Member States Reporting under REACH art. 117

Fields marked with * are mandatory.
General Information
Please note that depending on what your answers are throughout the questionnaire, hidden questions may show up, so please disregard the numbering in case it does not follow a logic order.
A glossary is available in the section 'background document'.
1. Which Member State are you reporting for?*
Belgium
2. Primary contact person's name*
3. Please provide an email address for the primary contact person*
info@environment.belgium.be
Theme 1 - Information on the Competent Authority
4. Please explain how Competent Authorities are organised for the operation of REACH in your country? (Please note that this Section does not include information on enforcement authorities that will be covered under Theme 9 on enforcement)
There is 1 Competent Authority in Belgium.
5. How many Competent Authorities are responsible for REACH?*
A description of each Competent Authority will be asked in the following sections. Similar series of questions corresponding to the number of Competent Authorities you enter will appear below.
1

6. What is the name of the Competent Authority?**
Risk Management of Chemical Substances Unit
Department of Product Policy and Chemical Substances
DG Environment
Federal Public Service
Health, Food Chain Safety and Environment
7. What is the address of the Competent Authority? *
Eurostation-Blok II
2 nd Floor
Victor Hortaplein 40, box 10 B - 1060 Brussels
BELGIUM BELGIUM
BELGIOW
8. What is the email address of the Competent Authority?**
catheline.dantinne@environnement.belgique.be
+32(0)2 524.95.87 10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction
10. What part of REACH does this part of the Competent Authority deal with? Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction Registration
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction Registration Other If Other, please list the other parts of REACH that this part of the Competent Authority deals with:* CLH, nano, endocrine disruptors, PBT, read across, REACH & other legislation
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction Registration Other If Other, please list the other parts of REACH that this part of the Competent Authority deals with:* CLH, nano, endocrine disruptors, PBT, read across, REACH & other legislation 11. From what part of Government does this part of the Competent Authority have authority from?*
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction Registration Other If Other, please list the other parts of REACH that this part of the Competent Authority deals with:* CLH, nano, endocrine disruptors, PBT, read across, REACH & other legislation 11. From what part of Government does this part of the Competent Authority have authority from?* Please choose one or more answers.
10. What part of REACH does this part of the Competent Authority deal with?* Please choose one or more answers. All Evaluation Risk Assessment Helpdesk Authorisation Restriction Registration Other If Other, please list the other parts of REACH that this part of the Competent Authority deals with:* CLH, nano, endocrine disruptors, PBT, read across, REACH & other legislation 11. From what part of Government does this part of the Competent Authority have authority from?*

Consumer Protection

Economy/Industry

Other

f Other, please list the other part of Government the Competent Authority gets authority from: *			
NA			
12. Please specify the market REACH:*	umber of staff of the Comp	petent Authority w	orking on the implementation of
12			
Time Equivalent).*	ised staff in the following c		e quantify these skills in FTE (Full
	Number of FTE		
Toxicologist	2		
Ecotoxicologist	2.5		
Chemist	1		
Exposure Assessor	0,5		
Risk Assessor	1		
Risk manager	2		
Economist	0		
IT	0.5		
Communication	0		
Other	2.5		
14. Is the level of expert REACH?*	ise of the Competent Author	ority adequate to	deal with all requirements under
	ne expertise (eg . by public ter staff is inadequately resou		wing reasons:

15. Are the staff of the REACH Competent Authority involved in other chemical legislation?*

Lack of expertise in socio-economic analysis and risk communication, lack of expertise for specific endpoints in toxicology, specific expertise e.g. epidemiology, process engineering,

An insufficient number of employees,

Reduced operating funds.

Yes

No No

16. What other chemical legislation are the staff of the REACH Competent Authority involved in?*
Please choose one or more answers.
☐ PIC Regulation
Food legislation
Workers Protection legislation
Cosmetics
Medical devices
□ Biocides
□ CLP
Pesticides Pesticides
□ POPs
Other
If Other, please list the different legislations here:*
Mercury, SAICM, Nanomaterials, OECD, endocrine disrupters, PBT
17. Are there any other institutions (agency, institute, regional authorities) that the Competent Authority
works with in relation to REACH issues?*
Yes
○ No
If Yes, please list the other institutions that the Competent Authority works with:*
- Walloon Region - Directorate-General for Agriculture, Natural Resources and the
Environment (DGARNE),
- Brussels-Capital's Region - Brussels Institute for the Management of the Environment (BIME),
- Flemish Government - Environment, Nature and Energy Department - Environment Inspection Service,
- Federal Public Service Economy, Self Employed and Energy (Helpdesk),
- Federal Public Service Economy, Self Employed and Energy (Helpdesk), - Federal Public Service Employment, Labour and Social Dialogue,
- Federal Public Service Economy, Self Employed and Energy (Helpdesk),
 Federal Public Service Economy, Self Employed and Energy (Helpdesk), Federal Public Service Employment, Labour and Social Dialogue, Customs government, Scientific Institute of Public Health.
- Federal Public Service Economy, Self Employed and Energy (Helpdesk), - Federal Public Service Employment, Labour and Social Dialogue, - Customs government, - Scientific Institute of Public Health. 18. Does the Competent Authority outsource any of its work?*
 Federal Public Service Economy, Self Employed and Energy (Helpdesk), Federal Public Service Employment, Labour and Social Dialogue, Customs government, Scientific Institute of Public Health.
- Federal Public Service Economy, Self Employed and Energy (Helpdesk), - Federal Public Service Employment, Labour and Social Dialogue, - Customs government, - Scientific Institute of Public Health. 18. Does the Competent Authority outsource any of its work?*

If yes, please provide details on who the Competent Authority outsources parts of its work to:*
External technical experts and scientists.
The BE legislator has established a Scientific Committee REACH whose members are working for universities and scientific institutes. This committee can offer advice to the BECA.
And on what type of expertise is outsourced:*
Specific fields of (eco)toxicology, risk management, endocrine disruptor, market study
19. Does the Competent Authority have appropriate financial resources?**
1 = Very low (not appropriate at all); 2 = Low (of some relevance but not of any great significance); 3 = Medium (reasonably appropriate); 4 = High (highly appropriate); 5 = Very high (completely appropriate) 1 2 x 3 4 5
20. Does the Competent Authority have appropriate technical resources (understood in terms of
expertise, skills and competences of the staff)?*
1
21. Does the Competent Authority have appropriate human resources (understood in terms of number of
staff)?**
x 2

0 4

5

The absence of the compensation for the CLH work in RAC has an negative impact on staff capacity. This is a reason why Belgium has no second RAC member.
Theme 2: Information on cooperation and communication with other
Member States, the European Chemicals Agency (ECHA) and the
Commission
23. How could the communication and collaboration for REACH between Member States be improved?*
1,800 character(s) maximum
RiME meetings are a good platform for communication between MS. Collaboration is more and more effective (on specific substances, in the context of RMO analysis for instance).

22. Space is available below to provide further comments on the resourcing of the Competent Authority.

24. How could the collaboration with other agencies in your country be improved?*

1,800 character(s) maximum

From early 2013 on, in Belgium the coordination of the implementation of REACH is laid down in a Cooperation Agreement between the different federal and regional authorities competent for REACH. The Agreement has the force of law.

Financial resources by these authorities are foreseen for the coordination (secretariats of 3 committees: policy, enforcement, scientific) by 2 FTE and for the external expertise by the scientific committee (Scientific Committee REACH).

The policy committee is in particular a forum to exchange information on general (policy) issues and to approve initiatives of the BECA (for substance evaluation, Annex XV, ...). The collaboration with the other BE authorities is a learning process and the policy committee facilitates the communication between the BE authorities. The exchange of information on substances that give concern on the environment and occupational health should be further improved to initiate action by BECA.

25. How could the communication and collaboration with ECHA be improved?*

The communication via email from ECHA to MS could be improved. In order to avoid the loss of emails, as happened previously, ECHA is suggested to use the same mailing list as the COM or to clearly identify the group concerned, e.g., differentiate between the MS and the CA.

For some aspects (e.g. Security Officers Network), the communication by ECHA is well improved: the information on the roles and tasks are well defined, answers are provided to questions within a reasonable time.

30. What is (are) the email address(es) of the Helpdesk(s)?*
reachinfo@economie.fgov.be
31. What is (are) the telephone number(s) of the Helpdesk(s)?*
+ 32 (0) 800 120 33
 32. What is the institutional structure of the Helpdesk(s)?* X Separate independent entity(ies) Part of Competent Authority Part of business association/chamber of commerce Other
If other, please specify*

33. Please quantify these skills in FTE (Full Time Equivalent).* Number of FTE Toxicologist Ecotoxicologist Chemist 2 Exposure Assessor Risk Assessor Risk manager Economist 0 IT Communication Other 0 34. Is the level of expertise adequate to respond to all enquiries?* X Yes O No If 'no', please specify what expertise is missing:* 35. For which topics does the national helpdesk feel it necessary to refer the enquirer to the ECHA helpdesk?* REACH-IT, IUCLID

36. What are the services offered by the Helpdesk?*
Please choose one or more answers. X Website X Newsletter Advice services Trainings Mediation / conflict resolution X Other
If 'Other', please specify:*
 Presentations / workshops Regular meetings with industry representatives
37. In which language(s) are these services accessible?*
French, Dutch & English
38. Is the same Helpdesk used to provide help to Industry on CLP?* Yes X No
39. Does the Helpdesk receive any non-governmental support?* Ves X No
40. Please describe the Helpdesk quality assurance mechanisms:* Each answer is checked by a second person.

41. Is ISO9000 norm in place?*

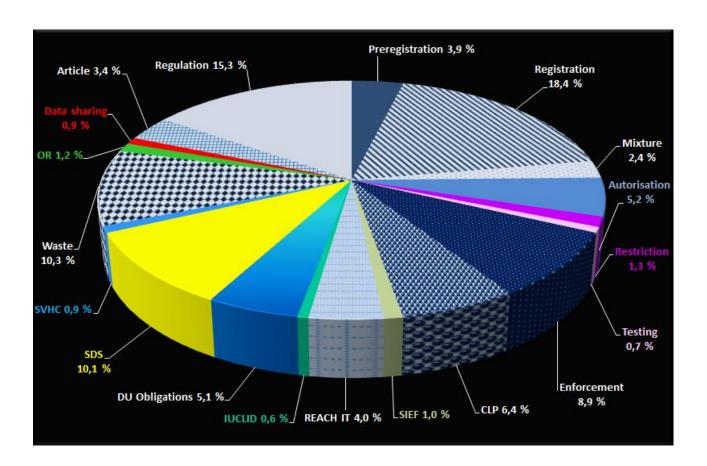
O Yes

45. What is the company size of enquirers? (please specify the percentage of the total each of them represent)*

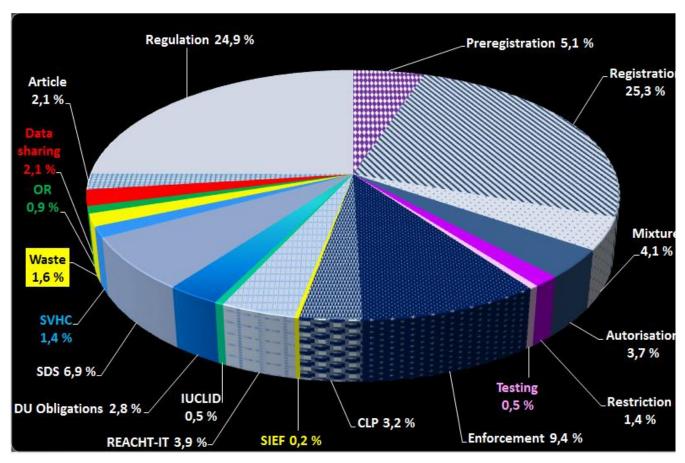
If no information is available for a specific type of company, please indicate N/A in the corresponding box.

	%
Large enterprises	N/A
Medium enterprises and Small enterprises	80-90%
Micro enterprises	N/A
Other	N/A

46. For each type of enquiry received, please provide the percentage of the total number of enquiries during the reporting period: **YEAR 2015** + **2016**



46. For each type of enquiry received, please provide the percentage of the total number of enquiries during the reporting period: **YEAR 2017**



Pre-registration*

Please insert a figure. The individual percentages should add up 100% altogether.

Registration*

2015 + 2016 : 18,4 % 2017 : 25,3 %

Evaluation*

2015 + 2016 : 0 % 2017 : 0 %

Authorisation*

2015 + 2016 : 5,2 % 2017 : 3,7 %

Restriction*

Testing (Information requirement/registration)*

2015 + 2016 : 0,7 % 2017 : 0,5 %

Data sharing*

2015 + 2016 : 0,9 % 2017 : 2,1 %

```
Enforcement*
```

```
2015 + 2016 : 8,9 %
2017 : 9,4 %
```

CSR preparation*

```
2015 + 2016 : 0 %
2017 : 0 %
```

CLP Classification*

```
2015 + 2016 : 6,4 %
2017 : 3,2 %
```

CLP Labelling*

```
Included in CLP Classification
```

CLP Packaging*

```
Included in CLP Classification
```

CLP Classification and labelling inventory*

```
Included in CLP Classification
```

SIEFs*

```
2015 + 2016 : 1,0 %
2017 : 0,2 %
```

REACH-IT*

```
2015 + 2016 : 4,0 %
2017 : 3,9 %
```

IUCLID*

```
2015 + 2016 : 0,6 %
2017 : 0,5 %
```

Downstream user obligations*

```
2015 + 2016 : 5,1 %
2017 : 2,8 %
```

Only	representative	obligations*

2015 + 2016 : 1,2 %
2017 : 0,9 %

Obligations regarding articles*

```
2015 + 2016 : 3,4 %
2017 : 2,1 %
```

Safety Data Sheets*

```
2015 + 2016 : 10,1 %
2017 : 6,9 %
```

SVHC*

2015	+ 2016 : 0,9 %
2017	: 1,4 %

Other*

2015 + 2016 : 28 % 2017 : 30,6 %

47. Are enquiries received mostly:*

'Straight-forward' is understood as those enquiries that can be answered without performing any prior research.

'Complex' is understood as those enquiries that require a minimum level of research before been answered or that demand exhaustive elaboration.

- X Complex
- Straightforward
- No information

48. What proportion of enquiries received are deemed to be: 1) straight forward*

Please provide an approximate estimation as an average per year. The individual percentages should add up 100% altogether.

50 %

2) complex*

50 %

49. How long, on average, does it take to respond to the following types of questions? 3 > 2 1 No 2 info 50

		nours	uay	days	week	weeks	weeks	11110				
	Straight forward questions*	0	0	X	0	0	0	0				
	Complex questions*	0	©	0	X	0	0	0				
50.	Are any types of enquiry out	tsourced?	·									
	X Yes											
	O No											
51.	51. What types of enquiry are outsourced?*											
Pl	ease choose one or more answers.											
	Pre-registration											
	Registration											
	Evaluation											
	Authorisation											
	Restriction											
	Testing											
	Enforcement											
	CSR preparation											
	X CLP											
	□ SIEFs											
	X REACH-IT											
	X IUCLID5											
	Downstream user oblig											
	Obligations regarding atSafety Data Sheets	rticles										
	SVHC											
	X Other (please list)											
	N Other (pieuse list)											
If Other, please list the other types of enquiries that are outsourced:*												
Bi	Biocides											

Biocides			

52. Does the Helpdesk seek feedback on its performance?*
X Yes
No
If yes please specify by whom and what the result was:*
Feedback received from clients and federations. Results: prompt response, helpful and clear guidance.
53. Does the Helpdesk review its performance and consider ways to improve its effectiveness?*
X Yes
O No
If yes, what were the measures taken to improve its effectiveness?*
Preparation of 'standard answers'. Continuous update of questions database.
54. How could the cooperation between Helpdesks <u>under</u> Helpnet be improved?
1,800 character(s) maximum
The cooperation between helpdesk works very well. The Helpex helps a lot to answer
the questions received by the Belgian REACH helpdesk.
55. How could the cooperation between Helpdesk <u>outside</u> Helpnet be improved?
1,800 character(s) maximum
The Belgian helpdesk REACH is already working with the Belgian federations but
also the European federations. An important element is the distribution of information
through the conferences, workshop

56. How frequently do you use HelpEx?*
Daily
X Weekly
Monthly
Less frequently
Theme 4: Awareness raising activities
57. Has the Member State carried out any specific awareness raising activities?*
X Yes
O No
58. What types of activities have been carried out?*
Please choose one or more answers.
Television spots
Articles in Newspapers
Radio spots
X Speaking events
☐ Information seminar
Telephone surveys
X Leaflets and newsletters
Articles in industry magazines
X Website / Social Media
Other
If other, please list the activities that have been carried out:*

59. Who is the target audience for your awareness raising activities?*
Please choose one or more answers.
Consumers directly
Consumers indirectly through multipliers (media, associations etc)
☐ SME in downstream sectors
All companies in downstream sectors
SMEs in chemicals sector
X All companies in chemicals sector
Other
If 'Other', please specify:**
60. Please describe how the information was adapted for the specific target audience:

61. How effective was each type of activity?

 $1 = Very \ low \quad (not \ appropriate \ at \ all); \ 2 = Low \quad (of \ some \ relevance \ but \ not \ of \ any \ great \ significance); \ 3 = \quad Medium \ (reasonably \ appropriate); \ 4 = High \ (highly \quad appropriate); \ 5 = Very \ high \ (completely \ appropriate)$

If you have not ticked an activity in question 59, please state N/A.

	1	2	3	4	5	N/A
Television spots*	0	0	0	0	0	X
Articles in Newspaper*	0	0	0	0	0	X
Radio spots*	0	0	0	0	0	X
Speaking events*	0	0	0	Х	0	0
Information seminar*	0	0	0	0	0	X
Telephone surveys*	0	0	0	0	0	X
Leaflets and newsletters*	0	0	х	0	0	0
Articles in industry magazines*	0	0	0	0	0	X
Websites / social media*	0	0	0	Х	0	0
Other*	0	0	0	0	0	Х

	Websites / social media*	0	0	0	Х	0	0
	Other*	0	0	0	0	0	X
	Do you measure the effectiveness	s of the	activi	ties?*			
	Yes X No						
63.	If yes, how?*						

64. Do you have a REACH webpage/website?*
X Yes
O No
65. Do you have a single webpage for REACH or multiple pages?
Single webpage
X Multiple webpages
66. How frequently is the REACH webpage visited (per month)?
© 1-100
0 101-500
© 501-5000
© 5001+
X No information
Theme 5: Information on the promotion of the development, evaluation
and use of alternative test methods
67. Does the Member State contribute to EU and/or OECD work on the development and validation of
alternative test methods by participating in relevant committees?*
Yes
○ No
68. What has been the overall public funding on research and development of alternative testing in
your Member States each year?*
Euros 0 10,000 Euros 10,001-100,000
Euros 100,001-1,000,000
More than Euros 1, 000, 000
No information
69. Please mention other relevant activities carried out on information on the Promotion of the Development, Evaluation and Use of Alternative Test Methods:
No information

Theme 6: Information on participation in REACH Commission and ECHA expert groups / committees (Forum, REACH Committee, MSC, RAC, SEAC, CARACAL, RCN, Helpnet)

a.	
70. How effective is the work of the FORUM Committee?*	

1 = Very low (not appropriate at all); 2 = Low (of some relevance but not of any great significance); 3 = Medium (reasonably appropriate); 4 = High (highly appropriate); 5 = Very high (completely appropriate)

1
2

345

71. Please specify if needed:

1,800 character(s) maximum

There are opportunities for improvement.

72. How could the effectiveness be improved?

1,800 character(s) maximum

Effectiveness could be improved e.g.

- by reducing the time alotted to information transfer during plenary meetings (pure messaging) and replacing this by decision making events;
- by reducing the time alotted to contemplations/discussions during plenary meetings (e.g. LESS Break Out Groups sessions and replacing this by focusing more on handing out practical instruments/tools in support of inspection work;
- by structuring communication in replacement of present disperse messaging interaction
- by empowering WGs / individual WG members towards entrepreneurship and innovation (e.g. LESS ECHA MORE MS)

73. How effective is the work of the REACH Committee?*

12

x 3

\(\sigma \)

O 5

74. Please specify if needed:

1,800 character(s) maximum

The effectiveness is depending on the subject. The lobbying of the industry has sometimes too much influence on the work of the REACH Committee. The presidency of the Committee lacks sometimes neutrality.

The role of the RAC / SEAC Secretariat representative (by ECHA) could be more active during the Committee meeting.

We have seen an improvement in the quality of the preparatory documents. However the delay for delivery is not satisfactory.

. How could the effectiveness be improved?	
1,800 character(s) maximum	
ee above	

- _1
- 0 _
- W 2
- x 4
- © <u>5</u>

77. Please specify if needed:

Efficiency seems to have increased in 2017.

78. How could the effectiveness be improved?

1,800 character(s) maximum

- Some remarks were already mentioned in the previous reports of 2010 & 2015 and no favorable change was observed. Therefore, Belgium asks the Commission to take carefully into account the comments and the suggestions of improvements made by the Member States.
- Information obtained by ECHA (and its experts) should reach the members in due time in order to prepare for the meetings.

- Although timing within the REACH procedures is limited, it is important to allow room for consulting experts on the issues that are being discussed.
- New information often comes up within the meeting discussions. This doesn't leave time for verification or consultation within the MS.
- Specific expertise is sometimes lacking.

79. How effective is the work of the Risk Assessment Committee (RAC)?*	
O 1	
© <u>2</u>	
x 3	
© <u>5</u>	
80. Please specify if needed:	
1,800 character(s) maximum	
RAC benefits from the experience of several members who were involved in former scientific committees. Also the support of the RAC secretariat is very helpful.	
81. How could the effectiveness be improved? 1,800-character(s) maximum	
Some remarks were already mentioned in the previous reports of 2010 & 2015 and no favorable change was observed. Therefore, Belgium asks the Commission to take carefully into account the comments and the suggestions of improvements made by the Member States. The workload has considerably increased for the last years due to the higher number of submitted dossiers (application for authorisation).	
As a consequence, the pressure is increasing for the members due to the short time for commenting the dossiers. The fast track procedure is time gaining, but has a negative impact on quality of the assessment by the RAC.	
Some members are lacking of experiences as well as support from their MS, which restrict them to take the rapporteurship for dossiers.	
Another issue is the lack of coordination between the different EU committees (SCOEL,BPC,EFSA)	
The non-remuneration of the members for CLH dossiers.	
ECHA should provide a substantial remuneration for the Member States that nominate committee members in order to ensure a full participation of all members.	
Although the workload of this committee will continue to rise, it is advisable not to exceed a requency of 5-6 meetings/year of maximum 3-4 days/meeting. Priority should be given to careful planning of meeting agendas to allow for sufficient time for substance-related discussions.	

- 4
- © <u>2</u>
- © <u>3</u>
- X 4
- © <u>5</u>

83. Please specify if needed:

1,800 character(s) maximum

In general SEAC works quite efficiently.

The guidance provided to rapporteurs (authorisation) by ECHA is extensive and greatly appreciated. ECHA sometimes tries to push the opinions too fast through the Committees, but speed for speed's sake is way of working that should be avoided and the independence of the rapporteurs should be respected.

In the last couple of years the Commission has also become too involved in the plenary discussions in terms of content.

Some members are lacking experience as well as support from their MS, which restrict them to take the rapporteurship for dossiers. It is also clear that not all members are contributing equally which puts even more strain on the members that actually do take up rapporteurships.

Rapporteur appreciate the fact that ECHA has taken measure to increase the time of consultation to 2 weeks in general.

Don't have specific view on the new way to register to be rapporteur.

84. How could the effectiveness be improved?

1,800 character(s) maximum

Care should be taken that all members have an equal workload and that they remain able to act independently. They must not be forced to arrive at their conclusions rashly and be given sufficient time to do their work in a conscientious fashion. The last couple of years more members have been taking part in the different processes, but this can still be improved.

The restriction process has gained momentum since 2010 and many problems have already been acknowledged and resolved. Other ways to increase the effectiveness are being sought by the restriction Task Force and will show their usefulness (or not) in the coming years.

85. Ho	w effective is the work of the CARACAL (Competent Authorities for Reach and CLP)?*
0	1
	2
	3
	4
	5
The are	ase specify if needed:
represer	up deals with political issues and the interpretation of REACH where all the MS are nited, together with the COM and ECHA. It enables to have a real overview of the REACH on in all the other fora and to identify the gaps and needs.
represei discussio	up deals with political issues and the interpretation of REACH where all the MS are nted, together with the COM and ECHA. It enables to have a real overview of the REACH

1,800 character(s) maximum

Some remarks were already mentioned in the previous reports of 2010 & 2015 and no favorable change was observed. Therefore, Belgium asks the Commission to take carefully into account the comments and the suggestions of improvements made by the Member States.

The duration/frequency of the meetings should be adapted. In its current form, all the agenda points cannot be discussed in detail. Furthermore, the political and technical discussions are mixed. It is suggested to have some more logic grouping of the agenda points. We also would like to have clear decision after a discussion in the CARACAL – some agenda point were discussed several times without conclusions.

- 0 1

- © 2 © 3 x 4 © 5

89. Please specify if needed:
1,800 character(s) maximum
90. How could the effectiveness be improved?
1,800 character(s) maximum
91. How effective is the work of the HelpNet Committee?*
1 0
2 X 3
4
© 5
92. Please specify if needed
1,800 character(s) maximum
Many documentations, guidance and information are given during the Helpnet Committee.
93. How could the effectiveness be improved?
1,800 character(s) maximum
No opinion

Theme 7: Information on Dossier Evaluation and Substance Evaluation activities

D	ossi	ier	ev	al	uat	tio	n

94. Has the Member State been involved in Dossier evaluation within the reporting period?*
© Yes
O No
95. How many testing proposal draft decisions have you evaluated within the reporting period?*
Please insert a figure.
2015, 2016, 2017 : 0
96. How many proposals for amendment have you issued within the reporting period?*
Please insert a figure.
2015, 2016, 2017 : 0
2013, 2010, 2017 . 0
97. On average how many persons-days are dedicated per year to dossier evaluation (excluding
presence in the Member State Committee)?*
Please insert a figure.
5 days
98. Do you outsource dossier evaluation to external contractors?*
© Yes
◎ No
If yes, please specify the expertise outsourced:*

99. Do you consider that the dossier evaluation process, as currently structured, has to date served its
purpose?*
© Yes
O No
100. How could it be improved?
1,800 character(s) maximum
The quality of many registration dossiers is not good enough to fulfill the purposes of the REACH registration process. The compliance check of only 5% of the dossiers is not good enough to ensure the good functioning of the key processes of REACH such as substance evaluation. Lots of time is spend on this process (decision making), while many dossiers are still not compliant. Efficiency should increase in the decision making phase.
The Forum could also help on issues about registration dossiers that are not (to be) managed through compliance check or substance/dossier evaluation.
We recommend a pilot project seeking at checking the conformity of the registration dossiers with the reality on the field (for instance: are all applications by covered companies indeed included in the dossier? are all the potential exposures included? Is the volume range correct? Is the trade name(s) of the substance correct?).
It is important to launch this initiative in the frame of the Forum activities as the collaboration on such initiative is considered as an important enabling factor and also because the exchange on information to validate the gathered data might prove necessary for the validation.
101. Have you carried any follow-up actions in relation to dossier evaluation within the reporting period?*
♥ Yes♦ No
140
If yes, please describe enforcement actions and results obtained:
ECHA issued a certain amount of SONCs (statement of non-compliance) following dossier evaluation decisions for BE companies. Sometimes the company contacted spontaneously the BECA or the Enforcement Department, willing to update their dossier in order to end the SONC. In the other cases the Enforcement Department made a site visit in order to urge the company to update their dossier. Close cooperation and good communication between BECA, the enforcement department and ECHA was necessary to manage the SONCs. In general the companies are willing to update their dossier with the right information.
Substance evaluation
102. Has the Member State been involved in substance evaluation within the reporting period?* Yes No

103. How many substances evaluated resulted in a draft decision within the reporting period?*

Please insert a figure.

2015: 4 from 2014 evaluations, however, 1 needed to be dropped due to seize manufacture 2016: 3 from 2015 evaluations

2016: 3 from 2015 evaluations **2017:** 1 from **2016 evaluations 2018:** 1 from **2017 evaluations**

104. On average, how many person-days have been employed in the evaluation of each substance

within the reporting period?*

Please insert a figure.

62 person-days (8h/day)

		1		1.	
 Indicate if possible what tas Searching for additional in and/or constituents 					re on transformation products
Understanding and evalua	nting in	depth i	nformati	ion on s	pecific topics
Developing a solid argume	entation	n to sup	port the	Draft D	ecision
consideration (legal, scien	tific, pr	oportio	nality,	.)	ft decision which requires careful
	0	1-5	6-10	>10	
Toxicologist*	0	x	0	0	-
Ecotoxicologist*	0	x	0	0	
Chemist*	0	x	0	0	
Risk Assessor*	x		©	0	
Social-Economic Analyst*	x	0	0	0	
	0	x	0	0	
Exposure Assessor*					1

108. Do you outsource substance evaluations to external contractors?*
○ Yes○ No
If yes, please specify the expertise outsourced:*
Genotox, ED, read-across
109. Have you collaborated with other Member States in any of these evaluations within the reporting period?* Yes No If yes, please specify the nature of the collaboration:*
Preparing in mutual conciliation draft decisions of very similar substances
110. Have you initiated any action under other REACH processes as a consequence of substance evaluation performed by you or another Member States (e.g. Annex VI dossier for harmonised C&L, annex XV dossier for SVHC ID or restriction, other non-REACH regulatory action) within the reporting period?* X Yes No
Anne XV C&L dossier for 1,2,4-triazole and 2,4,6-TTBP
AITHE AV COLL GUSSIEL TOL 1,2,4-CHOZUIE AITU 2,4,0-1 LDF

Financial resources can be allocated to substance evaluation for scientific advices on specific topics – it's case by case (less than 40.000€/y)	done
112. Do the fees delivered for evaluation equate the financial resources involved in substance evaluation?	
O Yes O No	
113. Do you foresee an increase of resources dedicated to substance evaluation in the coming years Ves No	?
114. Have you encountered any problems while carrying out the substance evaluation? Ves No	
/If yes, please specify:	
A correct evaluation asks sometimes for specific scientific knowledge that is very difficult to	find
Understanding and applying the administrative protocols (IUCLID) to exchange information is from straightforward.	s far
The bad quality of some registration dossiers makes the evaluation more difficult.	
Theme 8: Annex XV Dossiers (restriction and identification of SVHC) at other points related to the identification of SVHC	nd
·	nd —
other points related to the identification of SVHC	
other points related to the identification of SVHC Annex XV Restriction Dossiers 115. Has the Member State been involved in the preparation of Annex XV Restriction Dossiers within	

period?*

Please insert a figure.

117. Among these how many were co-prepared with other Member States/ECHA?* Please insert a figure.
N/A
118. How many person-days were dedicated to the development of Annex XV restriction dossiers?* Please insert a figure. N/A
119. How many person-days were dedicated to the assessment of Annex XV restriction dossiers?* Please insert a figure. N/A
120. How many times a representative of your Member State has been nominated rapporteur under the Risk Assessment Committee (RAC) within the reporting period?* Please insert a figure. 2015:1 (CLH); 2016:0:2017:0
121. How many times a representative of your Member State has been nominated rapporteur under the Socio-Economic Committee (SEAC) within the reporting period?* Please insert a figure. 2015: 1 (autorisation _MRBC) + 8 (MINECO)
2016: 1 (autorisation _MRBC) + 13 (MINECO) 2017: 0 (autorisation _MRBC) + 1 (MINECO)
122. How many times a representative of your Member State has been nominated co-rapporteur under
the Risk Assessment Committee (RAC) within the reporting period?*
Please insert a figure. 2015:0;2016:0;2017:0
123. How many times a representative of your Member State has been nominated co-rapporteur under
the Socio-Economic Committee (SEAC) within the reporting period?*
Please insert a figure.
2015: 0 (autorisation_MRBC) + 0 (MINECO)
2016: 4 (autorisation_MRBC) + 0 (MINECO)
2017: 9 (autorisation_MRBC) + 0 (MINECO)

124. What expertise is available for preparing Annex XV restriction dossiers (available FTE per year)

NIETS INVULLEN of 0

	0	1-3	4-6	7-9	>9
Chemist*	0	0	0	0	0
Toxicologist*	0	0	0	0	0
Ecotoxicologist*	0	0	0	0	0
Epidemiologist*	0	0	0	0	0
Economist*	0	0	0	0	0
Enforcement*	0	0	0	0	0
Legal*	0	0	0	0	0
Policy*	0	0	0	0	0
Exposure Assessor*	0	0	0	0	0
Risk Assessor*	0	0	0	0	0
Other (please list):*	0	χ©	0	0	0

If Other, please list:* 0.5 = policy, legal, enforcement support

125. Do you outsource Annex XV restriction dossiers?*

O Yes

O No

If yes, please specify the expertise outsourced:*
126. Is the Member State satisfied with the levels of access to outsourced expertise?*
1 = Very low (not appropriate at all); 2 = Low (of some relevance but not of any great significance); 3 = Medium (reasonably appropriate); 4 = High (highly appropriate); 5 = Very high (completely appropriate)
© 3 © 4
© 5
Please provide additional comment if needed:
1,800 character(s) maximum
127. Has there been any enterprises consultation/involvement in the preparation of Member State
dossiers? *
© Yes
O No
100 IC
128. If yes, what was the level of involvement of enterprises in the preparation of Member State
dossiers?*
1 = Very low (not involved at all); 2 = Low (involved but not of any great significance); 3 = Medium (reasonably involved); 4 = Hig (highly involved); 5 = Very high (fully involved)
1
© 2
© 5

Please provide additional comment if needed:
1,800 character(s) maximum
129. Among these enterprises, were there SMEs also consulted/involved in the preparation of Member
State dossiers?*
O Yes
O No
130. If yes, what was the level of involvement of SMEs in the preparation of Member States dossiers?*
1 = Very low (not involved at all); 2 = Low (involved but not of any great significance); 3 = Medium (reasonably involved); 4 = Hig
(highly involved); 5 = Very high (fully involved) 1
3
© 5
Please provide additional comment if needed:
1,800 character(s) maximum
Annex XV SVHC Dossiers
131. Has the Member State been involved in the preparation of Annex XV SVHC Dossiers?*
O Yes
□ No
100 H
132. How many Annex XV SVHC dossiers has the Member State prepared within the reporting period?*
Please insert a figure. 2015: 2
2016 : 0

2017: 0

133. Among these how many were co	o-prepared with other Member State/ECHA?*
Please insert a figure.	
2015 :	
2016 : N/A 2017: N/A	_
134 How many person-days were de	dicated to the development of Annex XVSVHC dossiers?*
Please insert a figure.	diction to the development of rimies 11 + 5 + 11e dossions.
2015 :	
2016 : N/A	_
2017 : N/A	
135. How many person-days were de	dicated to the assessment of Annex XV SVHC dossiers?*
Please insert a figure.	
2015 :	
2016: 3 person-days (dossiers of o	ther MS)
2017: 6 person-days (dossiers of o	ther ivis)
136. How many times a representativ	e of your Member State has been nominated rapporteur under the
Member States Committee (MSC) w	within the reporting period?*
Please insert a figure.	Tunn the reporting period.
2015 : 0 but we don't know exact	ctly what is meant here with 'rapporteur'.
2016: 0 but we don't know exac	ctly what is meant here with 'rapporteur'.
2017: 0 but we don't know exac	ctly what is meant here with 'rapporteur'.
127 Hayr many dassians managed by	other Member States has the Member State contributed to on
137. How many dossiers prepared by	other Member States has the Member State contributed to or
commented upon within the reporting	g period?*
Please insert a figure.	
2015 : 3 SVHC dossiers	
2016: 3 SVHC dossiers	
2017: 10 SVHC dossiers	

138. What expertise is available for preparing Annex XV SVHC dossiers (in FTEs available per year)?

	0	1-3	4-6	7-9	>9
Chemist*	0	x	0	0	0
Toxicologist*	0	x	0	0	0
Ecotoxicologist*	0	x	0	0	0
Economist*	x [©]	0	0	0	0
Enforcement*	x [©]	0	0	0	0
Legal <mark>*</mark>	0	x	0	0	0
Policy*	0	x	0	0	0
Exposure Assessor*	0	x	0	0	0
Risk Assessor*	x	©	©	0	0
Other*	0	0	0	0	0

If otl	her,	please	specify:*

139.	Do you	outsource the	preparation of Annex	XVSVHC	dossiers?*
------	--------	---------------	----------------------	--------	------------

Yes

O No

If yes, please specify the expertise outsourced:*
140. Is the Member States satisfied with the levels of access to outsourced expertise?*
1 = Very low (not appropriate at all); 2 = Low (of some relevance but not of any great significance); 3 = Medium (reasonably appropriate); 4 = High (highly appropriate); 5 = Very high (completely appropriate)
© 5
Please provide additional comment if needed:
1,800 character(s) maximum
141. Has there been any enterprises consultation/involvement in the preparation of Member State
dossiers?*
© Yes
No No
142. If yes, what was the level of involvement of enterprises in the preparation of Member State
dossiers?*
1 = Very low (not involved at all); 2 = Low (involved but not of any great significance); 3 = Medium (reasonably involved); 4 = High
(highly involved); 5 = Very high (fully involved) 1
© 3
© 5

Please provide additional comment if needed:
1,800 character(s) maximum
143. Among these enterprises, were there SMEs also consulted/involved in the preparation of Member State dossiers?*
© Yes
□ No
144. If yes, what was the level of involvement of SMEs in the preparation of Member State dossiers?*
1 = Very low (not involved at all); 2 = Low (involved but not of any great significance); 3 = Medium (reasonably involved); 4 = Hig (highly involved); 5 = Very high (fully involved) 1 2.
© 2 © 3
© 4
© 5
Please provide additional comment if needed:
1,800 character(s) maximum
Other points related to the identification of SVHC
145. Do you consider that there is enough coordination between ECHA and Member States during the implementation of the SVHC Roadmap?
O Yes
© No

If No, how could this be improved?
146. What were the financial and human resources dedicated to SVHCs identification (both screening and preparation of an Annex XV dossier) before and after the agreement on the SVHCs Roadmap in March 2013?
Theme 9: Information on REACH enforcement activities N/A
Theme 10: CLP enforcement activities N/A
Theme 11: Information on the effectiveness of REACH on the protection of human health and the environment, and the promotion of alternative methods, and innovation and competition
239. Do you think that the effects of REACH would be better evaluated at a Member State or at EU level?
Member State level
© EU level

240. Please provide a brief explanation of your response: 1,800 character(s) maximum
As a result of the Belgian policy :
- Environmental monitoring (air and water) is carried out at the regional level, but it is quite unrealistic to monitor all substances covered by Reach,
- Human biomonitoring is carried out at the federal level and the FASFC (The Belgian Federal Agency for the Safety of the Food Chain) contributes to the analysis contaminants found in the food chain.
In Flanders human biomonitoring (HBM) is specifically mentioned as a legal instrument for evidence-based environmental health policy making. HBM has been financed by the Flemish Government since 2002. A large number of environmental pollutants have been measured in a representative sample of the Flemish population in 3 age groups: newborns and their mothers, adolescents and adults. In addition to the general HBM, specific human biomonitoring is carried out in known hot spots (e.g. repetitive measurement of lead in blood near a zinc smelter in Hoboken). One of the primary goals of HBM in Flanders is the determination of time trends of biomarker measurements to evaluate the effect of existing policies and measures. One of the new aims is to obtain reference values for the Flemish population, not only for traditional pollutants but also for newer emerging chemicals. The reference values will be the basis for comparison with data from international studies, and for the comparison with data from high risk populations e.g. residents of specific locations (hot spots) within Flanders or specific subgroups in the population which may be vulnerable due to specific diets, habits, social behavior, health status etc. As the Flemish human biomonitoring program is framed in a program for action, the study results are always coupled to environmental monitoring and modeling data in the phased policy translation process of the results (http://www.milieu-en-gezondheid.be/English/).
1,800 character(s) maximum
Theme 12: Other issues / recommendations / ideas
242. Please provide any further information on the implementation of REACH that the Member State considers relevant:
2,500 character(s) maximum
1. Recommendations
Access to external specialists

Due to budget restrictions, the access to external specialists is quite limited. Difficulties are also encountered in identifying and contacting the Belgian expert networks (e.g. bioaccumulation for substances with a specific character such as highly fluorinated compounds). It seems that ECHA is in a better position to identify the experts available in the different fields of REACH and therefore to develop such expert networks.

Data for nanomaterials

Currently, there is a lack of data provided by industry on nanomaterials within the registration framework. An overview of the type of data on nanomaterials provided by industry is needed by the MSs in order to obtain information on f.e. the possible adaptations made to the proposed tests, the eventual specific characterization of the nanomaterials, the availability of a review containing information on (eco)toxicity of the nanomaterial, etc.

2. Issue

CMR substances

In particular for CMRs classified substances (ref: Article 68(2)): We acknowledge the progress made in relation to this topic. Nevertheless, we emphasize the need to achieve results timely in order to implement this article to protect consumers from the CMRs substances. We are also in favor of the plans to prioritize the CLH work for the classification of (potential) CMR substances and believe that COM/ECHA should offer the necessary support to reach that goal.

0	Yes
0	Ne
If Yes	please provide a brief description of the documents that you are uploading (you may upload more
than	one document):*
1.	Annex 1 Rapport Helpdesk 2017 19 Mars 2018.docx
The	document refers to the "Theme3 - Operation of the National Helpdesk and Provision of
Cor	nmunication to the Public of Information on Risks of Substances".

It describes more in detail the activities of the Belgian Helpdesk for the year 2015.

243. Do you wish to upload documents in support of this submission? *

Please upload your file

You may upload one or more documents.