

## Comparative analysis of the management of links of interest by the competent authorities for risk assessment and delivery of marketing authorisation of pesticides in the EU Member States

- 1- Study on the competent authorities that carried out the health and environmental risk assessment in the context of the registration of glyphosate in Europe (2017-2022)

Under its two missions <sup>1</sup> relating respectively to the collection and processing of alerts issued by citizens and by various institutions on the one hand, and to the deontology rules applying to scientific and technical expertise, on the other hand, the cnDAspe has been led on several issues to take an interest in the expertise process leading to the marketing of phytopharmaceutical products within the European Union.

This process is largely based on the contribution of the Member States, whether as rapporteur countries or co-rapporteurs of registration files, or as participants in peer reviews within EFSA's expert committees. Hence, the cndAspe was led to examine the rules that various competent authorities have set themselves in terms of managing links of interest. In doing so, it observed substantial differences which could have an impact on the conclusions of the EU expertise reports, and therefore ultimately on the risks incurred for health or the environment, in France as in the other Member States. It has therefore decided to initiate a comparative study of the rules for managing links of interest, which will gradually be deployed for all competent authorities within the EU.

A first analysis focused on the competent authorities that issued the draft Renewal Assessment Report on Glyphosate as part of the renewal process which is in progress <sup>2</sup>, and that undertook the renewal assessment for the previous run <sup>3</sup>.

The methodological note presented in appendix 1 explains how the cnDAspe proceeded to collect and process the relevant information on the management of links of interest, by consulting the documents accessible on the websites of the various competent authorities.

For the purposes of comparing the approaches adopted and the rules adopted, this information has been reported on a standardized form (see appendix 2) which focuses on 17

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<sup>1</sup> Article 4 of Law n° 2013-316 of April 16, 2013 on the independence of health and environmental expertise and the protection of whistleblowers. See at the end of this note a summary of the mandate of the cnDAspe

<sup>2</sup> Nébih [National Food Chain Safety Office, Hongrie], Ctgb [Board for the Authorisation of Plant Protection Products and Biocides, Pays-Bas] et KEMI [Sweden Agency suédoise for chemical products],

<sup>3</sup> BfR, German Federal Institute for Risk Assessment

criteria deemed essential, inspired by the management rules set out in the document Decision of the Executive Director of the European Food Safety Authority on Competing Interest, retained as the reference text<sup>4</sup>.

This first analysis will be gradually enriched with data collected on the other national competent authorities in the EU.

Appendix 2 presents the results of this study in the form of a table summarizing the rules for managing the links of interest of the 4 national agencies as well as of EFSA. It is followed by a note of comments from the cnDAspe on the main differences observed between the various expertise agencies.

### **Background information on the cnDAspe's remit :**

It is an independent Commission created by French law that is tasked with (i) examining both deontology, or good conduct and best practices, in scientific expertise dealing with public health and/or environmental matters ; and (ii) receiving and processing whistleblower reports.

The cnDAspe receives the public health and/or environmental-related whistleblower reports, via [its website](#). The commission's role is to accompany the whistleblower through the reporting process and to ensure that all complaints are responded to by the responsible public authorities following the rules and delays detailed in French law. The commission is not a first response institution, nor does it carry out itself field interventions.

For its work in deontology or good conduct, the cnDAspe accompanies 34 French public research and expertise institutions. It supports the sharing of best practices among these institutions, especially concerning the procedures to prevent conflicts of interest, and transparency and dialogue with civil society.

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[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

## Appendix 1 :

### Summary of the methodology followed for the collection and comparative analysis of information on the management rules regarding links of interest within the competent authorities in the Member States

Collection of relevant documents from a search on the website of the body under review using the website's internal search engine, using the following generic keywords: interest, independence, declaration of interest, conflict of interest, code of conduct, internal control, internal audit, competing interest, selection of experts, integrity.

For non-English speaking countries, translation of the keywords into the national language (Google Translation) and back translation into French of the titles of the first 10 documents returned by the site's internal search engine. Google-translation of documents with relevant titles.

Reading of the documents collected and retrieval of the information on the criteria on a common standardised form (Appendix 2).

When some criteria could not be filled in, additional search of relevant documents on the website of the studied authority, with specific keywords.

Reading of the additional documents collected and retrieval of the information on the missing criteria.

For the criteria that are not filled in after these two steps, the necessary information was requested from the organisation under review. Pending information on the criteria labelled as "nf" (information not found).

Invitation of the the reviewed organisation to proceed to a critical review of the results obtained by.

Reading of the additional documents and opinions thus obtained, then finalisation of the synthesis document (appendix 2).

Publication of a first comparative document, regularly updated with data from other national competent authorities within the EU.

## Appendix 2 :

### Results of the comparative analysis for 17 criteria characterizing the management of conflicts of interest

The comparative analysis grid contains 17 criteria considered important in relation to the management of links of interest (LoI). The answers may differ according to the status of the experts (in the Actors column, a distinction is made between the institution's internal experts [IE], external experts [EE], and members of the institution's management [MO]). Response options are provided for some questions, with results expressed as Yes or No or sometimes as Duration. Some criteria could not be filled in because the corresponding information could not be found in the documents consulted; they are noted as nf (not found). In some cases, the criteria are not applicable (na).

Criteria for assessing the management of links of interest in competent authorities		Actors	France	The Netherlands	Sweden	Hungary	Germany
			<i>Anses</i>	<i>Ctgb</i>	<i>KEMI</i>	<i>Nebih</i>	<i>BFR</i>
Period of consultation of the organization's website (month/year)			03/2022	03-04/2022	04/2022	04-05/2022	05/2022
Obligation to complete an DoI prior to recruitment (yes/no)		EE	yes	yes	nf	na	yes
		IE	yes	yes	nf	yes	yes
		MO	yes	yes	nf	nf	nf
Internet publicity of the DoI form (yes/no)			yes	yes	no	no	yes
Duration of past period covered by the DoI (years)			5	5	nf	nf	nf
How accessible are the criteria for analysing links of interest?	On request; not freely available on the Internet (yes/no)		no	nf	nf	nt	nf
	Open access on the Internet (yes/no)		yes	no	no	no	no

Criteria for assessing the management of links of interest in competent authorities		Actors	France	The Netherlands	Sweden	Hungary	Germany
			<i>Anses</i>	<i>Ctgb</i>	<i>KEMI</i>	<i>Nebih</i>	<i>BfR</i>
Is the management of Lol differentiated according to the intensity of the Lol (yes/no)	EE	yes	no	nf	na	nf	
	IE	yes	no	nf	nf	nf	
	MO	yes	no	nf	nf	nf	
Duration of the period taken into account for the analysis of LI (years)			5	5	nf	nf	nf
What is the structure in charge of Dol analysis?	Internal entity (yes/no)	EE	yes	yes	nf	na	nf
		IE	yes	yes	nf	nf	nf
		MO	yes	nf	nf	nf	nf
	Internal entity + stakeholders (yes/no)	EE	no	no	nf	na	yes
		IE	no	no	nf	nf	nf
		MO	no	nf	nf	nf	nf
	Independent external entity (yes/no)	EE	no	no	nf	na	nf
		IE	no	no	nf	nf	nf
		MO	no	nf	nf	nf	nf
What is the accessibility of experts' and staff's Dol?	On request; not freely available on the Internet (yes/no)	EE	no	no	nf	na	yes
		IE	no	no	nf	no	nf
		MO	no	no	nf	no	nf
	Open access on the Internet (yes/no)	EE	yes	no	no	na	yes
		IE	yes	no	no	no	no
		MO	yes	yes	no	no	no

Criteria for assessing the management of links of interest in competent authorities		Actors	France	The Netherlands	Sweden	Hungary	Gernany
			<i>Anses</i>	<i>Ctgb</i>	<i>KEMI</i>	<i>Nebih</i>	<i>BfR</i>
What is the accessibility of the DoI of the members of the entity in charge of analysing them?	On request; not freely available on the Internet (yes/no)	EE	nf	no	nf	na	nf
		IE	no	no	nf	no	nf
		MO	nf	nf	nf	no	nf
	Open access on the Internet (yes/no)	EE	nf	yes	no	na	no
		IE	yes	yes	no	no	no
		MO	nf	nf	no	no	no
What is the minimum frequency requirement to update DoI (/year)?	EE	1	1	nf	na	nf	
	IE	1	1	nf	nf	nf	
	MO	1	1	nf	nf	nf	
Is there a requirement to update in case of significant change (yes/no)? If so, what is the associated deadline (months) ?	EE	yes : nf	yes : nf	nf	na	yes : -	
	IE	yes : nf	yes : nf	nf	Yes: 1	nf	
	MO	yes : nf	yes : nf	nf	nf	nf	

Criteria for assessing the management of links of interest in competent authorities		Actors	France	The Netherlands	Sweden	Hungary	Gernany
			<i>Anses</i>	<i>Ctgb</i>	<i>KEMI</i>	<i>Nebih</i>	<i>BfR</i>
Is there a check on the accuracy of the Dol content?	By sampling (yes/no)	EE	no	nf	nf	na	nf
		IE	no	nf	nf	nf	nf
		MO	no	nf	nf	nf	nf
	Exhaustive (yes/no)	EE	no	nf	nf	na	nf
		IE	no	nf	nf	nf	nf
		MO	no	nf	nf	nf	nf
	Minimum frequency (/year)	EE	-	nf	nf	na	nf
		IE	-	nf	nf	nf	nf
		MO	-	nf	nf	nf	nf
How long is the Dol archived (years)?			10	nf	nf	50	nf
Is the list of members accessible for all expert committees and governance bodies?	On request; not freely available on the Internet (yes/no)		no	nf	nf	nf	no
	Open access on the Internet (yes/no)		yes	nf	nf	nf	yes

Criteria for assessing the management of links of interest in competent authorities		Actors	France	The Netherlands	Sweden	Hungary	Germany
			<i>Anses</i>	<i>Ctgb</i>	<i>KEMI</i>	<i>Nebih</i>	<i>BfR</i>
What are the obligations before a new activity (consultant, other employer...)?	Prior information (yes/no)	EE	no	yes	nf	na	nf
		IE	yes	yes	nf	yes	yes
		MO	yes	yes	nf	nf	nf
	Prior agreement (yes/no)	EE	no	yes	nf	na	nf
		IE	yes	yes	nf	yes	yes
		MO	yes	yes	nf	nf	nf
	Duration of the period during which the new duties must be notified (years)	EE	no	no	nf	na	nf
		IE	no	no	nf	nf	nf
		MO	no	no	nf	nf	nf
What is the minimum period before a new activity with a "major" interest can be accepted (years)?		EE	no	no	nf	na	nf
		IE	no	nf	nf	nf	nf
		MO	no	no	nf	nf	nf
Is there a regular audit of the implementation of the rules for managing links of interest?	Via internal structure (yes/no)	/	yes	nf	nf	nt	nf
	Via internal structure + stakeholders (yes/no)	/	no	nf	nf	nt	nf
	Via independent external structure (yes/no)	/	no	yes	nf	nt	nf
	Minimum frequency (/year)	/	nf	5	nf	nt	nf

DoI : declaration of interests (assumed publicly available)

LI : Link of interest

nf : Not found

na : not applicable

CoI : Conflict of interest

EE : External expert

IE : Internal expert

MO : Management officer



## Appendix 3

### Complementary document:

EFSA's rules for managing conflicts of interest, according to the same criteria, in order to serve as a benchmark for the comparison

Period of consultation of the organization's website (month/year) : 02/22		Acteurs	Union Européenne
			EFSA
Obligation to complete an DoI prior to recruitment (yes/no)		EE IE MO	yes yes yes
Internet publicity of the DoI form (yes/no)		/	yes
Duration of past period covered by the DoI (years)		/	5
How accessible are the criteria for analysing links of interest?	On request; not freely available on the Internet (yes/no)	/	no
	Open access on the Internet (yes/no)	/	yes
Is the management of LoI differentiated according to the intensity of the LoI (yes/no)		EE IE MO	no no no
Duration of the period taken into account for the analysis of LI (years)		/	2
What is the structure in charge of DoI analysis?	Internal entity (yes/no)	EE IE MO	yes yes yes
	Internal entity + stakeholders (yes/no)	EE IE MO	no no no
	Independent external entity (yes/no)	EE IE MO	yes no no
What is the accessibility of experts' and staff's DoI?	On request; not freely available on the Internet (yes/no)	EE IE MO	no no no
	Open access on the Internet (yes/no)	EE IE MO	yes yes yes
What is the accessibility of the DoI of the members of the entity in charge of analysing them?	On request; not freely available on the Internet (yes/no)	EE IE MO	nf nf nf
	Open access on the Internet (yes/no)	EE IE MO	nf nf nf
What is the minimum frequency requirement to update DoI (/year)?		EE IE MO	1 1 1
Is there a requirement to update in case of significant change (yes/no)? If so, what is the associated deadline (months) ?		EE IE	yes : 1,5 yes : 1,5

		MO	yes : 1,5
Is there a check on the accuracy of the DoI content?	By sampling (yes/no)	EE	yes
		IE	no
		MO	no
	Exhaustive (yes/no)	EE	no
		IE	no
		MO	no
	Minimum frequency (/year)	EE	2
		IE	nf
		MO	nf
How long is the DoI archived (years)?			10
Is the list of members accessible for all expert committees and governance bodies?	On request; not freely available on the Internet (yes/no)		no
	Open access on the Internet (yes/no)		yes
What are the obligations before a new activity (consultant, other employer...)?	Prior information (yes/no)	EE	no
		IE	yes
		MO	yes
	Prior agreement (yes/no)	EE	no
		IE	yes
		MO	yes
	Duration of the period during which the new duties must be notified (years)	EE	no
		IE	no
		MO	2
What is the minimum period before a new activity with a "major" link of interest can be accepted (years)?		EE	nf
		IE	2
		MO	2
Is there a regular audit of the implementation of the rules for managing links of interest?	Via internal structure (yes/no)		no
	Via internal structure + stakeholders (yes/no)		yes
	Via independent external structure (yes/no)		yes
	Minimum frequency (/year)		1 ; 5

## Comments on the comparative analysis of the internal rules for managing links of interest posted by the five competent authorities which carried out the health and environmental risk assessment in the context of the process to renew approval of the glyphosate in Europe (2017-2022)

The Competent Authorities (CAs) selected for this test comparison are those that co-produced the draft Renewal Assessment Report on Glyphosate (publication in June 2021), i.e. ANSES (France), Nébih (Hungary), Ctbg (Netherlands) and Kémi (Sweden), as well as the one that wrote the draft Assessment Report during the previous renewal run as rapporteur State (BfR, Germany).

Preliminary note: the following comments are based on information obtained from the websites of the competent authorities (CAs). The CA directorates were invited to comment on the results of this consultation, which gave them the possibility to complete the publicly available information or to correct errors in the interpretation of these data (all answered<sup>5</sup>). As a benchmark, the same information was retrieved from EFSA's online documents.

### 1- Transparency

- Two CAs (KEMI and Nebih) do not provide the possibility to consult on their website documents describing the internal rules for managing links of interest.

This does not mean that such documents do not exist or that they cannot be obtained on request, as evidenced by the answer of Nébih to the invitation to correct any error or omission sent to the 5 CAs. Nonetheless, this situation does not meet the EU transparency requirements. This raises doubts about how these documents have been developed (among other issues, the implication of independent external stakeholders in their development is questionable) and how they are actually used.

- The Dutch CA does not make public the Dols of its internal or external experts, only the Dols of the Board members and of the Secretariat director (who manages the scientific activity) are openly available on the Internet. The policy of transparency is stronger at Anses, which is in line in this respect with EFSA's rules. Anses applies this rule to the members of its governance bodies as well as to its experts (internal and external). There is a similar difference between Ctbg and Anses in terms of the possibility to know the criteria for analysing links of interest.

- The case of the BfR is intermediate. The Dols of the members of its various Advisory Committees are not accessible on the institution's website, only their affiliations are public. The content of these Dols may be indirectly known if assuming that the format used for the

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<sup>5</sup> We have no comments on the results presented for KEMI'. The answer by Nébih provided some information that had not been found on its website. Nébih specifies that there is "not any external expert regarding to the authorization process". Ctbg clarified several points and underlines the difference between its scientific personnel which undertakes the evaluations and its Board that takes the decisions relative to marketing authorisations. BfR puts forward that its activities of risk assessment are exclusively performed by its employees, who are often civil servants, with no assistance or advice from any external persons ; also, its funding sources exclude contributions from trade or industry..Anses provided clarifications and corrective information.

members of the BfR Scientific Council is also applicable to them, which is not specified. The Dols of internal experts are not public.

## **2- Management of links of interest (Lols)**

The links of interest of the experts and managers of the two CAs for which the information could be consulted are examined over a period of 5 years, which is longer than at EFSA (2 years). Anses, moreover (and not EFSA or Ctgb), sets rules for the management of Lols that take into account the assessment of the force of these links. All three require an annual update and whenever there is a substantial change in the situation (this is also the case at Nébih, according to its answer to the letter from cnDAspe); EFSA (but not Anses and Ctgb) specifies that this update must take place within one and a half months of such a change. A situation of CI must be solved within a month by an internal expert, according to the answer by Nébih. Anses and Ctgb state that the Dols of the members of the entities that assess the LIs of internal and external experts are themselves publicly available; this is also the case at Anses for the management personnel.

Within the BfR, only internal agents are authors of expertise reports. Their links of interest are assessed during recruitment according to a system set by law. The comments provided after receiving the document sent by cnDAspe state that the procedure of declaration of interests set by EFSA is not applicable to BfR civil servants and employees, an opinion that cnDAspe does not share. Any secondary activity must be declared in order to assess a risk of conflict of interest, such activity being then prohibited. The members of the various BfR committees are listed on the CA website. They are chosen on the basis of their skills, after a call for external applications; a large number of scientific personalities belong to economic entities directly linked to the objects of these committees.

EFSA checks the accuracy of the information provided in the Dols (for external experts) on a random basis repeated every 2 years, which is not the case for the 2 CAs. This is not the case at Ctgb. Anses may assess the consistency of the information provided by the Dols of external experts and other sources of information it has (CV and public data).

Like EFSA, the 2 CAs for which the information could be consulted require prior information and agreement before taking up a new position with LIs with the activity of their previous employer, for internal experts and members of governance bodies, a requirement extended to external experts by the Ctgb. This applies for 2 years after leaving the Agency, at EFSA, 3 years for Anses, a period not specified by the Ctgb.

## **3- External audit**

EFSA regularly audits its general policy (every 5 years) and practice (every year) in the area of LI management, with the general audit being entrusted to an independent external entity and the annual one being carried out by an ad hoc committee of its Board. The Anses carries out an internal audit for this purpose (without external involvement); this information was not found for the Ctgb.

## Provisory conclusion

Significant differences in terms of transparency and prevention of conflicts of interest are noted between the 5 competent authorities for the assessment of risks related to plant protection products which were the subject of this comparative analysis. These differences are likely to have consequences on how the experts of these different entities evaluate the scientific data that they select and examine.

This situation is likely to generate mistrust on the part of citizens towards the objectivity and scientific rigor of the process of health and environmental risk assessment as it is currently carried out for glyphosate and for the other pesticides placed on the market in Europe.

This conclusion is based on the public documents describing the rules that are to be followed by the competent authorities. The actual practice of each institution is likely to deviate more or less from these written rules, which this comparative study does not have the means to assess. Transparency on these practices, both internally and vis-à-vis external stakeholders, is important to maintain the vigilance of each institution on compliance with its commitments.

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