procedures was performed on a selection of ten National Competent Authorities from different member states (NCAs). This analysis was based on (i) the identification of 17 criteria aiming at characterizing good practices for LoIs management; (ii) a survey of ten NCAs, based on an analysis of their institutional websites and their responses to official mail requests.

Results The comparative analysis showed: (i) a frequent lack of transparency of NCAs regarding their procedures for managing LoIs; (ii) a significant heterogeneity between the NCAs' LoIs management rules, even though they are in charge of comparable missions regarding the marketing of PPPs; (iii) substantial gaps between the LoIs management procedures adopted by several NCAs and the good practices that are promoted by EFSA.

Current limits on their practices regarding LoIs management might open ways for undue external influences on scientific expertise, and ultimately impact negatively the risk management options adopted by national or European authorities. Limitations of this study and its extension for a more thorough overview of the current LoIs management practices are also discussed.

Conclusions LoIs management and transparency rules need to be improved across NCAs, given their contribution as (co-)rapporteurs or peer reviews participants to the health and environmental risk assessment steps of the EFSA processes. To this end, a common minimum set of rules should be defined by EFSA; recommendations are proposed, based on the best practices implemented by the investigated NCAs. Such progress would contribute promoting high-quality unbiased scientific expertise and enhance EU citizens' trust.

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Keywords Links of interest, Declaration of interest, Conflicts of interest, Safety agencies, Code of conduct, Independence, Risk management, Risk assessment, Pesticides, Plant protection products

Background

Over the last decades, the influence of corporate interests on environmental and public health regulations has attracted growing concern and public attention. Scientists, public authorities and NGOs have stressed the need to limit the influence of corporations on scientific expertise [1], especially multinational companies marketing products that are potentially toxic to health and the environment. A growing body of work describes the many forms the influence strategies of those external stakeholders can take (e.g., hiding scientific results, creating artificial scientific debates, promoting alternative research fields) and provides theoretical concepts to analyze this influence, e.g., doubt manufacturing [2–5], ghostwriting [6, 7], regulatory capture [8, 9], revolving door processes [10–12], production of ignorance [13, 14], undone science [15, 16], or funding bias [17–23]. Problematic corporate influence has been described in various sectors, including, among others, tobacco [24–26], chemicals [27–30], climate change [3, 4], nutrition [19, 31, 32], asbestos [4, 33], and pesticides [11, 34–37].

In response to these concerns, and to ensure a high level of public health and environmental protection, authorities that deliver scientific expertise to inform decision-makers and the public at large have adopted procedures that are supposed to guarantee their independence. Most importantly, regulatory agencies have promoted procedures aiming at identifying and managing the links of interests (LoIs) of the actors involved in the expertise processes, in particular procedures for disclosing the financial relationships between experts and industries, in order to prevent conflicts of interest. In the European Union (EU), within several public agencies, the application of rules for the management of LoIs (also simply called "interests") is one of the means used to promote impartiality and, in particular, to reduce the risks of corporate influence. This promotion of LoIs management procedures has been directly linked to that of transparency [38]. Indeed, from the 1990s onward, a movement advocating for more transparency in scientific and public life has been growing in close connection with the rise of the European regulatory agencies system. This movement promotes both expanded access to data of public interest and the unveiling of non-public relationships of officials or experts with private interests (e.g., in the form of disclosure policies).

This article explores how several national expertise agencies take into account the issue of links of interest and the requirement of transparency, based on a particularly controversial case, that of the regulation of plant protection products (PPPs). It analyzes the procedures put in place by a selection of EU expertise agencies involved in the evaluation of active substances and PPPs within the EU, and the accessibility of information on these procedures. A large number of regulations, the main ones being Directive 2009/128/EC and Regulation (EC) 1107/2009, covers the delivery of marketing authorizations (MAs) for PPPs. The regulatory framework determines that the active substances of PPPs be subject to a centralized approval procedure at the EU level. Along this procedure, the European Food Safety Authority (EFSA) delivers scientific opinions to help the European Commission decide whether to approve (or renew) active substances or not. EFSA's opinion is based on scientific evaluation reports prepared by National Competent Authorities of different member states (NCAs), appointed as rapporteurs. Subsequently, the commercial formulations containing the active substances approved at EU level are subject to a national authorization procedure, which is also based on NCAs scientific evaluations.

Thus, EFSA's scientific expertise plays a central role in PPPs regulation. Today, aiming at "*building and maintaining trust*" in its independence, EFSA set the objective of ensuring "*a high level of transparency across all its activities, [including] independence-related processes*" [39]. It presents transparency as a "*key value*" [40] and claims that "*openness and transparency of the EU risk assessment process in the food chain contributes to greater legitimacy of the Authority in pursuit of its mission, strengthens confidence in the Authority's work and, ultimately, ensures its democratic accountability vis-à-vis consumers, business operators and the public*" [41]. EFSA also promotes a good LoIs management as a way to improve the reliability of its work. In 2018, following numerous criticisms regarding its LoIs management policy by the European Parliament [42, 43], by the European Court of Auditors [44], and by Non-Governmental Organizations [10, 45], EFSA updated its rules regarding competing interest management [46]. NCAs also play a central role in PPPs regulation. Indeed, as pointed out above, EFSA's expertise is largely based on their contributions—acting either as *Rapporteur states* for active substances or during the *Peer review* process. This raises the question of the rules NCAs adopt in terms of LoIs management and transparency, and of their consistency with EFSA guidelines.

The research presented in this article was conducted in response to preliminary findings by the French Commission for Deontology and Alerts in Public Health and the Environment (*Commission nationale de la déontologie et des alertes en matière de santé publique et d'environnement*—cnDAspe). The cnDAspe took the initiative, under its legal missions (see Additional file 1), to investigate the expertise process leading to the delivery of MAs for PPPs within the EU. It identified substantial differences between NCAs and gaps compared to EFSA's good practices [46]. It issued an opinion stating that, in order to create a context that promotes unbiased expertise in support to EFSA, and in view to enhance European citizens' trust, LoIs management rules should be (i) harmonized across the contributing NCAs, especially with regard to transparency; and (ii) in line with the best available standards [47]. To contribute to this public interest objective, members of the cnDAspe and the first author of this article have undertaken a more extensive comparative analysis of the rules applied among a variety of EU NCAs for PPPs assessment regarding LoIs management. To our knowledge, this type of comparative analysis has not yet been performed to date. Its objectives are: (i) to draw the attention of experts, Authorities, and European elected representatives to the current state of LoIs management in the NCAs supporting EFSA's remit; (ii) to identify the best practices currently implemented by the investigated NCAs; (iii) to propose a set of minimum common rules, to which EFSA could require the NCAs to commit. These rules would include public access requirements on the NCAs websites, in a transparent manner.

Materials and methods

Seventeen criteria were selected to characterize key LoIs management practices, and were classified into three categories (Tables 1, 2, 3): (1) *Organization of the LoIs management*: these criteria describe the organization implemented within the investigated NCAs, with regard to LoIs; (2) *Accessibility*: these criteria describe how accessible are the different components of the LoIs management systems, e.g., DoIs, lists of committee members; and (3) *LoIs assessment*: these criteria describe how LoIs are evaluated, e.g., intensity graduation, duration of the past periods covered by the DoI. The criteria selection is based on (i) rules now in effect at EFSA [46]; (ii) good practices observed in certain NCAs; and (iii) proposals from members of the cnDAspe. These criteria will be considered as good reference practices in the remainder of this paper.

Additional file 2 describes the selected criteria in detail. The file presents these criteria in a non-hierarchical way. Yet, it is clear that certain criteria are essential and are minimum prerequisites for LoIs management and transparency. For example, the existence of disclosure policies and the verification of DoIs are essential. Easy and free access to DoIs by the public can also be considered as a minimum requirement for transparency.

Ten NCAs were selected (Table 4) so as to (i) obtain a diverse sample of member states, taking into account the EU regulatory zonal system of authorization for PPPs, divided into three zones: North, Central and South [48]; (ii) include the NCAs that co-produced the draft renewal assessment report for glyphosate, as part of the 2021 renewal regulatory process, because the glyphosate risk assessments have been overtly criticized, especially with regard to potential conflict of interests (CoI) issues [34–36].

In addition, EFSA and the European Chemicals Agency (ECHA) were also examined, as European-level Competent Authorities, to provide an indicative benchmark (Additional file 2).

For each NCA investigated, the selected criteria were filled in (i) on the basis of the information available on the NCA institutional website, collected with a systematic method including searching predefined keywords with the NCA website search engine (see Additional file 2). The free online translation tool Google Translate was used where necessary; (ii) distinguishing between three types of individuals ('actors' of the expertise processes): external experts (EE), internal experts (IE), and management officers (MO).

Then, each NCA was sent the retrieved results specific to the information available on its website, with an official letter from the cnDAspe (Additional file 1), requesting the NCA to (i) provide relevant information not found online, if deemed appropriate; (ii) correct possible misunderstandings and inaccuracies. The cnDAspe letter specified a time limit of one month before publication of the results online [47]. The corrections made were traced, noting whether they were justified by a NCA internal document sent to the cnDAspe, or only by a formal letter signed by an authoritative person within the investigated NCA (Additional file 2).

Results

For the ten selected NCAs, the retrieved information is detailed in Tables 1, 2, 3 (for ECHA and EFSA, see Additional file 2). The overall data collection was carried out between February and December 2022; the collection period specific to each NCA is mentioned with each set of results.

EFSA and five NCAs replied to the cnDAspe letter: Anses (France), BfR (Germany), Ctgb (Netherlands), KEMI (Sweden), and Nébih (Hungary). None of these NCAs called into question the approach and the method used by the cnDAspe. Needs for corrections or additions

Table 1 Comparative analysis for the 'Organization of the LoIs management' criteria category

Selected criteria for assessing the management of links of interest\ Competent Authorities		Actors	Center zone					North zone		South zone		
			Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
			BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)			**05/2022**	**03–04/2022**	**09/2022**	**04–05/2022**	**10/2022**	**04/2022**	**08/2022**	**03/2022**	**11/2022**	**12/2022**
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt			**Yes, 29/06/2022**	**Yes, 29/06/2022**	**No**	**Yes, 24/06/2022**	**No**	**Yes, 20/06/2022**	**No**	**Yes, 22/06/2022**	**No**	**No**
1	Obligation to complete a DoI prior to recruitment (YES/NO)	EE	YES	YES	nf	nf	nf	nf	nc	YES	YES	nf
		IE	nf	YES	nf	nf	nf	nf	nf	YES	YES	nf
		MO	nf	YES	nf	nf	nf	nf	nf	YES	YES	nf
2	Minimum frequency requirement to update DoI (/year)	EE	nf	1	nf	nf	nf	nf	nc	1	nf	nf
		IE	nf	1	nf	-	nf	nf	nf	1	nf	nf
		MO	nf	1	nf	-	nf	nf	nf	1	nf	nf
3	Requirement to update DoI in case of significant change (YES/NO) If so, associated deadline (months)	EE	YES: -	YES: -	nf	nf	nf	nf	nc	YES: -	0,5	nf
		IE	nf	YES: -	nf	YES	nf	nf	nf	YES: -	0,5	nf
		MO	nf	YES: -	nf	YES	nf	nf	nf	YES: -	0,5	nf
4	Structure in charge of DoI analysis — Independent external entity (YES/NO)	EE	nf	NO	nf	nf	nf	nf	nc	NO	NO	nf
		IE	nf	NO	nf	nf	nf	nf	nf	NO	NO	nf
		MO	nf	nf	nf	nf	nf	nf	nf	NO	NO	nf
	Internal entity + stakeholders (YES/NO)	EE	YES	NO	nf	nf	nf	nf	nc	NO	NO	nf
		IE	nf	NO	nf	nf	nf	nf	nf	NO	NO	nf
		MO	nf	nf	nf	nf	nf	nf	nf	NO	NO	nf
	Internal entity (YES/NO)	EE	nf	YES	nf	nf	nf	nf	nc	YES	YES	nf
		IE	nf	YES	nf	nf	nf	nf	nf	YES	YES	nf
		MO	nf	nf	nf	nf	nf	nf	nf	YES	YES	nf

Table 1 (continued)

Selected criteria for assessing the management of links of interest\ Competent Authorities		Actors	Center zone					North zone		South zone		
			Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
			BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)			05/2022	03–04/2022	09/2022	04–05/2022	10/2022	04/2022	08/2022	03/2022	11/2022	12/2022
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt			Yes, 29/06/2022	Yes, 29/06/2022	No	Yes, 24/06/2022	No	Yes, 20/06/2022	No	Yes, 22/06/2022	No	No
5	Check on the accuracy of the DoIs contents	Exhaustive (YES/NO) EE	nf	NO	nf	nf	nf	nf	nc	YES	nf	nf
		IE	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf
		MO	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf
		By sampling (YES/NO) EE	nf	NO	nf	nf	nf	nf	nc	YES	nf	nf
		IE	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf
		MO	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf
		Minimum frequency (/year) EE	nf	NO	nf	nf	nf	nf	nc	1	nf	nf
		IE	nf	NO	nf	nf	nf	nf	nf	1	nf	nf
		MO	nf	NO	nf	nf	nf	nf	nf	1	nf	nf
6	How long is the DoI archived (years)		nf	nf	nf	*50*	nf	nf	nf	10	nf	nf

Table 1 (continued)

Selected criteria for assessing the management of links of interest\ Competent Authorities		Actors	Center zone					North zone		South zone		
			Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
			BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)			05/2022	03–04/2022	09/2022	04–05/2022	10/2022	04/2022	08/2022	03/2022	11/2022	12/2022
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt			Yes, 29/06/2022	Yes, 29/06/2022	No	Yes, 24/06/2022	No	Yes, 20/06/2022	No	Yes, 22/06/2022	No	No
7	Obligations of experts and personnel before a new activity (consultant, other employer, advocating NGO…)	Prior agreement (YES/NO) EE	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
		IE	nf	YES	nf	nf	nf	nf	nf	YES	nf	nf
		MO	nf	YES	nf	nf	nf	nf	nf	YES	nf	nf
		Prior information (YES/NO) EE	nf	YES	nf	nf	nf	nf	nc	NO	nf	nf
		IE	nf	YES	nf	nf	nf	nf	nf	YES	nf	nf
		MO	nf	YES	nf	nf	nf	nf	nf	YES	nf	nf
		Duration of the period during which the new duties must be notified and publicly available online (years) EE	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
		IE	nf	NO	nf	nf	nf	nf	nf	NO	nf	nf
		MO	nf	NO	nf	nf	nf	nf	nf	NO	nf	nf
8	Minimum period before a new activity with a "major" interest can be accepted (years)	EE	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
		IE	nf	nf	nf	nf	nf	nf	nf	3	3	nf
		MO	nf	NO	nf	nf	nf	nf	nf	3	3	nf

Table 1 (continued)

Selected criteria for assessing the management of links of interest\ Competent Authorities		Actors	Center zone					North zone		South zone		
			Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
			BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)			**05/2022**	**03–04/2022**	**09/2022**	**04–05/2022**	**10/2022**	**04/2022**	**08/2022**	**03/2022**	**11/2022**	**12/2022**
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt			**Yes, 29/06/2022**	**Yes, 29/06/2022**	**No**	**Yes, 24/06/2022**	**No**	**Yes, 20/06/2022**	**No**	**Yes, 22/06/2022**	**No**	**No**
9	Regular audit of the implementation of the rules for managing links of interest	Via independent external entity (YES/NO)	nf	YES	nf	nf	nf	nf	nf	NO	YES	nf
		Via internal entity + stakeholders (YES/NO)	nf	NO	nf	nf	nf	nf	nf	NO	NO	nf
		Via internal entity (YES/NO)	nf	NO	nf	nf	nf	nf	nf	YES	NO	nf
		Minimum frequency (YES/NO)	nf	5	nf	nf	nf	nf	nf	1	1	nf

Table 2 Comparative analysis for the *'Accessibility' criteria category*

Selected criteria for assessing the management of links of interest \ Competent Authorities			Actors	Center zone					North zone		South zone		
				Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
				BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)				05/2022	03–04/2022	09/2022	04–05/2022	10/2022	04/2022	08/2022	03/2022	11/2022	12/2022
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt				Yes, 29/06/2022	Yes, 29/06/2022	No	Yes, 24/06/2022	No	Yes, 20/06/2022	No	Yes, 22/06/2022	No	No
10	Internet publicity of the DoI form (yes/no)			YES	YES	NO	NO	NO	NO	NO	YES	YES	NO
11	Accessibility of the criteria for analyzing links of interest	Open access on the Internet (YES/NO)		NO	NO	NO	NO	NO	NO	NO	YES	NO	nf
		On request (YES/NO)		nf	nf	nf	nf	nf	nf	nf	NO	nf	nf
12	Accessibility of experts' and staff's DoI	Open access on the Internet (YES/NO)	EE	YES	NO	nf	nf	nf	NO	nc	YES	YES	nf
			IE	NO	NO	NO	NO	NO	NO	NO	YES	nf	nf
			MO	NO	YES	NO	NO	NO	NO	NO	YES	nf	NO
		On request (YES/NO)	EE	nf	nf	nf	nf	nf	nf	nc	NO	NO	nf
			IE	nf	nf	nf	nf	nf	nf	nf	NO	nf	nf
			MO	nf	nf	nf	nf	nf	nf	nf	NO	nf	Nf
13	Accessibility of the DoI of the members of the entity in charge of analyzing experts' and staff's DoI	Open access on the Internet (YES/NO)	EE	NO	YES	nf	nf	nf	NO	nc	YES	nf	Nf
			IE	NO	YES	NO	NO	NO	NO	NO	YES	nf	Nf
			MO	NO	nf	NO	NO	NO	NO	NO	YES	nf	Nf
		On request (YES/NO)	EE	nf	NO	nf	nf	nf	nf	nc	NO	nf	Nf
			IE	nf	NO	nf	nf	nf	nf	nf	NO	nf	Nf
			MO	nf	nf	nf	nf	nf	nf	nf	NO	nf	Nf

Table 2 (continued)

Selected criteria for assessing the management of links of interest \ Competent Authorities		Actors	Center zone					North zone		South zone		
			Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
			BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)			05/2022	03–04/2022	09/2022	04–05/2022	10/2022	04/2022	08/2022	03/2022	11/2022	12/2022
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt			Yes, 29/06/2022	Yes, 29/06/2022	No	Yes, 24/06/2022	No	Yes, 20/06/2022	No	Yes, 22/06/2022	No	No
14	Accessibility of the list of members for all expert committees and governance bodies	Open access on the Internet (YES/NO)	YES	nf	nf	nf	nf	nf	nf	YES	YES	nf
		On request (YES/NO)	NO	nf	nf	nf	nf	nf	nf	NO	NO	nf

Table 3 Comparative analysis for the 'LoIs assessment' criteria category

Selected criteria for assessing the management of links of interest \ Competent Authorities	Actors	Center zone					North zone		South zone		
		Germany	Netherlands	Poland	Hungary	Czech Republic	Sweden	Finland	France	Italy	Bulgaria
		BfR	Ctgb	Ministry of Agriculture	Nébih	ÚKZÚZ (CISTA)	KEMI	Tukes	Anses	Ministero della Salute	БАБХ (BFSA)
Period of consultation of the authority's website (month/year)		**05/2022**	**03–04/2022**	**09/2022**	**04–05/2022**	**10/2022**	**04/2022**	**08/2022**	**03/2022**	**11/2022**	**12/2022**
Receipt by the cnDAspe of a response letter (yes/no) and date of receipt		**Yes, 29/06/2022**	**Yes, 29/06/2022**	**No**	**Yes, 24/06/2022**	**No**	**Yes, 24/06/2022**	**No**	**Yes, 22/06/2022**	**No**	**No**
15 Duration of past period covered by the DoI (years)		nf	5	nf	nf	nf	nf	nf	5	3	nf
16 Duration of the past period taken into account for the analysis of LI (years)		nf	5	nf	nf	nf	nf	nf	5	3	nf
17 Management of LI differentiated according to the intensity of LI (YES/NO)	EE	nf	NO	nf	nf	nf	nf	nc	YES	nf	nf
	IE	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf
	MO	nf	NO	nf	nf	nf	nf	nf	YES	nf	nf

DoI(s) Declaration(s) of Interest, *LoI(s)* Link(s) of Interest, *nf* not found (using our systematic collection method), *nc* not concerned, e.g., Authorities not requesting any external expert, in any evaluation, any expertise, any committee, any scientific council or equivalent, etc. *EE* external expert, *IE* internal expert, *MO* management officer; numbers: see the specific description of each criterion in the left column of the tables

Table 4 Investigated competent authorities

Regulatory Zone	Authority		Country	Acronym
	National language	English		
North ($n=2$)	Kemikalieinspektionen	Swedish Chemicals Agency	Sweden	KEMI
	Turvallisuus- ja kemikaalivirasto	Finnish Safety and Chemicals Agency	Finland	Tukes
Center ($n=5$)	Bundesinstitut für Risikobewertung	German Federal Institute for Risk Assessment	Germany	Bfr
	College voor de toelating van gewasbeschermingsmiddelen en biociden	Dutch Board for the Authorisation of Plant Protection Products and Biocides	Netherlands	Ctgb
	Ministerstwo Rolnictwa i Rozwoju Wsi	Ministry of Agriculture and Rural Development	Poland	-
	Nemzeti Élelmiszerlánc-biztonsági Hivatal	National Food Chain Safety Office	Hungary	Nébih
	Ústřední kontrolní a zkušební ústav zemědělský	Central Institute for Supervising and Testing in Agriculture	Czech Republic	ÚKZÚZ
South ($n=3$)	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail	French Agency for Food, Environmental and Occupational Health & Safety	France	Anses
	Българска агенция по безопасност на храните	Bulgarian Food Safety Agency	Bulgaria	BFSA
	Ministero della Salute	Ministry of Health	Italy	-

were mentioned (Additional file 2) in a small number of cases: of the five responses received (corresponding to 5 NCAs × 17 criteria = 85 filled-in criteria in total), corrections or additions were made for 7 filled-in criteria (approximately 8%).

The BfR considers that EFSA's DoIs good practice is not relevant for its agents, mostly civil servants, who are subject to specific German legal obligations (not detailed in the BfR response), a stand that may be challenged, EU-level requirements being considered as minimum requirements to be applied in each Member State. This disagreement was also traced (Additional file 2).

Three main findings can be drawn from the comparative analysis:

(i) A frequent lack of transparency on the part of NCAs regarding their procedures for managing LoIs: LoIs management procedures are often absent from agency websites. Overall, the result "nf" (not found) represents 67% of the tables data, this proportion reaching 52% for the NCAs that replied to the cnDAspe letter. These proportions suggest, as a whole, a low level of transparency and a limited effort to remedy it, even in the case of specific questions directly asked by a public entity officially commissioned on LoIs management. Illustrative is the response letter of one of the investigated NCAs, for which none of the criteria could be filled in, stating that "*We have no comments on the results [...] before the publication*". This situation can be reasonably considered as not responding to the "*high level of transparency across all activities*" [39] mentioned by EFSA, and as unfavorable for "*building and maintaining trust*" in the independence of the studied NCAs and for ensuring their "*democratic accountability*" [41].

(ii) A significant heterogeneity between the NCAs' official procedures on LoIs management rules. Discrepancies relate to significant issues, e.g., check on the accuracy of the DoIs content; audits of the implementation of the LoIs management rules; duration of the past period considered for the LoIs analysis when hiring or accrediting new experts; staff obligations before accepting a new activity. This heterogeneity also applies to transparency practices, e.g., accessibility of the list of members for all expert committees and governance bodies, and of the corresponding DoIs; accessibility of the criteria for LoIs analysis. More specifically, the list of members for all expert committees and governance bodies could be found only for three NCAs out of ten, and the criteria for LoIs analysis was found for only one NCA. This situation is not compatible with the similar functions NCAs play in the EU MA process for PPPs, where free movement of authorized products is a key principle. This heterogeneity might have an influence on PPPs risk regulation and, ultimately, on the level of protection provided to people (workers, operators, residents, by-standers, consumers) and to the environment. This level of protection should not vary substantially depending on which NCAs were selected to participate to the regulatory risk assessments.

(iii) Substantial gaps between the LoIs management procedures adopted by several NCAs and the good practices promoted by EFSA [46]. For instance: the DoIs of the external experts could be found for only three NCAs out of ten; the DoIs of the management officers could be found for only two; the explicit mention of a check on the accuracy of the DoIs content could be found for only one. However, these procedures are part of the good practices promoted by EFSA.

This study also aimed at proposing a common minimum set of rules that EFSA could require the NCAs to commit to. We present our proposal in the Discussion section, as a logical consequence of our analysis on how the NCAs actually implement good practices.

Discussion

This section will successively discuss the main results of the comparative analysis, the limitations of the study, and recommendations to improve the management of LoIs in the EU and to strengthen the confidence of citizens in their institutions and expertise agencies.

The main results of this study are associated with significant issues regarding deontology and effectiveness of EU public policies. First, investigated NCAs significantly lack transparency on their LoIs management practices, which should be an essential component of their working process. A large amount of basic information on LoIs management turns out not to be easily available on their institutional website. The low number of responses received by the cnDAspe, an independent and public body, officially mandated by the French authorities to make proposals for improving deontology practices in expertise processes, is surprising and worrying. Those observations obviously do not meet the legitimate expectations of the general public regarding transparency. Secondly, our work shows high degree of heterogeneity in NCAs practices, which might result in significant differences in the conclusions of expertise processes. These differences may limit the achievement of the EU's objective of ensuring a high level of human health protection in all its policies and actions [49]. An illustration of this issue is that of the renewal of glyphosate in 2017, which was marked by serious doubts of interference by industrial interests [50]. Because NCAs opinions and evaluations play a central role in PPPs regulation, poor LoIs management at the national level may yield negative consequences on the EU MA process for PPPs in general; it weakens the expertise of EFSA, whose work depends in part on that of the NCAs. Finally, our work suggests that essential procedures for assuring absence of CoI might not be implemented in certain NCAs, as per the best practices detailed in EFSA guidelines [46]. This situation weakens the expertise of EFSA, because of the contribution of the NCAs as (co-)rapporteurs or peer reviews participants to the health and environmental risk assessment steps of the EFSA processes, and raises concern vis-à-vis possibilities of external inappropriate influences on PPP regulation.

The research presented in this article has several limitations. First, it is based on a simple method of data collection: to understand how NCAs manage LoIs, we gathered information by exploring their websites in a first step. This approach has several shortcomings: websites are not always up to date; English versions of websites do not always exist and are sometimes more limited than their national counterparts; the use of translation applications for website exploration when necessary is less effective in finding the information needed. However, this method has several advantages: it is easily reproducible; it gives a general picture of the information that is readily available to the public who understands the language in which NCAs' websites are written (or in English, when NCAs have English version of their websites). In addition, mail exchanges, with the support of an official public body (cnDAspe), gave the NCAs the opportunity to provide complements and corrections to the data retrieved from their website, leading, if necessary, to more accurate characterization of the LoIs management rules. We cannot rule out the hypothesis that some NCAs might have in-depth but non-open access LoIs management rules. Yet, none of the response messages contested or challenged the method adopted by the cnDAspe and the way it had converted the information it could retrieve. The main criticism received came from the BfR, and did not relate to the method, but to the applicability of certain criteria to BfR's type of organization and personnel. We view the few corrections requested by the responding NCAs, all based on information not available online, as an indirect evidence of reliability of the data presented in this paper.

Secondly, the research analyzes the procedures that NCAs declare have in place to manage LoIs, but it does not inform on NCAs actual practices. This has two main implications. On the one hand, practices might deviate from adopted procedures. A qualitative survey, using interviews and observations, would allow an assessment of possible implementation gaps; we have not conducted it, but it is worthwhile being considered. The article shows, however, that even with regard to formal procedures, there is room for improvement in the ways NCAs manage LoIs and transparency. On the other hand, formal procedures for managing LoIs are sometimes unclear or difficult to interpret. As a result, some of the criteria used were sometimes difficult to include in the analysis and in the comparison tables, e.g., in case of incomplete data with an unspecified scope. However, most of the criteria were clear and the uncertainties do not question the main conclusions of the study. Overall, our work may be viewed as an indirect and approximate analysis, yet informative, of the existing LoIs management rules in each NCA taking part to the EU MA process for PPPs. It could be completed subsequently, taking into account the other NCAs involved in the PPP regulatory processes and additional relevant criteria.

Improving the management of LoIs in EU expertise agencies is just one of many actions [51–54] (e.g., maintaining public funding for research to reinforce regulatory expertise, protecting scientific editors from industry influence, etc.) that need to be taken to achieve the goal of protecting regulation from undue corporate influence [2, 3, 13, 55–57]. Addressing the weaknesses shown by our study—i.e., lack of transparency, heterogeneity, gaps with good practices—is nevertheless very important. Not only would it reinforce the quality of the EU expertise system, but it could also contribute to improve public confidence in European institutions on the subject of environmental health and food safety. Pesticide residues in food top the list of food safety-related concerns among Europeans [58]. Yet, as for information on that topic and other risks [58, 59], between a quarter and a third of European citizens (2019: 35%; 2022: 28%) do not trust the European institutions. Authors have suggested there is a link between this distrust and lack of transparency [45, 60]. Before considering the option of "coping with mistrust" [61], the EU should continue its efforts to enhance public confidence. Along with other evolution (e.g., public engagement [62]), increasing transparency and robustness of LoIs management could help.

In order to consolidate LoIs management in the NCAs that contribute to EFSA's work on PPP, the authors of this paper state that a common minimum set of good practices should be targeted. It could include some of the LoIs management rules already in place in some NCAs: (i) taking into account a 5-year period for LoIs analysis, as implemented at Ctgb; (ii) including regular frequentation relationships (e.g., cohabitants, close family members, close colleagues, co-members of advocating associations, etc.) in the scope of the persons considered by DoIs, as implemented at the Italian Ministry of Health; (iii) managing LoIs according to their degree of intensity, as implemented at Anses; (iv) auditing the LoIs management rules once per year by an external independent entity, as exposed by the Italian Ministry of Health; (v) requiring the regular update of the DoIs, with a yearly minimum frequency, and in case of significant change, as implemented at Ctgb. In this latter case, a maximum time limit of 15 days could be specified, as implemented at the Italian Ministry of Health; (vi) checking the accuracy of the DoIs content, e.g., against the information presented in the resume transmitted by the examined person, and against public information available on the Internet, as implemented at Anses on samples of DoIs; (vii) requiring a prior agreement before a member of senior staff could accept a new activity, as implemented at Ctgb, with a 3-year minimum period before accepting a new activity associated with a 'major' LoI, as implemented at the Italian Ministry of Health; (viii) ensuring an open access on the Internet to the criteria used for analyzing expert's and staff"s LoIs, and to the list of members of all expert committees and governance bodies, as implemented at Anses. Insofar as these rules are already adopted in some NCAs, one may consider that they could be applied in all NCAs because they have comparable missions. Improving harmonization based on common minimum rules under the auspices of EFSA is essential. Subsidiarity should not be opposed to such endeavor given the consequences of local weaknesses on the EU-level protection of health and the environment. This harmonizing approach is promoted in other EU MA processes. For instance, the European Medicines Agency's LoIs management rules apply to all competent Authorities taking part in the MA process of innovative medicinal products. This example shows the feasibility of such a harmonized approach.

Moreover, our investigation led us to identify interesting LoIs management rules that have not been adopted by EFSA so far. Two examples: (i) adopting an approach more sensitive to the intensity of LoIs. Some agencies adopt an approach distinguishing three-level of intensity [63, 64]—"major" interests, "minor" interests, and "no interest". From this perspective, "minor" LoIs do not preclude participation in the expertise process, but all other participants should be informed of such links. Such a tuned approach could contribute to preventing the pool of available skilled experts from drying up in some cases; (ii) expanding the definition of funding sources of scholars involved as external experts; their declaration of interests could "*include all resources of private origin, regardless of the form and channel, direct or indirect*" [65]. Such a change would address the European Parliament's repeated requests on this matter [66].

Conclusion

Effective LoIs management, meeting the best available practices aiming at preventing conflicts of interest and including a high level of transparency, is key to promoting high-quality unbiased expertise and "*trust in the trustworthy*" among EU citizens. Consequently, regarding the expertise procedures for PPPs' health and environmental risk assessments and marketing authorizations, the EU LoIs management rules should be (i) more homogeneous between the different National Competent Authorities; (ii) better in line with reference good practices, in particular with regard to those adopted by EFSA; (iii) and more transparent, with open access on the Internet to the main documents related to the LoIs management, e.g., analysis criteria, management rules, public declarations of interest, audit reports.

Allowing verification by external independent entities is also likely to promote trust in the independence of the scientific expertise in support of EFSA.

Abbreviations

CoI(s)	Conflict(s) of interest
DoI(s)	Declaration(s) of interests
EE	External expert
EFSA	European Food Safety Agency
EU	European Union
IE	Internal expert
LoI(s)	Link(s) of interest
MA	Marketing authorizations
MO	Management officer
NCA	National Competent Authority
nf	Not found
nc	Not concerned
PPP	Plant protection products

Supplementary Information

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Additional file 1. Template of the letters sent by the cnDAspe to the investigated competent authorities, including a short notice on the cnDAspe's remit.

Additional file 2. Selected criteria, filled in for the investigated competent authorities; detailed method used for data collection.

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Author contributions
GK acquired, analyzed, interpreted the retrieved data regarding LoI management rules, and drafted the article. GP made substantial contributions to the analysis and interpretation of the results, and to the writing of the manuscript. SD made substantial contributions to the interpretation of the results and substantively revised the manuscript. DZN was a major contributor in designing the study, analyzing and interpreting the data, writing the manuscript, and administrating the study. All authors read and approved the final manuscript. The authors of this paper contributed in their personal capacities rather than as representatives of the cnDAspe or other bodies; their views do not necessarily reflect the decisions or the stated policy of their institutions.

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