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Commission nationale DAspe
Déontologie et Alertes en santé publique et environnement

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

Update and extension of the document issued in june 2022

11 April 2023

Under its two missions [1] relating respectively to the collection and processing of alerts issued by citizens or 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 health or environmental risk management options, 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 other competent authorities within the EU.

A first analysis allowed to test the methodology of this comparative analysis; it focused on the competent authorities that issued the draft Renewal Assessment Report on Glyphosate as part of the renewal process which is in progress [2], and that undertook the renewal assessment for the previous run [3]. The present analysis is extended to 4 other CAs as well as to the European Chemicals Agency (ECHA).

The methodological note presented in appendix 1 explains how the cnDAspe proceeded to collect and process the relevant information on the management of links

[1] 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

[2] Anses (France), Nébih [National Food Chain Safety Office, Hungary], Ctgb [Board for the Authorisation of Plant Protection Products and Biocides, The Netherlands] and KEMI [Sweden Agency for chemical products],

[3] BfR, German Federal Institute for Risk Assessment

of interest, by consulting the documents accessible on the websites of the various competent authorities and by asking them for additions and corrections to the data available online.

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 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[4]. These criteria are exposed in the table of appendix 2. This analysis is gradually enriched with data collected on other national competent authorities in the EU.

Appendix 3 presents how EFSA and ECHA respectively position themselves on these different criteria. Due to its major role in the development of standards for the risk assessment of chemical substances, via its "OECD Guidelines for the Testing of Chemicals" programme[5], the positioning of the group of national coordinators of the guidelines program of the OECD (WTN) has also been considered in this same appendix.

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

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; and (ii) receiving and processing of public health and/or environmental whistleblower reports.

The cnDAspe receives the public health and/or environmental-related whistleblower reports, via its website. The commission's role is to then accompany the whistleblower through the reporting process and to ensure that all complaints are responded to by the competent 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 management of conflicts of interest procedures and dialogue with civil society.

[4] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

[5] https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

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, with relevant references.

After these two steps, the criteria that are not filled are labelled as "nf" (information not found)

Request for a critical review of the results obtained by the reviewed organisation.

Reading of the additional documents and opinions backed by relevant references 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 instances, the item could not be informed and is nc (not concerned).

		Centre zone					North zone		South zone		
Criteria for assessing the management of links of interest in competent authorities	Actors	Germany	The Netherlands	Hungary	Poland	Czech Republic	Finland	Sweden	France	Italy	Bulgaria
		BfR	*Ctgb*	*Nébih*	*Ministry of Agriculture and Rural Development*	*ÚKZÚZ (CISTA)*	*Tukes*	*KEMI*	*Anses*	*Ministero della Salute (DGISAN)*	***БАБХ*** *(BFSA)*
Period of consultation of the organization's website (month/year)		*05/2022*	*03-04/2022*	*04-05/2022*	*09/2022*	*10/2022*	*08/2022*	*04/2022*	*03/2022*	*11/2022*	*12/2022*
Obligation to complete a DoI prior to recruitment (yes/no)	EE IE MO	yes nf nf	yes yes yes	nf nf nf	nf nf nf	nf nf nf	nc nf nf	nf nf nf	yes yes yes	yes yes yes	nf nf nf
Internet publicity of the DoI form (yes/no)		yes (1)	yes	no	no	no	no	no	yes	yes	no
Duration of past period covered by the DoI (years)		nf	5	nf	nf	nf	nf	nf	5	3	nf

How accessible are the criteria for analysing links of interest?	On request; not freely available on the Internet (yes/no)		nf	nf	nf	nf	nf	nf	nf	no	nf	nf
	Open access on the Internet (yes/no)		no	no	no	no	yes	no	no	yes	nf	nf
Management of LoI differentiated according to the intensity of the LoI (yes/no)		EE	nf	no	nf	nf	nf	nc	nf	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
Duration of the period taken into account for the analysis of LI (years)			nf	5	nf	nf	nf	nf	nf	5	3	nf
What is the structure in charge of DoI analysis?	Internal entity (yes/no)	EE	nf	yes	nf	nf	nf	nc	nf	yes	nf	nf
		EI	nf	yes	nf	nf	nf	nf	nf	yes	nf	nf
		MO	nf	nf	nf	nf	nf	nf	nf	yes	nf	nf
	Internal entity + stakeholders (yes/no)	EE	yes	no	nf	nf	nf	nc	nf	no	nf	nf
		EI	nf	no	nf	nf	nf	nf	nf	no	nf	nf
		MO	nf	nf	nf	nf	nf	nf	nf	no	nf	nf
	Independent external entity (yes/no)	EE	nf	no	nf	nf	nf	nc	nf	no	nf	nf
		EI	nf	no	nf	nf	nf	nf	nf	no	nf	nf
		MO	nf	nf	nf	nf	nf	nf	nf	no	nf	nf
Accessibility of experts' and staff's DoI	On request; not freely available on the Internet (yes/no)	EE	nf	nf	nf	nf	nf	nc	nf	no	nf	nf
		EI	nf	nf	nf	nf	nf	nf	nf	no	nf	nf
		MO	nf	nf	nf	nf	nf	nf	nf	no	nf	nf
	Open access on the Internet (yes/no)	EE	yes(1)	no	nf	nf	nf	nc	no	yes	nf	nf
		EI	no	no	no	no	no	no	no	yes	nf	nf
		MO	no	yes	no	no	no	no	no	yes	no	no
What is the accessibility of the DoI of the	On request; not freely available on	EE	nf	no	nf	nf	nf	nc	nf	no	nf	nf
		EI	nf	no	nf	nf	nf	nf	nf	no	nf	nf
		MO	nf	nf	nf	nf	nf	nf	nf	no	nf	nf

members of the entity in charge of analysing them?	the Internet (yes/no)												
	Open access on the Internet (yes/no)	EE	no	yes	nf	nf	nf	nc	no	yes	nf	nf
		EI	no	yes	no	no	no	no	no	yes	nf	nf
		MO	no	nf	no	no	no	no	no	yes	nf	nf
Minimum frequency requirement to update DoI (/year		EE	nf	1	nf	nf	nf	nc	nf	nf	nf	nf
		IE	nf	1	-	nf	nf	nf	nf	nf	nf	nf
		MO	nf	1	-	nf	nf	nf	nf	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 : -	yes : -	nf	nf	nf	nc	nf	yes : -	0,5	nf
		IE	nf	yes : -	yes	nf	nf	nf	nf	yes : -	0,5	nf
		MO	nf	yes : -	yes	nf	nf	nf	nf	yes : -	0,5	nf
Is there a check on the accuracy of the DoI content?	By sampling (yes/no)	EE	nf	no	nf	nf	yes(4)	nc	nf	yes(4)	nf	nf
		EI	nf	no	nf	nf	yes(4)	nf	nf	yes(4)	nf	nf
		MO	nf	no	nf	nf	yes(4)	nf	nf	yes(4)	nf	nf
	Exhaustive (yes/no)	EE	nf	no	nf	nf	yes(5)	nc	nf	yes(5)	nf	nf
		EI	nf	no	nf	nf	yes(5)	nf	nf	yes(5)	nf	nf
		MO	nf	no	nf	nf	yes(5)	nf	nf	yes(5)	nf	nf
	Minimum frequency (/year)	EE	nf	no	nf	nf	1	nc	nf	1	nf	nf
		EI	nf	no	nf	nf	1	nf	nf	1	nf	nf
		MO	nf	no	nf	nf	1	nf	nf	1	nf	nf
How long is the DoI archived (years)?			nf	nf	*50*	nf	nf	nf	nf	10	nf	nf
Accessibility of the list of members for all expert committees and governance bodies	On request; not freely available on the Internet (yes/no)		no	nf	nf	nf	nf	nf	nf	no	nf	nf
	Open access on the Infernet (yes/no)		yes	t	nf	nf	nf	nf	nf	yes	nf	nf
What are the obligations of		EE	nf	yes	nf	nf	nf	nc	nf	no	nf	nf
		EI	nf	yes	nf	nf	nf	nf	nf	yes	nf	nf

experts and personal before a new activity (consultant, other employer, NGO ...)?	Prior information (yes/no)	MO	nf	yes	nf	nf	nf	nf	nf	yes	nf	nf
	Prior agreement (yes/no)	EE										
		EI	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 (years)	EE										
		EI	nf	no	nf	nf	nf	nf	nf	no	nf	nf
		MO	nf	no	nf	nf	nf	nf	nf	no	nf	nf
What is the minimum period before a new activity with a "major" interest can be accepted (years)?		EE										nf
		IE	nf	nf	nf	nf	nf	nf	nf	3*	3	nf
		MO	nf	n	nf	nf	nf	nf	nf	3*	3	nf
Is there a regular audit of the implementation of the rules for managing links of interest?	Via internal structure (yes/no)		nf	no	nf	nf	nf	nf	nf	yes	nf	nf
	Via internal structure + stakeholders (yes/no)		nf	no	nf	nf	nf	nf	nf	no	nf	nf
	Via independent external structure (yes/no)		nf	yes	nf	nf	nf	nf	nf	no	nf	nf
	Minimum frequency (/year)		nf	5	nf	nf	nf	nf	nf	1	nf	nf
Receipt by the cnDAspe of a response letter from the organization studied (y/n) and date of receipt			yes, 29/06/22	yes, 29/06/22	yes, 24/06/22	no	no	no	yes, 20/06/22	yes, 22/06/22	no	no

Miscellaneous comments		The BfR considers that EFSA's DoI procedures do not apply to its agents, who are subject to specific legal obligations, an opinion that the cnDAspe does not share. The BfR relies on various advisory committees including members of economic entities directly		Nebih co-manages research departments with the Veterinary University of Budapest and the National Agricultural and Innovation Center, where the agency can draw resources of expertise. The cnDAspe sees them as potential external experts.					The response letter from ANSES (Ref. 2022-06-441; V. Ref. CNDA/ZC/2022-14) mentions an "Ethics control procedure prior to departures in the competitive sector", not transmitted and not found on the ANSES website.	The scope of the persons concerned by DoIs includes second-degree relatives and those with "regular relationships".	The Internet page "Information on the law on the prevention and identification of conflicts of interest" is empty. https://bfsa.egov.bg/wps/portal/bfsa-web/home/access-information/information-conflict-of-interest-prevention-and-establishment-act/information-conflict-of-interest-prevention- and-

		linked to the work carried out at the BfR.									establish ment-act/; Consulte d on 14/12/202 2

DoI : declaration of interests (assumed publicly available)
LI : Link of interest
nf : Not found
nc: not concerned - case of organizations not requesting any External Expert (EE), in any evaluation, any expertise, any committee, any Scientific Council or equivalent, etc
EE : External expert
IE : Internal expert
MO : Management officer

Appendix 3

Complementary document:

EFSA's, ECHA's and OECD WNT[6] rules for managing conflicts of interest, according to the same criteria, in order to serve as a benchmark for the comparison

Criteria for assessing the management of links of interest in competent authorities		Actors	European Union		OECD Working Group of National coordinators of the TGs programme (WNT)
			EFSA	*ECHA*	
Obligation to complete an DoI prior to recruitment (yes/no)		EE IE MO	yes yes yes	yes yes yes	nf nf nf
Internet publicity of the DoI form (yes/no)			yes	yes	nf
Duration of past period covered by the DoI (years)			5	5	nf
How accessible are the criteria for analysing links of interest?	On request; not freely available on the Internet (yes/no)		no	no	nf
	Open access on the Internet (yes/no)		yes	yes	nf
Is the management of LoI differentiated according to the intensity of the LoI (yes/no)		EE IE MO	no no no	no no no	nf nf nf
Duration of the period taken into account for the analysis of LI (years)			2	5	nf
What is the structure in charge of DoI analysis?	Internal entity (yes/no)	EE IE MO	yes yes yes	yes yes yes	nf nf nf
	Internal entity + stakeholders (yes/no)	EE IE MO	no no no	no no no	nf nf nf
	Independent external entity (yes/no)	EE IE	yes no	no no	nf nf

[6] OECD Working group of National coordinators of the Test guidelines programme (WNT)

		MO	no	no	nf
What is the accessibility of experts' and staff's DoI?	On request; not freely available on the Internet (yes/no)	EE	no	no	nf
		IE	yes	no	nf
		MO	no	no	nf
	Open access on the Internet (yes/no)	EE	yes	yes	nf
		IE	no	yes	nf
		MO	yes	yes	nf
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	no	no	nf
		IE	no	no	nf
		MO	nf	no	nf
	Open access on the Internet (yes/no)	EE	yes	yes	nf
		IE	yes	yes	nf
		MO	nf	yes	nf
What is the minimum frequency requirement to update DoI (/year)?		EE	1	1	nf
		IE	1	1	nf
		MO	1	1	nf
Is there a requirement to update in case of significant change (yes/no)? If so, what is the associated deadline (months) ?		EE	yes : 1,5	yes : -	nf
		IE	yes : 1,5	yes : -	nf
		MO	yes : 1,5	yes : -	nf
Is there a check on the accuracy of the DoI content?	By sampling (yes/no)	EE	yes	no	nf
		IE	no	no	nf
		MO	no	no	nf
	Exhaustive (yes/no)	EE	no	no	nf
		IE	no	no	nf
		MO	no	no	nf
	Minimum frequency (/year)	EE	2	-	nf
		IE	nf	-	nf
		MO	nf	-	nf
How long is the DoI archived (years)?			10	-	nf
Is the list of members accessible to all expert committees and governance bodies?	On request; not freely available on the Internet (yes/no)		no	no	nf
	Open access on the Internet (yes/no)		yes	yes	nf
What are the obligations before a new activity	Prior information (yes/no)	EE	no	no	nf
		IE	yes	yes	nf
		MO	yes	yes	nf
	Prior agreement (yes/no)	EE		no	nf
		IE	yes	yes	nf
		MO	yes	yes	nf

(consultant, other employer...)?	Duration of the period during which the new duties must be notified (years)	EE	-	no	nf
		IE	2	no	nf
		MO	2	2	nf
What is the minimum period before a new activity with a "major" interest can be accepted (years)?		EE	-	nf	nf
		IE	2	2	nf
		MO	2	2	nf
Is there a regular audit of the implementation of the rules for managing links of interest?	Via internal structure (yes/no)		no	yes	nf
	Via internal structure + stakeholders (yes/no)		yes	no	nf
	Via independent external structure (yes/no)		yes	no	nf
	Minimum frequency (/year)		1 ; 5	1	nf
Receipt by the cnDAspe of a response letter from the studied Authority (yes/no) and date of receipt			yes, 17/03/2023	no	no

nf : Not found
CoI : Conflict of interest
EE : External expert
IE : Internal expert
MO : Management officer

Comments on the comparative analysis of the internal rules for managing links of interest posted by ten competent authorities of EU member states[7]

Preliminary remark : 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 by cnDAspe, which gave them the possibility to complete the publicly available information or to correct errors in the interpretation of these date[8]. As a benchmark, the same information was retrieved from EFSA's and ECHA's online documents.

1- Transparency

- The first striking observation is that six CAs among the ten that were examined (KEMI/Sweden, Nebih/Hungary, Tukes/Finland, BFA/Bulgaria, the competent administrations of Poland and of the Czech Republic) do not provide the possibility to consult on their website documents describing the internal rules for managing links of interest. The same observation can be made for the OECD program for the development of "guidelines for the testing of chemicals"[9]. Only the list of members of its working group of national program coordinators (WNT) is public; on the other hand, the composition of the various committees that issue proposals for hazard and exposure characterization (Working Party on Hazard Assessment (WPHA), Working Party on Exposure Assessment (WPEA), etc.), for validation by the WNT, are not accessible, nor are their DoIs, if any.

  This does not mean that such documents do not exist or that they cannot be obtained on request. However, this situation does not meet the EU transparency requirements. This raises doubts about how these documents - if they exist - have been developed (among other issues, the involvement of independent external stakeholders in their development is questionable) and how they are actually used.

[7] Among them, five carried out the health and environmental risk assessment in the context of the approval of glyphosate in Europe (2017-2022)

[8] Answers were received from the following authorities : KEMI (Sweden), Nébih (Hungary), Ctbg (The Netherlands), BfR (Germany), Anses (France) and EFSA; when this document was posted, the other authorities had not answered. KEMI stated that '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. Ctbg clarified several points and underlines the difference between its scientific personel 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 external advice ; also, its funding sources exclude contributions from trade or industry. Anses and EFSA provided clarifications and corrective information.

[9] This OECD programme is, along with definition of the « Good laboratory practices », one of the pillars of the mutual data recognition system that applies to all its member countries. The European agencies EFSA and ECHA rely on these technical guides for the assessment of the risks associated with chemical substances, in particular pesticides. Similarly, the national authorities competent to issue marketing authorizations for pesticides.

- The Dutch CA does not make publically available the DoIs of its internal or external experts (that are registered internally), only the DoIs of the Board members are freely available on the Internet. The policy of transparency is stronger at Anses, which is in line in this respect with EFSA rules. The Anses applies this rule to the members of its governance bodies as well as to its internal and external experts. There is a similar difference between Ctgb and Anses in terms of the possibility of knowing the criteria for analysing links of interest. Regarding the competent office of the Italian health ministry, DoIs of external experts are accessible online, but not those of internal experts nor of members of governance bodies.

- The case of the BfR is intermediate. The DoIs of the members of its various Advisory Committees are not accessible on the institution's web site ; only their affiliations are public. The content of these DoIs may be indirectly known by assuming that the format used for the members of the BfR Scientific Council is also applicable to them, which is not specified. The DoIs of internal experts are not public.

2- Management of links of interest (LoIs)

- 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, or 3 years (Italy), which is longer than at EFSA (2 years) and similar to that at ECHA . Anses, moreover (and not EFSA, ECHA nor Ctgb), sets rules for the management of LoIs that take into account an assessment of the strengh of these links. All four require an annual update and whenever there is a substantial change in the situation ; EFSA (but not ECHA nor the 2 CAs) specifies that this update must take place within one and a half months after such a change; this delay is 15 days in Italy. The Ctgb and ECHA state that the DoIs of the members of the entities that assess the LIs of internal and external experts are themselves publicly available; this information is not provided by the Italian authority which however specifies that this analysis is done by an internal entity.

Within the BfR, only internal agents are the authors of expert reports. Their links of interest are assessed during recruitment according to an internal system that is not explained; 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 advisory committees are listed on its website. They are chosen on the basis of their skills, after a call for external applications; There are a large number of scientific personalities belonging to economic entities directly linked to the objects of these committees.

EFSA checks the accuracy of the information provided in the DoIs (for external experts) on a random basis repeated every 2 years, which is also the case for Anses but not for ECHA nor Ctbg. This information is not provided by the other competent authorities.

- Like EFSA and ECHA, 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, ECHA , 3 years at Anses and in Italy, 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. An independent international visitation commission performs an audit every five years at the Ctbg ; this audit includes a check on DoIs. This external audit takes place yearly in Italy. It is undertaken internally at ECHA and only bears on external experts. The information was not found for the other CAs that were examined.

Provisory conclusion

Significant differences in terms of transparency and prevention of conflicts of interest are noted between the 9 competent authorities for the assessment of risks related to plant protection products which were the subject of this comparative analysis. Because of absence of information, one cannot rule out the hypothesis that these differences might 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 assessing the risks to health and the environment as it is currently carried out for pesticides placed on the market in Europe.

This conclusion is based on the public documents describing the rules supposed to be followed by the relevant 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 their commitments. The presence within the governance bodies of the competent authorities of representatives of different categories de stakeholders is a means to increase this transparency.