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Analysis of different preferences for the EU's regulatory options for endocrine disruptor identification criteria using argumentation theory

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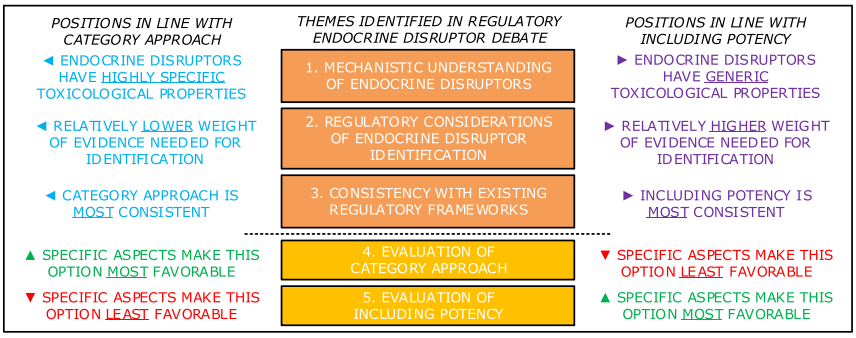
HIGHLIGHTS

- Argumentation analysis was used to study EU regulatory endocrine disruption debate.
- Stakeholders disagree on best option: 'category approach' vs 'including potency'.
- Contrasting preferences were supported by different lines of arguments.
- Five topical *themes* and 21 *issues* with contrasting positions were identified.
- Key themes included scientific, weight-of-evidence and regulatory considerations.

GRAPHICAL ABSTRACT



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ABSTRACT

What criteria are most suitable to identify endocrine disrupting substances (EDSs) for regulatory purposes in the EU? The results of the European Commission's public consultation, as part of the process to establish identification criteria for EDSs, show that different regulatory options are supported. Some respondents prefer an option including hazard characterization considerations, whereas others prefer an option that avoids these considerations and introduces several hazard-identification based weight-of-evidence categories. In this study, the argumentation underlying the different preferences for identification criteria are analyzed and compared using pragma-dialectical argumentation theory (PDAT). All responses of non-anonymous, national governments that submitted a response in English (n = 17) were included. Responses of other stakeholder organizations were included if a Google News search returned an opinionated presence in the media on the subject (n = 9). Five topical *themes* and 21 underlying *issues* were identified. The *themes* are 1) mechanistic understanding of EDSs, 2) regulatory considerations related to the identification of EDSs, 3) consistency with existing regulatory frameworks, and 4) evaluations of specific issues related to a category approach and 5) related to including potency. We argue that two overarching (implicit) 'advocacy coalitions' can be discerned, that adopted contrasting *positions* towards the identified *themes* and *issues*. Among these 'coalitions', there appears to be consensus about the necessity of having 'science-based' criteria, though different perspectives exist as to what the most accurate

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mechanistic understanding of EDSs entails. To move the discussion forward, we argue that a societal dialogue would be beneficial, where EDS science and regulation are discussed as interrelated themes.

1. Introduction

For several years, the European Commission (EC) has been working towards the regulation of endocrine-disrupting substances (EDSs), most notably in the areas of pesticides and biocides. The EU's Plant Protection Products Regulation (PPPR, No. 1107/2009) required the Commission to adopt identification criteria to establish whether a pesticide active substance should be considered an endocrine disrupting substance (EDS). The EU's Biocidal Products Regulation (BPR, No. 528/2012) contains a similar requirement for such criteria. In the 2014 Roadmap of the Commission (EC, 2014), four options for criteria were presented. These options mainly differ as to the weight of evidence necessary to identify an EDS as such (see Table 1 for a description of these options, and the key criteria).

As part of the selection of the criteria, an impact assessment was performed, which also included a public consultation. In this consultation, information was requested about the various potential impacts of the four options for criteria: the range of substances that could be identified under each option, the potential for substitutability of these identified substances and anticipated socio-economic impacts, among other aspects (EC, 2015). Notably, there was also room to provide general comments, which was used as an opportunity by many respondents to state which option they preferred, and which they opposed, along with supporting argumentation.

The report on the results of the public consultation (EC, 2015) has shown that there are different perspectives among respondents about what the ultimate criteria should entail. The main aim of the present paper is to analyze and compare the argumentation underlying different option preferences of governmental entities (e.g. national governments) and of prominent stakeholder organizations (e.g. NGO's or industry organizations), as stated in their responses.

We were particularly interested in the debate about the EDS identification criteria, because it is characterized by ongoing controversy, both in terms of science and policy. There is general agreement on the scientific definition of an EDS, proposed by the WHO (2002): *'an endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations'*. Accordingly, this definition includes three key elements: 1) exposure to the exogenous substance should cause an adverse health effect; 2) disruption of the function of the endocrine system should be the mechanism of action; and 3) there should be a causal relationship between the exposure, the mechanism of action and the adverse effect. However, practical use of this definition and the key elements has led to much debate. Clahsen et al. (2019b) have shown that there are fundamental differences of opinion between EDS experts in how weight-of-evidence evaluations for EDS should be performed, and whether there are systematic approaches available and useful for establishing causality, among other aspects. These elements are crucial for the development of sound science-informed methodologies for the identification of EDSs, irrespective of the ultimately selected option.

The complexity of EDS policy is related to the high stakes surrounding the practical uses of EDSs. Many substances linked to endocrine disruptive effects, such as the plastics constituent Bisphenol A or certain pesticides, are high production volume substances that have widespread applications in contemporary society. Some stakeholders argue that the availability and use of some (potential) EDSs could be associated with substantial economic value, both directly and indirectly (see e.g. ADAS, 2011; PlasticsEurope, 2019). Others refer to the significant potential health impacts and related economic costs (see e.g. Rijk et al., 2016; Norden, 2014). Amidst these stakes, the lobby of the chemical industry has been accused of deliberately obstructing regulatory action against EDSs (Horel and CEO, 2015), while there are also EDS experts that question the motives of NGOs for deliberately maintaining the issue of EDS on the public and legislative agenda (Dietrich et al., 2016).

Table 1
Description of the four policy options proposed by the EC, including the key identification criteria. Bold phrases highlight the key elements of that option.

Policy option	Description based on information provided in EC (2014)	Key criteria to identify a substance as EDS
Option 1 ("Interim criteria")	The **interim criteria** as included in the PPPR and BPR will remain in place (see point 3.6.5. in the legal text of the PPPR and Article 5.3 in the legal text of the BPR).	• Carcinogenic category 2 and Reproductive toxicant category 2 under the EU"s classification, labelling and packaging regulation (CLP, No. 1272/2008) for carcinogenic, mutagenic and reproductive toxic (CMR) substances • Reproductive toxicant cat. 2 under CLP and occurrence of toxic effect to endocrine organ (note: a substance *may* then be identified as EDS)
Option 2 ("WHO/IPCS definition")	The **WHO/IPCS definition** of an endocrine disruptor will be used to identify EDSs, in combination with several weight-of-evidence requirements (see EC, 2014 for more information).	• Exposure to the substance causes an adverse health effect • As mechanism of action, disruption of the function the endocrine system is identified • There is a causal relationship between the mechanisms of action and the adverse effect
Option 3 ("Category approach")	The WHO/IPCS definition of an EDS, including the outlined weight-of-evidence requirements, will be used as a basis to identify EDS, but **additional categories** will be included that refer to different strengths of evidence. Next to category I (**'endocrine disruptor'**), which is equivalent to option 2, the categories II (**'suspected endocrine disruptors'**) and III (**'endocrine active substances'**) are added. The specific weight-of- evidence requirements related to the two additional categories can be found in EC (2014).	• Category I: see criteria for Option 2 above. • Category II: substances could be allocated to this category on the basis of some evidence for endocrine--mediated adverse effects, but which is not sufficient to warrant placement in Category I • Category III: substances could be allocated to this category on the basis of some in vitro or in vivo evidence indicating a potential for endocrine mediated adverse effects
Option 4 ("Potency inclusion")	The WHO/IPCS definition of an endocrine disruptor will be used, but a **potency threshold** will be included to discriminate between high potency and low potency EDS. Further information on weight-of-evidence requirements is not specifically mentioned.	• The same criteria as applying to Option 2, but with the inclusion of potency as an element of hazard characterization

To ensure a maximally systematic, unbiased and impartial analysis of the argumentation put forward in the selected responses, we used pragma-dialectical argumentation theory (PDAT). With PDAT, the analyst can identify the standpoints and the underlying structure of argumentation put forward. When the same or strongly similar arguments, or clusters of arguments, are repeatedly occurring in multiple responses, this points to the presence of important topics in the debate on EDS identification criteria. In this study, we distinguish two levels of such topics: broad, topical *themes* (e.g. about the broad mechanistic understanding of EDSs) and underlying *issues* touching upon specific aspects of a *theme* (e.g. about the role of timing of exposure). When multiple perspectives towards a *theme* have been observed, these are referred to as contrasting *positions*.

Based on our earlier work in Clahsen et al. (2019a), we discern different dynamics, social stations and underlying drivers of argumentation in science-policy controversies, as illustrated in Fig. 1. From this framework, we derived two pertinent topics of interest for our analysis. First, we are particularly interested in distinguishing science-based argumentation from normative value judgments. This notion provides the starting point for the identification of *themes* and thereby focused the scope of our analysis. That is, the main focus is on the intrinsic properties of the regulatory options, and how these relate to existing perspectives on EDS science and regulation, rather than on discussing arguments pertaining to the potential consequences of implementing one of the four policy options. Second, we study the alignment of arguments in implicit or explicit 'advocacy coalitions' (after Sabatier and Jenkins-Smith, 1993). The use of the concept of 'advocacy coalitions' serves as a heuristic to delineate groups of actors that share the same policy preferences, use similar supportive arguments by referring to the same *themes* and *issues*, and adopt the same *positions* towards these *themes* and *issues*. Note that advocacy coalitions, in the true meaning of the concept, cannot be identified in this study, since actual interactions within and between coalitions cannot be studied. Specific attention will be given to the distribution of governmental entities and stakeholder organizations over these 'coalitions'.

We specified five research questions from the aim of our study:

1. What types of option preferences exist among the identified responses?
2. What arguments have been put forward in favor of or against the four regulatory options for identification criteria (see Table 1)?
3. What topical *themes*, underlying *issues*, and contrasting *positions* towards these *themes* and *issues* can be derived from the range of arguments identified?

4a. To what extent can (implicit) advocacy coalitions be identified?
4b. How are governmental entities and prominent stakeholder divided over these advocacy coalitions?

Research question 1 is addressed by a document analysis. Research question 2 is addressed by the analysis of arguments using PDAT, while research questions 3, 4a and 4b are addressed by the subsequent categorization of arguments.

2. Methods

2.1. Pragma-dialectical argumentation theory (PDAT)

PDAT was developed by van Eemeren and colleagues (van Eemeren and Grootendorst, 1984; see also van Eemeren et al., 2010) to remedy an experienced lack of a systematic way to study argumentation in different social contexts, such as argumentation in scientific discussions or argumentation in 'daily life'. In pragma-dialectics, argumentation is viewed as aiming at resolving a *difference of opinion* by critically testing the acceptability of the standpoints at issue.

PDAT provides a model of argumentation that enables an analysis and evaluation of argumentation. A full analysis of the argumentation provides an analytic overview consisting of a characterization of the difference of opinion, the standpoints, the discussion stages, the *argumentation structure* and the *argument schemes*. An *argumentation structure* provides a complete overview of standpoints and all the underlying

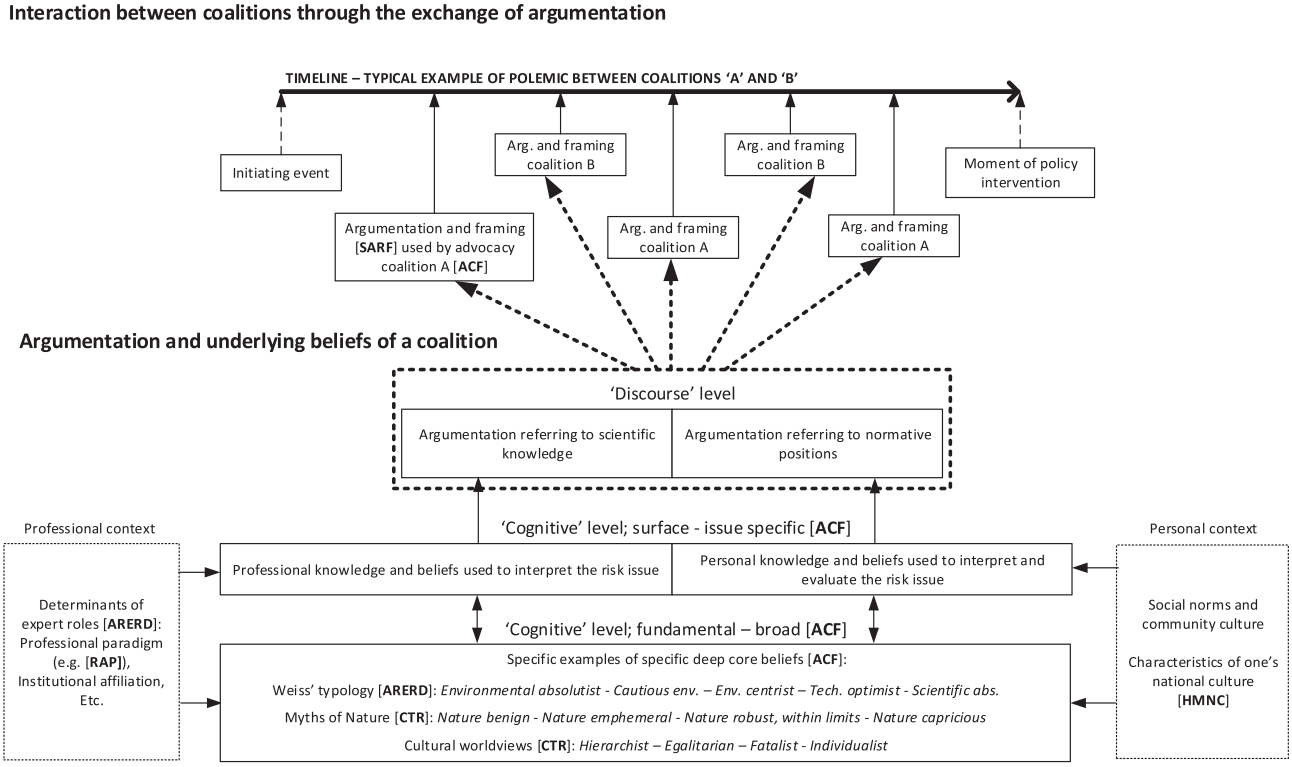


Fig. 1. Overarching framework of Clahsen et al., 2019a.

argumentation, including hierarchal relationships. PDAT distinguishes three types of *argumentation structures*: *multiple argumentation*, *coordinative argumentation* and *subordinative argumentation*. *Argument schemes* provide the specific relationships between individual arguments. Since the aim of this study is to identify and categorize the range of arguments, rather than analyzing the (logical) links between individual arguments, *argument schemes* have not been identified here. Furthermore, from the perspective of PDAT, it is not appropriate to use the concept of *difference of opinion* in the context of this study. There is no explicit argumentative exchange between the various respondents, since all responses are aimed at the Commission. In our analyses, we use the terms *themes, issues* and *positions* to refer to topical and broad (*themes*) or more specific topics (*issues*) that appear to be under discussion, and the often contrasting *positions* towards the identified *themes* and *issues*, respectively.

2.2. Selection of responses included in the argumentation analyses

For our analysis, we used the publicly available database of the Commission. The public consultation elicited 27.087 responses in total. Fig. 2 shows our selection procedure. The Commission only made public non-confidential and non-email responses (n = 22.269). Responses of individuals were excluded, leaving 818 responses of affiliated responses. From these, we selected responses of governmental entities and of prominent stakeholder organizations.

2.2.1. Selection of governmental entities

We identified responses from 19 national governmental entities, based on their selected identification as a 'Public authority', excluding one levy board, three anonymous responses, four non-English responses and three local governments' responses.

2.2.2. Selection of stakeholder organizations

The public consultation questionnaire generated responses from 788 non-governmental stakeholder organizations, a number too large to subject to argumentation analysis. We therefore focused on those stakeholder organizations that were the most prominent in the societal and political debate on the EDS identification criteria. Accordingly, we performed an online search of news media outlets using Google News (date of search: 26 February 2018) to identify stakeholder organizations that have an 'opinionated' presence in the debates. Stakeholder selection criteria were 1) inclusion only when an explicit opinion was provided to any of the four proposed options in at least one of the selected news articles 2) exclusion of governmental entities and 3) exclusion of professionals or experts providing their opinion on a personal basis. We identified 18 stakeholder organizations on the basis of these selection criteria, nine of which participated in the public consultation and were included in our analysis.

2.3. Identification of the preferred policy option in each response

The type of preferred policy option was identified by selecting the key sentence or phrase that appeared to most explicitly convey the preferred policy option in each response. Document A1 in the appendix substantiates this procedure, by presenting the key sentence or phrase that we used to discern the range of preferred policy options.

2.4. Argumentation analyses

PDAT was used to reconstruct the argumentation structure for the selected responses. These argumentation structures consist of all standpoints and any underlying *single*, *multiple*, *coordinative* or *subordinative* argumentation that the analysts have encountered in the responses, including the hierarchal relationships.

To reduce the influence of possible personal bias and style of analysis on reconstructing argumentation structures, the argumentation structure of one response (ECPA) was reconstructed independently by two authors (LM and SCSC). The resulting minor differences were discussed with a third author (BG), who provided recommendations for the analysis of the other responses. The argumentation structures of all other responses were reconstructed by one author (LM) and reviewed by a second author (SCSC). Note that we only analyzed the contents of the responses as these were presented in the database of the Commission. No other documents attached to these responses were included in the analyses.

2.5. Identification of themes

Based on our earlier work, we are particularly interested in distinguishing arguments related to scientific knowledge from arguments related to evaluations based on normative values (see also Fig. 1). In the context of this study, the starting point for the identification of *themes* was one *theme* touching upon the scientific understanding of EDSs, and one *theme* related to the more normative and political considerations surrounding the debate on the EDS identification criteria.

2.6. Categorization of arguments

After the identification of the *argumentation structures*, each individual argument in each of the *argumentation structures* received preliminary labels that were used to group them into 'preliminary argument categories'. That is, each argument was provisionally labelled to gain broad insight in the breadth and scope of all topics addressed. These provisional labels were then reviewed, and the wide variety of labels was reduced to a smaller amount of 'preliminary argument categories' by grouping similar labels under one category. Accordingly, all arguments in all argumentation structures were appointed to such an argument category. Note that these labels and categories were only used in this part of the analysis, as an intermediate step to later distinguish the ultimate *themes* and underlying *issues*. The argument categorization procedure is also shown in Fig. 3.

2.7. Identification of underlying issues

The initial list of 'preliminary argument categories' appeared to be too crude. That is, most of these argument categories spanned multiple relevant topics that should be analyzed and discussed individually. For each argument, it was identified which *issue* it addressed. Through the process of filling the categorization table response-by-response, thereby first appointing each argument to one of the preliminary argument categories, and subsequently adding to each argument the *issue* it touched upon, the list of *themes* and *issues* was extended, revised and refined through an iterative process. This process was performed by one author (SCSC), with regular consultation of co-authors IvK, TGV, AHP and EL.

2.8. Identification of contrasting positions

During the categorization process, the contrasting *positions* towards the identified *themes* and *issues* became clear. For each *theme*, such *positions* were discerned. Each individual argument was then assigned to one of the two *positions* and coded with directional arrows and colors (see also Document A2). This procedure was performed separately by two authors (SCSC and AHP), with regular consultation of co-authors IvK, TGV and EL.

3. Results

3.1. Characterization of the responses

From the selection process, 28 responses were identified as being eligible for this study. Two EU member states had separate responses

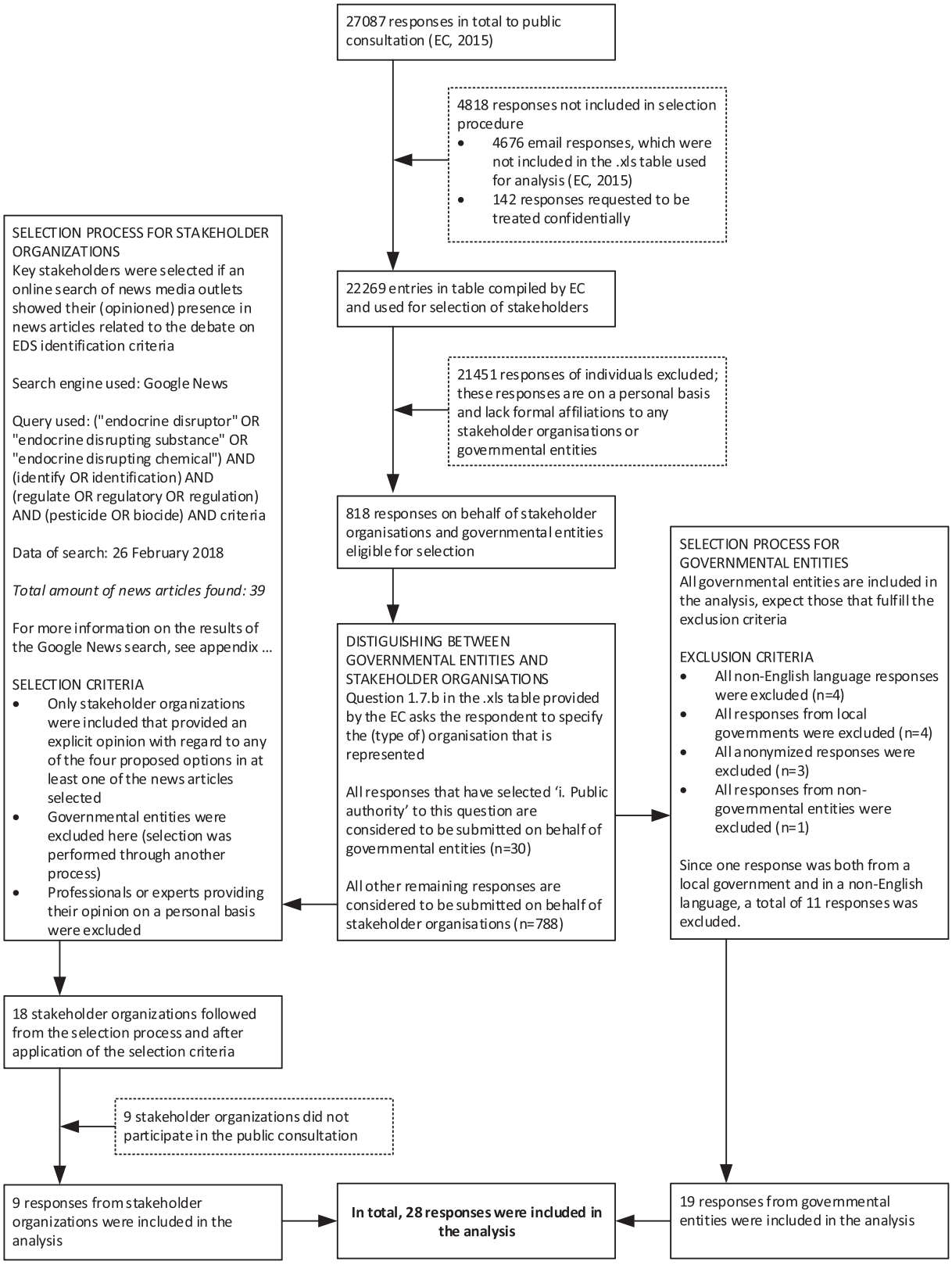


Fig. 2. Flow chart of the procedure used to select the responses of stakeholder organizations and governmental entities.

from different national agencies, while the standpoints and supporting argumentation put forward were essentially the same. The Danish VFA response refers to the contents of the Danish EPA response, so these responses were considered as one. Also, the responses of the two Austrian agencies were taken together, as these were practically identical. Accordingly, 26 unique responses were taken forward in the analyses; 17 of governmental organizations and 9 of stakeholder organizations (see Table 2).

Six types of option preferences were discerned from the identification of preferred policy preferences in each response. These all concern Options 3 and 4, or variations thereof, of the Roadmap of the Commission (EC, 2014); none of the included responses indicated a preference for Options 1 or 2. A brief discussion of the (predominantly negative) evaluation of Options 1 and 2 can be found in the appendix (see Document A3).

'Category approach' refers to those responses in which Option 3 of the Roadmap (i.e. adopting categories for different weights-of-

STEP 1 - 'plain' argumentation structure

Argumentation structure - reconstructed from response X

2.1.1 (= example of paragraph nr. of response X)
1 [Standpoint]
1.1 [Argument]
1.1.1 [Argument]

2.2.4 (= example of paragraph nr. of response X)
1 [Standpoint]
1.1 [Argument]
1.2 [Argument]
1.3 [Argument]

STEP 2 - arg. structure including preliminary labels

Argumentation structure - reconstructed from response X

2.1.1 (= example of paragraph nr. of response X)
1 [Standpoint] → **Label A**
1.1 [Argument] → **Label B**
1.1.1 [Argument] → **Label C**

2.2.4 (= example of paragraph nr. of response X)
1 [Standpoint] → **Label D**
1.1 [Argument] → **Label E**
1.2 [Argument] → **Label F**
1.3 [Argument] → **Label G**

STEP 3 - Processing argumentation structures into a 'categorization table'

Theme I	List of arguments	Response X	Response Y	Response Z
Preliminary arg. category 1	'Argument'	2.2.4 - 1	2.2.4 – 1.3	
	'Argument'		4.1 – 1.1	
	'Argument'			2.4.4 – 1.1b
Preliminary arg. category 2	'Argument'			2.3.1 – 1.1.1a
	'Argument'			2.1.2 – 2.1
Preliminary arg. category 3	'Argument'	2.1.1 – 1.1.1.1		

STEP 4 - Final version of categorization table; including identifiers for *issues*

Theme I	List of arguments	***Issue nr.***	Response X	Response Y	Response Z
Preliminary arg. category 1	'Argument'	***Issue* I-I**	2.2.4 - 1	2.2.4 – 1.3	
	'Argument'	***Issue* I-I**		4.1 – 1.1	
	'Argument'	***Issue* I-II**			2.4.4 – 1.1b
Preliminary arg. category 2	'Argument'	***Issue* I-III**			2.3.1 – 1.1.1a
	'Argument'	***Issue* I-IV**			2.1.2 – 2.1
Preliminary arg. category 3	'Argument'	***Issue* I-V**	2.1.1 – 1.1.1.1		

STEP 5 - Document A2: full list of identified arguments, divided over the identified *themes*, *issues* and competing *positions*

Theme I
Issue I-I
◄ 'Argument supporting position F' - Response X
◄ 'Argument supporting position F' - Response Y
► 'Argument supporting position G' - Response Z
► 'Argument supporting position G' - Response Z

Issue I-II
◄ 'Argument supporting position F' - Response Y
◄ 'Argument supporting position G' - Response Y

Issue I-III
◄ 'Argument supporting position F' - Response X
► 'Argument supporting position G' - Response Z
► 'Argument supporting position G' - Response Z

STEP 6 - Table IV: table showing which responses referred to which *themes* and *issues*

		Opt. A		Opt. B
		Respondent X	Respondent Y	Respondent Z
Theme I	*Issue* I-I	◄	◄◄	►►
	Issue I-II		◄	
	Issue I-III	◄		►►
Theme II	*Issue* II-I	◄◄◄		
	Issue II-II		◄	►
	Issue II-III	◄		
	Issue II-IV			►►►►

Table 2
Overview of the 26 responses included in this study. 'Preferred policy option' refers to one of the six identified option preferences. 'Respondent name' and 'respondent type' are as reported in the response. The label 'coordinated' was added when the response was submitted on behalf of an entire national government. The labels for 'respondent type' are based on the options provided in the consultation. Abbreviations: i. PA (EU)/(EEA)/(Non-EU) – Public authority located within the EU, in the European Economic Area or outside of the EU, respectively; vi. C/NGO – Consumer/Non-Governmental Organization; vii. I/TO - Industrial or trade organization.

Preferred policy option	Respondent name	Respondent type	ID nr.
Category approach	French coordinated	i. PA (EU)	1
	Danish EPA/VFA	i. PA (EU)	2
	Finnish TUKES	i. PA (EU)	3
	Swedish KEMI	i. PA (EU)	4
	Norwegian FSA	i. PA (EEA)	5
	BEUC	vi. C/NGO	6
	HEAL	vi. C/NGO	7
	PAN Europe	vi. C/NGO	8
	Endocrine Society	viii. Other	9
	EurEau	viii. Other	10
Different variations of category approach	Belgian coordinated	i. PA (EU)	11
	Dutch coordinated	i. PA (EU)	12
	German UBA	i. PA (EU)	13
Including potency	German BfR	i. PA (EU)	14
Including potency, and additional elements of hazard characterization	UK coordinated	i. PA (EU)	15
	BCPC	vi. C/NGO	16
	CEFIC	vii. I/TO	17
	ECPA	vii. I/TO	18
	PlasticsEurope	vii. I/TO	19
'Risk-based option'	Australian coordinated	i. PA (non-EU)	20
	Canadian coordinated	i. PA (non-EU)	21
	New Zealand coordinated	i. PA (non-EU)	22
	US coordinated	i. PA (non-EU)	23
	Health Canada	i. PA (non-EU)	24
No specific preference	Austrian AGES/UBA	i. PA (EU)	25
	Hungarian NICS	i. PA (EU)	26

evidence) is explicitly and unambiguously supported. 'Different variations of category approach' refers to responses that favor different altered versions of Option 3. 'Including potency' refers to responses that support Option 4 of the Roadmap (i.e. the inclusion of a potency consideration, in addition to the 2002 WHO/IPCS EDS definition). 'Including potency, and additional elements of hazard characterization' refers to responses that require Option 4 to be supplemented with additional elements of hazard characterization, such as severity and reversibility of effect; the inclusion of potency as the only element of hazard characterization is not considered sufficient to distinguish substances of high regulatory concern from those of low concern. 'Risk-based option' refers to an option not included in the EC's roadmap, but which is added here to reflect respondents' preference for risk-based, rather than hazard-based identification criteria. The essential difference with Option 4 of the Roadmap is the inclusion of exposure considerations. 'No specific preference' refers to those responses that either intentionally do not provide a specific option preference, or where a preference could not be reliably discerned from the response.

Table 3
Overview of five *themes*, 21 underlying issues and contrasting *positions*. Upper part: blue left- and purple right-pointing triangles indicate the major contrasting *positions*. Lower part: green up- and red down-pointing triangles indicate the (un)favorability of a category approach or including potency considerations, the key elements in Options 3 and 4 of the EC's roadmap, respectively.

Themes	Issues	Contrasting positions
1: Mechanistic understanding of EDSs	1.1: Timing of exposure and effects 1.2: Dose-response 1.3: Mixture effects 1.4: Assessment of environmental EDSs	◄ EDSs have highly specific toxicological properties ► EDSs have toxicological properties that are not different from those of other potentially hazardous substances
2: Regulatory considerations related to the identification of EDSs	2.1: Availability of EDS-related data 2.2: Quality and variability of data on EDSs 2.3: Establishing causality 2.4: Assessment of environmental EDSs	◄ Identification of EDSs should require a relatively lower weight of evidence ► Identification of EDSs should require a relatively higher weight of evidence
3: Consistency with existing regulatory frameworks	3.1: Consistency with PPP/BP regulations 3.2: Consistency with REACH regulation 3.3: Consistency with CLP Regulation 3.4: Consistency with Cosmetics Regulation 3.5: Usefulness of categorizing EDSs as a specific regulatory substance category	◄ Category approach is most consistent, or including potency is least consistent with existing regulatory frameworks ► Including potency is most consistent, or a category approach is least consistent with existing regulatory frameworks
4: Evaluations of specific issues related to a category approach	4.1: Practicality of applying a category approach 4.2: Anticipated impact on the categorization of substances 4.3: Anticipated impact on expert judgment processes 4.4: Anticipated impact on the amount of animals used in animal testing 4.5: Suitability of a category approach for dealing with environmental EDSs	▲ Specific aspects of a category approach make this option most favorable ▼ Specific aspects of a category approach make this option least favorable
5: Evaluations of specific issues related to including potency	5.1: Practicality of including potency 5.2: Anticipated consequences of including potency 5.3: Suitability of including potency for dealing with environmental EDSs	▲ Specific aspects related to including potency make this option most favorable ▼ Specific aspects related to including potency make this option least favorable

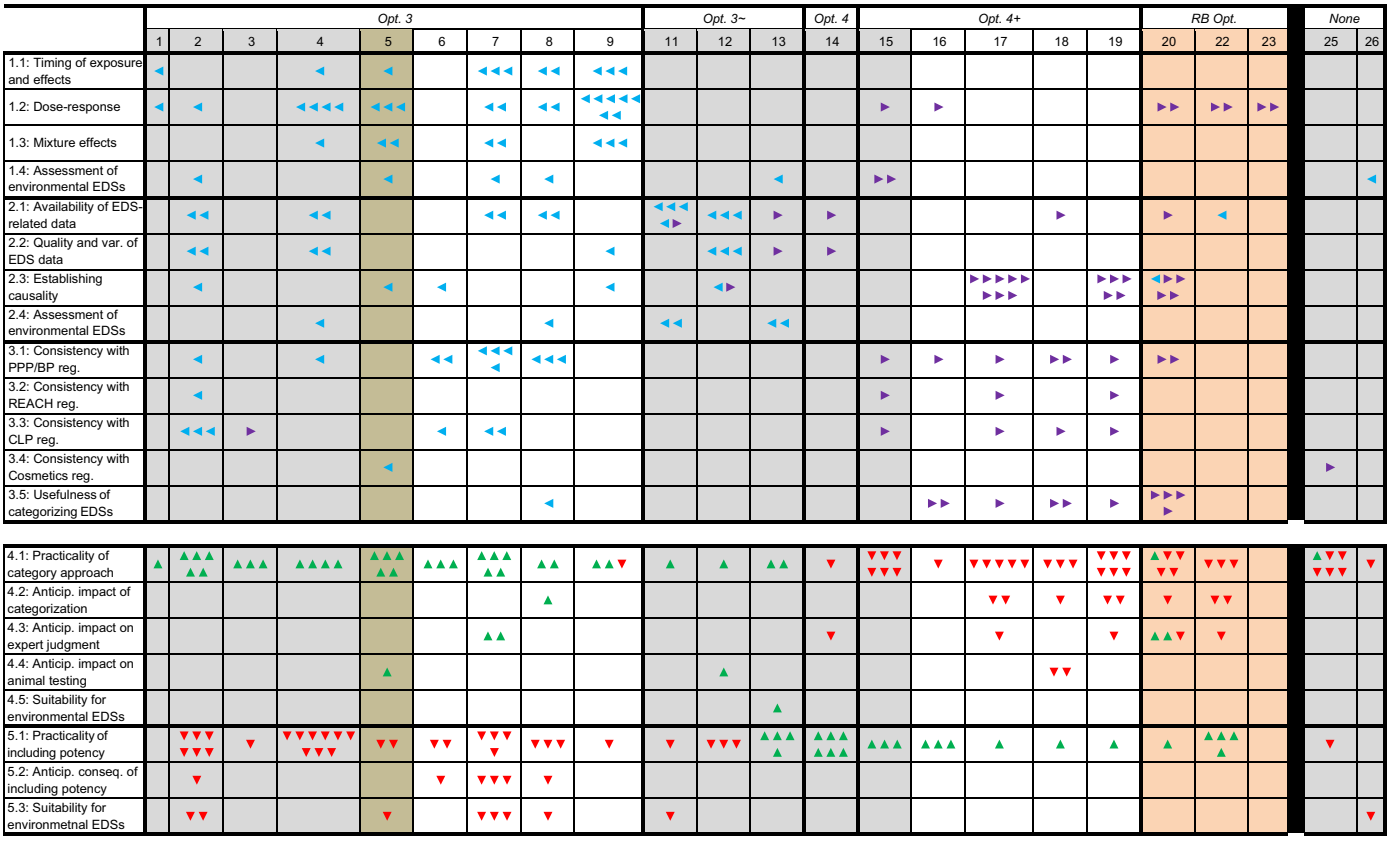
3.2. Identification of themes, underlying issues and contrasting positions

Five *themes* and 21 underlying *issues* were identified, as well as five sets of two contrasting *positions* that represent the two opposing perspectives as to each *theme* (see also Table 3).

Firstly, different *positions* were identified about whether the mechanistic activity and toxicological properties of EDSs are in fact different from those of other types of potentially hazardous substances, such that EDSs require specific study designs (*Theme 1*). We identified

Fig. 3. Simplified overview of the breakdown of argumentation structures into *themes*, underlying *issues* and particular *positions* of responses. Step 1 included the generation of all argumentation structures. To each of the standpoints and arguments in these argumentation structures, preliminary labels were added (step 2). In step 3, one document (categorization table) containing all arguments was developed, where all arguments were categorized into 'preliminary argument categories'. In step 4, issues were discerned in the categorization table to further distinguish relevant topics referred to in the responses. In step 5, document A2 was developed, which contains a list of all *themes* and *issues*, and the arguments considered to address these *themes* and *issues* was developed, including the *position* that the argument refers to (indicated by different colors and arrows). In step 6, Table IV was developed to summarize the information of document A2 into a table.

Table 4
Criteria options (first row) and respondents (second row; see table II for the list of respondents) plotted against the list of *issues* (abbreviated representation in first column; see table III for the list of *themes* and full name of the *issues*). The color of the column represents the type of respondent. All coloured columns are governmental entities: grey – EU member state, brown – member of the European Economic Union, orange – non-European government. Colorless columns are all stakeholder organizations. Number of triangles represent the number of arguments given per *issue* per response. Blue left- and purple right-pointing triangles (upper part), and green down- and red up-pointing triangles (lower part) indicate contrasting positions (see Table III for the list of contrasting *positions*). Columns of respondents 10, 21 and 24 were removed, since these would be empty (i.e. none of these responses included arguments related to the identified *issues*). Abbreviations: Opt. 3 – Category approach; Opt. 3~ - Different variations of category approach; Opt. 4 – including potency; Opt. 4+ - Including potency, and additional hazard characterization elements; RB Opt. – Risk-based option; None – No specific reference.



more different arguments supporting the *position* that EDSs have highly specific toxicological properties than arguments supporting the *position* that EDSs have toxicological properties that are not different from those of other potentially hazardous substances. Underlying *issues* are related to the timing of exposure and effects, dose-response relationships, mixture effects and the assessment of environmental EDSs. Of the four *issues*, only 'dose-response' and 'environment' elicited contrasting perspectives. Overall, most arguments were related to 'dose-response', suggesting that this may be the most contested (see Table 4).

Secondly, we identified differences in *positions* as to the level of weight of evidence available and necessary to identify EDSs in accordance with the proposed regulatory options (*Theme 2*). Underlying *issues* were the availability of EDS-related scientific data, their quality and variability, the strength of evidence to establish causality, and the use of data on environmental EDSs. In support of the *position* that the identification of EDSs should occur on the basis of 'lower' weight of evidence requirements, arguments addressing the 'availability of EDS-related data' were used most. To support the *position* that the identification of EDSs should occur on the basis of a 'higher' weight of evidence requirement, arguments addressing considerations of causality establishment make up the majority.

Thirdly, we recognized different perspectives as to the consistency of a category approach or an option including potency with existing regulatory frameworks (*Theme 3*). Underlying *issues* are related to their application in the PPPR, BPR, CLP REARCH industrial chemicals regulation and Cosmetics regulations, and to the usefulness of distinguishing EDSs as a distinct substance category that requires specific regulatory attention. To support the *position* that a category approach is most consistent, or including potency is least consistent with existing regulatory frameworks, arguments addressing the consistency with PPP/BP regulations were used most. In support of the contrasting *position*, arguments addressing the usefulness of categorizing EDSs were used most.

Fourthly, we noted that specific properties of a category approach appeared to be evaluated differently by different respondents (*Theme 4*). Underlying *issues* dealt with the practicality of applying a weight-of-evidence-based category approach, the anticipated consequences to the identification of substances and expert judgment processes under this option, the anticipated impact on animal testing needs, and its applicability to environmental EDSs. Arguments addressing the practicability of a category approach were used most in support of the two contrasting *positions* (i.e. specific aspects of a category approach make this option most or least favorable, respectively).

Fifthly, specific properties of an option including potency also appeared to be evaluated differently by different respondents (*Theme 5*). Underlying *issues* are related to the practicality and consequences of applying a potency threshold approach, anticipated consequences of the inclusion of potency and its applicability for environmental EDSs. Arguments addressing the practicability of including potency were used most in support of the two contrasting *positions* (i.e. specific aspects related to including potency make this option most or least favorable, respectively).

Document A2 shows how all arguments are related to these *issues*, and in which *positions* this resulted. Table 4 summarizes this data. Contrasting *positions* were made visible by different types of triangles. The

amount of triangles shows how many arguments associated with an *issue* were found in each response. Note that the amount of triangles depicted for each response also depends on the length of that response. In addition, the representation in tables III and IV of *themes* 1, 2 and 3 is different from that of *themes* 4 and 5, since the first three *themes* relate to general scientific, regulatory scientific and regulatory aspects and the fourth and fifth relate to specific properties concerning the options.

4. Discussion

We analyzed responses of 17 governmental entities and 9 stakeholder organizations to the Commission's public consultation related to the impact assessment of four options (proposed by the Commission) for criteria to identify EDSs for regulatory purposes. We used PDAT to identify the argumentation in support of the option preferences of the respondents. Through this analysis, we identified 21 *issues* that could be grouped into five *themes*. These five *themes* were: 1) the mechanistic understanding of EDSs, 2) regulatory considerations related to the identification of EDSs, 3) consistency of the options with existing regulatory frameworks, 4) evaluations of specific issues related to a category approach and 5) evaluations of specific issues related to the inclusion of potency.

4.1. Strengths and limitations

As far as we are aware, this is the first study that uses scientific argumentation analysis to better understand the variety of responses to the Commission's public consultation on impact of the EDS identification criteria. From the perspective of argumentation theory, the responses were not inherently argumentative by nature. Many responses consisted of a mix of (seemingly) non-argumentative information (e.g. information about the respondent), general comments towards or observations about options, and arguments put forward in favor or against a certain regulatory option. However, PDAT can only be used to study utterances that have an argumentative function (as compared to other communicative functions). Given the controversies and ensuing ambiguities surrounding EDS science and policy, we think it warranted to employ the strategy of *maximally argumentative interpretation* (van Eemeren et al., 2010) in this study. This means that borderline cases that may or may not have been intended as argumentative were nevertheless considered as such in the analyses.

Although we have strived to maximize impartial and unbiased analysis and categorization of arguments, the interpretation and understanding of the subject matter by the researchers inherently may have had an influence. We are aware that the influence of the researchers' personal or professional biases can never be eliminated entirely in this type of analysis. However, several steps were taken to minimalize these influences: 1) The actual argumentation analysis was performed by researchers (LM and SCSC) who are not involved and have no position or stake in the ongoing research and policy initiatives regarding EDS. This analysis was supervised by an expert in PDAT (BG), 2) the PDAT method is geared towards performing analyses that remain true to the essence of the text that is analyzed, 3) judgments of the 'truth value' and 'comparative weights' of the (premises used in the) identified arguments were explicitly out of the scope of this article, due to the highly subjective nature of such evaluations, 4) the structured procedure for categorizing all arguments enabled us to retrace the steps followed and choices made during the categorization process and 4) almost all steps were performed by two or more authors. An exception is the development of Document A1, but also here the findings were repeatedly corroborated with co-authors IvK, TGV, AHP and EL.

The Commission's consultation was performed to support the impact analysis of their four proposed regulatory options. Although the consultation did not focus on scientific and regulatory considerations of the options per se, our analysis shows that the responses put forward a wealth of arguments related to these topics. Accordingly, this consultation provides a rare opportunity to analyze and compare the argumentation and explicit regulatory preferences of a wide range of influential actors in the EDS science and policy debates. The Commission released a report on the results on the public consultation (see EC, 2015), with the aim to discuss the results of the consultation in the context of an impact assessment. This is different from the aims of this paper.

We assumed that the twenty six analyzed responses sufficiently represent the range of 818 responses on behalf of organizations. This point was most relevant for the selection process of stakeholder organizations, since all English language responses from non-anonymous, national governmental entities were included in this study. We consider that there is an inherently limited amount of influential stakeholder organizations (particularly NGO's, umbrella or lobby organizations active at the EU level) that will be both able and willing to dedicate the time, resources and expertise to have an active presence in the complex scientific, societal and regulatory debates on the EU's EDS regulation. We consider that online media presence, in terms of participation in newspaper articles or opinion papers appearing in the media, is an adequate proxy for this 'active presence' typical for influential stakeholders. In addition, we found that several non-included respondents explicitly referenced the responses of such key EU-level umbrella or lobby organizations as representing their official policy position. For example, we identified about 16 additional responses not included in our analysis (of both industrial parties and national-level trade unions) that refer to the CEFIC response as completely, or at least partly, representing their specific position.

4.2. Observations regarding the substance of the identified themes and issues

Of the five themes that were identified, only *themes* 1, 2 and 3 are discussed here, since these touch upon generic science and regulatory issues related to EDSs.

4.2.1. The science underlying science-based policy (theme 1)

The necessity of the criteria to be 'science-based' is explicitly emphasized in many responses and appears to attract wide consensus. However, the diversity in arguments used indicate that there are multiple interpretations of what this 'scientific basis' should be. Most notable is the substantial attention for the issue 'dose-response'. This issue resembles a known difference in perspectives occurring in the scientific debate on EDSs. For instance, it is disputed whether monotonic dose-response curves should remain the standard for assessing the toxicity of EDSs, in accordance with the centuries-old toxicological paradigm that dose is the key determinant of toxicity (contrast Vandenberg et al., 2012 with Autrup et al., 2015 and Beausoleil et al., 2016). The option to use non-linear dose-response models in risk assessment procedures was discussed in the context of the US EPA's proposed rulemaking (US EPA, 2018) and recent supplemental notice (US EPA, 2020) on transparency in regulatory science.

Notably, arguments used in support of positions in line with both a category approach and an option including potency contained references to scientific opinions of EFSA (2013) and JRC (2013), both established scientific bodies of the EU. However, different *positions* were supported by referring to the same document, possibly through selective referencing or interpretative ambiguity of the content in the report. For example, the ECPA response refers to the following conclusion of EFSA, to support a risk assessment approach (i.e. including hazard identification, hazard characterization and exposure) to the identification of EDSs: *"… endocrine disruptors can be … subject to risk assessment, where both hazard and exposure are considered in regulatory decision making. This is also the conclusion reached by the EFSA Scientific Committee in their Scientific Opinion published in March 2013 (lines 577-581 of ECPA response)"*. Alternatively, the HEAL response refers to another conclusion of the same Scientific Opinion, to support their

critical position towards the inclusion of potency and further elements of hazard characterization: *"page 42-43 of EFSA – there is no scientific basis to include severity, irreversibility, critical effect or potency in the identification of EDCs (lines 385-386 of HEAL response)"*. The response of the Danish EPA refers to EFSA's Scientific Opinion to support their criticism about option 4 (including potency): "*Option 4 is not in line with recommendations from: … - The EFSA scientific committee, which in its scientific opinion discusses potency considerations as a part of the hazard characterization, not as part of the (hazard) identification of endocrine disruptors (EFSA, 2013) (lines 474, 490-492 of Danish EPA response)*". In the responses of HEAL, PAN Europe and the Danish EPA, the JRC is referenced as remarking that the inclusion of potency in any EDS regulatory identification criteria lacks a scientific basis. These examples show how scientific opinions that are generally considered as authoritative and scientifically legitimate can be used to substantiate a particular policy preference, either by allowing for multiple interpretations of their scientific definitions and content, or by attributing different weights to the arguments put forward.

In most responses, it is explicitly supported that their preferred option is 'science-based', although the use of scientific arguments varies substantially. This may stem from uncertainty in the scientific evidence, leading to interpretative ambiguity. It may also be driven by selective use of science-based evidence, to serve the needs of the 'advocacy coalition' to support their normative regulatory preferences.

4.2.2. Weight-of-evidence considerations for identifying EDSs (theme 2)

The European Union chemical substances legislations, such as PPPR, BPR and REACH have provisions that require producers and downstream users to generate a minimum set of safety data for the respective substance. This data will be used to assess whether a substance fulfills the ultimately adopted criteria. Presumably, the starting point for these criteria will be the WHO/IPCS definition, which will subsequently require data that fulfills its key elements. The second *theme* relates to the weight of evidence that is considered both required and achievable to identify a substance as an EDS.

In support of the *position* that the identification of EDSs should occur on the basis of 'lower' weight of evidence requirements, arguments mostly touched upon the limited availability of EDS-related data. Particularly the Dutch and Belgian government responses use arguments referring to data-gaps in the regulatory assessment of EDSs. This finding is consistent with Dutch literature on this issue, where a discrepancy between the testing guidelines included in the EU's relevant regulatory frameworks and the data necessary to fulfill the WHO/IPCS definition is observed (see RIVM, 2016). Several arguments related to the contrasting *position* referred to the abundance or sufficiency, or positive developments regarding (the generation of) EDS-related data.

To support the *position* that the identification of EDSs should occur on the basis of a 'higher' weight of evidence requirement, arguments addressing causality considerations are predominantly used. These are particularly related to availability of alternative explanations for causality, and accordingly, the weight of evidence required to establish an EDS as such. First, a wide variety of potential influences are considered to potentially provide alternative explanations for relationships between exposure to a substance and the incidence of endocrine disruption related adverse health effects. Examples are the existence of other biochemical and physiological mechanisms besides endocrine disruption and the effects of physiological stresses and physical interactions (e.g. temperature). Second, arguments referred to the need to identify EDSs on the basis of certain weight-of-evidence requirements. For example, in the responses of CEFIC and PlasticsEurope, it was stated that EDSs should only be identified "*when there are clear adverse effects unambiguously caused by a well identified and empirically described mode of action" (CEFIC response: lines 289–291; PlasticsEurope response: lines 258–260)*. Alternatively, a contrasting *position* was supported by arguments related to the difficulty of establishing causality between exposure to EDSs and ED-mediated adverse health effects. For example, arguments refer to limitations in current regulatory testing strategies, the ubiquitous nature of exposure to EDSs and the multi-factorial nature of EDS-related adverse effects.

The observation that there are different perspectives as to the weight of evidence that is required and achievable for identifying EDSs is in line with insights from our earlier work. Based on an argumentation analysis of two pertinent publications in the field of EDSs science, Clahsen et al. (2019b) found that different perspectives among EDS experts occurred about the weight of evidence required to propose a certain policy measure. One side argued that objective methods to evaluate the weight of evidence exist and that Bradford Hill's *criteria* are an adequate starting point to establish causality in an unequivocal manner, whereas the other side argued that objective methods to evaluate the weight of evidence do not exist and Bradford Hill's *viewpoints* cannot be applied unequivocally. The researchers assert that this difference in perspectives was at least partly a manifestation of normative ambiguity, a term that refers to differences in (ethical) norms and values (see e.g. Renn, 2008). Accordingly, they conclude that addressing such normative elements in the debate on EDS science may benefit more from opening up the debate to interested and affected parties, than by performing more research.

Since the contrasting *positions* identified here are similarly at least partly normative in nature, normative judgments and not just purely scientific judgments need to be made, for the final selection of the preferred option. In this, the public consultation of the Commission is instrumental. This argumentation analysis shows that normative value judgments, which are often left implicit, can, and should be made explicit and distinguished from the purely interpretative judgment of the underlying science. Accordingly, instances of normative ambiguity could be addressed through broader stakeholder approaches, such as 'extended peer-community' approaches (see e.g. Ravetz, 1999) or participatory discourses (see e.g. IRGC, 2005; Renn, 2008).

4.2.3. Consistency of EDS identification criteria with existing regulations (theme 3)

Various respondents note that compatibility with existing regulatory frameworks is an important requirement for the ultimate identification criteria. The analysis of arguments addressing the consistency of EDS categorization with existing regulatory frameworks (*theme 3*) shows that there appear to be different perspectives towards the compatibility of either a category approach or an option including potency with existing formal provisions, and the wordings thereof, contained in the PPP, BP, REACH, CLP and Cosmetics regulations of the EU.

Supporters of a category approach mostly focused on the consistency of this option with the PPP and BP regulations. This may not be surprising, since the criteria to identify EDSs were specifically developed in the context of these regulatory frameworks. While supporters of an option including potency also addressed a range of arguments related to the consistency of the PPP and BP regulations with this option, most arguments addressed the usefulness of categorizing EDSs as a specific regulatory substance category. This is in line with the *position* referred to by several of these respondents in the context of *Theme* 1; from a toxicological point of view, EDSs are not necessarily different in terms of their toxicological properties, thus, it is not necessary to deal with EDSs differently from a regulatory perspective.

To support the *position* that either a category approach or an option including potency is most compatible with the PPP and BP regulations, different sections of the legal texts were cited. The key sections of these regulatory frameworks, and the different phrases, which relate to the circumstances under which potentially endocrine disrupting PPPs or BPs are approved, are outlined in Table 5. Some responses referred to the 'may cause' wording of the PPP and BP regulations. It is asserted that to identify an EDS in accordance with the WHO/IPCS definition, which includes the phrase 'consequently causes', requires a different and higher weight of evidence than the provisions of the PPP and BP regulations, which include 'may cause' wording. Adopting

Table 5
The key sections and different key phrases of the PPPR and BPR that have been referred to by different respondents to argue for either a 'lower' or 'higher' weight of evidence approach to the identification of EDSs.

Legislation	Key section	Key phrases
PPPR	*"An active substance, safener or synergist shall only be approved if, … it is not considered to have endocrine disrupting properties that* ***may cause*** *adverse effect in humans, unless* ***the exposure*** *of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use,* ***is negligible****, …" (Regulation (EU) No 1107/2009, Annex II, 3.6.5).*	'may cause' adverse effects 'negligible exposure' as exclusion criterion
BPR	*… "active substances which, … are considered as having endocrine-disrupting properties that* ***may cause*** *adverse effects in humans … may be approved if it is shown that …* ***the risk*** *to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use,* ***is negligible****" (Regulation (EU) No 528/2012, Article 5).*	'may cause' adverse effects 'negligible risk' as exclusion criterion

multiple categories that require lower weights of evidence than required for 'confirmed' EDSs is then considered much more appropriate, since this would enable the identification of 'potential' or 'suspected' EDSs, for which there may be indications of endocrine disrupting properties, but insufficient evidence to establish the substance as such. Alternatively, responses identified as favoring an inclusion of potency, inclusion of additional hazard characterization elements or the related risk-based option emphasized the 'negligible exposure' and 'negligible risk' exclusion clauses in the PPP and BP regulations, respectively. It was asserted that any assessment of EDSs under the PPP or the BP regulations would logically require a risk-based approach, since the exclusion clauses could inherently not be triggered without an assessment of relevant exposures. The use of references to specific provisions contained in existing regulatory frameworks was also identified in arguments about the consistency with other regulatory frameworks dealing with chemical substances (i.e. the REACH, CLP and Cosmetics regulations).

4.3. Observations regarding the similarities and differences between the responses

We observed clear differences between the option preferences of different governmental entities, and a similarly clear division between the arguments used to support the different *positions* that are in line with these preferred options. In all responses of the governmental entities that have been identified as explicitly supporting a category approach, or variations thereof (except that of the German UBA), arguments are used that consistently illuminate 'this side of the coin'. By contrast, all responses identified as supporting an option including potency, an option including additional hazard characterization elements or a risk-based option used arguments that consistently address 'this other side of the coin'. For *themes* 1, 2 and 3, virtually all *issues* addressed in support of a category approach (or variations thereof) had blue-left arrows, while simultaneously contra-arguments (purple right-arrows) were expressed in support of an option including potency, or the related two options (Table 4). Similarly, for *themes* 4 and 5, responses identified as being in favor of a category approach (or variations thereof, again excluding German UBA) consistently addressed arguments supporting this preference (green up-arrows), and against an inclusion of potency (red down-arrows). In responses identified as being in favor of an option including potency, a further supplemented hazard characterization option or a risk-based option, the opposite was found, where arguments in favor of including potency (green up-arrows), and against a category approach (red down-arrows) were consistently identified.

It appears that there is particular overlap between the arguments used in responses favoring a category approach. The similarities between the arguments put forward and *issues* addressed in, on the one hand, the French government and Nordic governmental institution responses and, on the other hand, the responses of the NGO's BEUC, HEAL and PAN Europe and the professional medical organization Endocrine Society are notable. Thus, one might argue, the category approach is supported by these parties for generally the same types of expressed reasons.

Where most national governments provided input to the consultation with 'one voice' (primarily through submitting a coordinated response, or a response from one key governmental institution), there are two complementary and partly divergent German responses. Both bring forward mostly arguments on *issues* related to considerations related to the identification of EDSs (*theme* 2) and evaluations of specific aspects related to including potency (*theme* 5). Accordingly, the German UBA and the German BfR both state that an option including potency is most suitable for managing EDSs that pose a risk to human health. Since the German BfR is mostly concerned with human health, their preference for an option including potency may not be surprising. However, the German UBA, also concerned with environmental stressors, notes that only a category approach is suitable for dealing with environmental EDSs. Accordingly, a category approach is the ultimately preferred option of the German UBA. Thus, it appears that the seemingly divergent *positions* are well in line, when viewed from the perspective of the organizations' remit, where UBA primarily takes environmental stress into consideration, while BfR focuses on human health.

Although the Commission proposed only one option that included one additional hazard characterization element (i.e., an option including potency), two additional versions of this option were observed in the analyzed responses: an option including further additional hazard characterization considerations, and a risk-based option that includes exposure considerations. Interestingly, geographically-based differences can be observed between the proponents of the three versions. The hazard-based responses have all been submitted by EU-based actors, whereas the risk-based option responses have all been submitted by non-EU governmental entities. Notably, all non-EU governmental entity responses appeal to the risk-based regulation of EDSs in their own countries, and generally criticize a hazard-based approach as being unnecessarily restrictive. Alternatively, the response of ECPA (18) may be exemplary for actors that would ultimately prefer a risk-based approach to EDSs regulation in the EU, but for pragmatic reasons opt for an option including potency, and additional elements of hazard characterization, which comes closest to a risk-based option but is still essentially hazard-based in nature. "Current EDS regulation in the EU is hazard-based and a switch to risk-based regulation would require complex legislative changes" is one of the arguments brought forward in the ECPA response.

Our results point to the existence of two overarching 'advocacy coalitions', consisting of the respondents that either have a preference for a category approach (or variations thereof) or for an option including potency (or one of the related two options). Among these coalitions, a wide range of arguments are put forward to support contrasting *positions* concerning scientific, regulatory scientific and regulatory arguments (i.e. *themes* 1 to 3) to support their contrasting option preferences. It should be noted that these coalitions may not be entirely homogeneous. With regard to the respondents that are ultimately sympathetic to a category approach, the French and Scandinavian governments and all NGO's used slightly different types of arguments and supported this option more unequivocally than the Belgian and Dutch governments and the German UBA, that included some reservations and require some adjustments. In addition, There are some (geography-based) differences between the arguments put forward and the exact options supported by the German BfR (supporting an option

including potency), the industrial trade organizations and the U.K. government (supporting an further supplemented hazard characterization option) and the non-EU trade partners (supporting a risk-based option not included in the consultation). Since this study using argumentation analysis is inherently cross-sectional in nature, it studies the state-of-affairs at one static moment in time and cannot assess any actual interaction between the respondents, this study cannot discern 'advocacy coalitions' as originally intended by Sabatier and Jenkins-Smith (1993). Future research should focus on the actual degree of interaction between responses considered part of the same 'advocacy coalition'.

The proposed existence of (implicit) advocacy coalitions, and the wide variety of disagreements among these coalitions, raises questions as to how proceed further with the issue of the EDS identification criteria. It should be noted that substances associated with endocrine disrupting properties are widely used, and societal impacts associated with these uses may be significant in terms of adverse health effects and environmental stress, but also with regard to economic well-being, competitiveness of chemical industries and innovative potential. We made explicit how arguments related to scientific knowledge were used in conjunction with arguments related to normative value-judgments. On this basis, we argue that, for the ultimately adopted EDS identification criteria to become accepted in the EU society, the debate on these criteria would benefit from a societal dialogue. Here, the various scientific, regulatory scientific and regulatory aspects should be explicitly approached as interrelated themes. This dialogue should be open to all interested and affected parties, and could be performed in accordance with inclusive approaches as proposed in contemporary risk governance literature (see e.g. IRGC, 2005; Renn, 2008).

5. Conclusion

In an analysis of the EU's public consultation related to the impact assessment to select identification criteria for the regulation of EDSs, five topical *themes* and 21 underlying *issues* were identified. For each *theme*, two contrasting *positions* were discerned; one most in line with a preference for a category approach (or variations thereof), and one most in line with a preference for including potency (or related options). Accordingly, we argue that two overarching (implicit) 'advocacy coalitions' can be identified, using a wide range of contrasting arguments, related to the five identified *themes*, to support their preferred option. Among these 'coalitions', there appears to be consensus about the necessity of the ultimate option to be science-based, although different perspectives were identified as to what the most accurate mechanistic understanding of EDSs entails. We identified geography-based differences between the option preferences of countries; all responses of EU-based parties ultimately preferred hazard-based options, whereas the responses on non-EU-based parties preferred a risk-based option not included in the consultation. To move the discussion on EDS identification criteria forward, we argue that a societal dialogue would be beneficial, in accordance with contemporary risk governance literature, where EDS science and regulation are explicitly discussed as interrelated themes.

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CRediT authorship contribution statement

Sander C.S. Clahsen: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing - original draft.**Lana Moss:**Formal analysis, Investigation, Writing - review & editing.**Irene van Kamp:** Conceptualization, Methodology, Writing - review & editing, Funding acquisition.**Theo G. Vermeire:**Conceptualization, Methodology, Writing - review & editing, Funding acquisition, Project administration.**Bart J. Garssen:**Conceptualization, Methodology, Writing - review & editing. **Aldert H. Piersma:**Conceptualization, Methodology, Writing - review & editing, Supervision, Funding acquisition.**Erik Lebret:** Conceptualization, Methodology, Writing - review & editing, Supervision, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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