Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Purpose and Context of the Consultation

a) The Fitness Check of the most relevant chemicals legislation excluding REACH
The European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)
and DG Environment) is conducting a fitness check on chemicals legislation (excluding REACH), as
well as related aspects of legislation applied to downstream industries.

Please note that the REACH Regulation is not covered by this exercise as it will be the subject of a separate evaluation, and a dedicated public consultation will be organised later this year.

The European Commission (DG GROW) has commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to undertake a supporting study to the preparation of this fitness check (the terms of reference are available online at - http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm). The current open online public consultation is part of the stakeholder consultation and its results will be analysed by the contractors. Please note that the results may also be used in the context of other studies in the chemicals field. The responses will be taken into consideration in the preparation of the Commission Staff Working Document, presenting the results of the fitness check.

For more details on the fitness check itself see:

- Fitness check background document
- DG GROW website
- DG ENV website

For more details on the REFIT Programme and public consultations:

- REFIT Programme
- Public consultations
- b) Structure of this questionnaire (pdf version available here)

The questionnaire is available in English, German and French and has five parts:

- Part I General Information about respondents (compulsory)
- Part II General Questions for respondents interested in chemicals legislation, but who may not be familiar enough with the existing legislative framework to answer more detailed questions (compulsory)
- Part III Specific Questions which require more extensive knowledge and/or experience of the chemicals and chemicals-related legislation (optional)

- Part IV Specific Questions on the CLP Regulation(optional)
- Part V Additional Comments (optional)

You may interrupt your session at any time and continue answering at a later stage. Once you have submitted your answers online, you can download a copy of the completed questionnaire.

To facilitate the preparation of your contribution, a pdf version of the questionnaire is available here.

c) Duration of the public consultation

The consultation will last for 12 weeks. Responses to the public consultation must be submitted by Friday 27 May 2016.

Privacy Statement: The collected personal data and all information related to the above-mentioned public consultation is stored on a computer of the external contractor, acting as processor, who must guarantee data protection and confidentiality as required by Regulation (EC) 45/2001.

Disclaimer: This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties. The suggestions contained in this document do not prejudge the form or content of any future proposal by the European Commission.

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Part I – General Information about Respondents

1. Address					
Contact name					
Organisation/company					
Country					
Email Address					
2. If you have a Transp	parency Register ID r	number, please	provide it below	'.	
If your organisation is	not registered, you h	ave the opport	unity to register i	now by following this <u>link</u> .	
If your entity responds individual/private perso		•		ider its input as that of a	'n

* 3. Received contributions may be published o contributor. Please state your preference with	n the Commission's website, with the identity of the regard to the publication of your contribution.
to documents under Regulation 1049/2001 or	sen, your contribution may be subject to a request for access a public access to European Parliament, Council and equest will be assessed against the conditions set out in the data protection rules.
My contribution may be published under the name prevent publication	indicated; I declare that none of it is subject to copyright restrictions that
My contribution may be published but should be ke prevent publication	ept anonymous; I declare that none of it is subject to copyright restrictions that
I do not agree that my contribution will be published	d at all
* 4. We might need to contact you to clarify son	ne of your answers. Please state your preference below:
I am available to be contacted	I do not want to be contacted
* 5. Please indicate whether you are replying to	this questionnaire as:
A citizen	A trade union
A business	A government or public authority
A non-governmental organisation (NGO)	An intergovernmental organisation
A consumer association	Academia or a research or educational institute
An industry association	Other
Other (please specify)	

6. If a business or industry association, please indicat between brackets correspond to NACE codes [multip	te your field(s) of interest or activity(ies) - the letters in le choice]:
Agriculture, forestry and fishing (A)	Manufacture of other non-metallic mineral products (C23)
Mining and quarrying (B)	Manufacture of basic metals (C24)
Manufacture of food products (C10)	Manufacture of fabricated metal products, except machinery and equipment (C25)
Manufacture of beverages (C11)	Manufacture of computer, electronic and optical products
Manufacture of tobacco products (C12)	(C26)
Manufacture of textiles (C13)	Manufacture of electrical equipment (C27)
Manufacture of wearing apparel (C14)	Manufacture of machinery and equipment (C28)
Manufacture of leather and related products (C15)	Manufacture of motor vehicles, trailers and semi-trailers (C29)
Manufacture of wood and of products of wood and cork exce furniture (C16)	Manufacture of other transport equipment (C30)
Manufacture of paper and paper products (C17)	Manufacture of furniture (C31)
Printing and reproduction of recorded media (C18)	Manufacture of games and toys (C32.4)
Manufacture of coke and refined petroleum products (C19)	Manufacture of medical and dental instruments and supplies (C32.5)
Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)	Other manufacturing(excluding manufacturing of toys or medical and dental instruments) (C32)
Manufacture of pesticides and other agrochemical products (C20.2)	Electricity, gas, steam and air conditioning supply (D)
Manufacture of paints, varnishes and similar coatings, printir ink and mastics (C20.3)	Water supply; sewerage; waste management and remediation activities (E)
Manufacture of soap and detergents, cleaning preparations,	Construction (F)
perfumes and toilet preparations (C20.4)	Wholesale and retail trade (G)
Manufacture of other chemical products (C20.5)	Transporting and storage (H)
Manufacture of man-made fibres (C20.6)	Professional, scientific and technical activities (M)
Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)	Other
Manufacture of rubber and plastic products (C22)	
Other (please specify)	

	The definition of small and medium turnover or the balance sheet of the http://ec.europa.eu/growth/smes/bu	e company. Please	e consult the	following w	/ebsite:		the annual
	Self-employed		Medium-	-sized enterpr	ise (under 25	0 employees	s)
	Micro-enterprise (under 10 employees	3)	Large co	mpany (250 e	employees or	more)	
	Small enterprise (under 50 employees	3)					
*	8. Please indicate the level at which	h your organisation	n is active:				
	Local	Regional (e.g. S	Scandinavia)		Global		
	National	EU			Not applicable	Э	
	Consultation on the regulato	ry fitness of ch	emicals leg	gislation	(excludin	g REAC	H)
	Part II – General Questions						
	9. How important is it in your view to order to achieve the following object					า* at EU-le	evel in
	*This comprises the chemical-related encompasses legislation governing measures, including chemical-related protection, chemicals controls and be found hemicals/ controls and be found hemicals/ controls and	g hazard identificat red aspects of legis	ion and class slation on wo	sification, a orker safety	s well as ris transport,	sk manag environm	ement ental
	**The internal market of the Europe and persons can move freely acros legislation is to have a single marke chemicals.	ss borders. One of	the key obje	ctives of ch	nemical and	d chemica	l-related
		1	2	3	4	5	I don't know
	Protecting human health						
	Protecting the environment				0		
	Ensuring a well-functioning internal market	et**					
	Stimulating competitiveness and innovation	on (

7. For businesses, please indicate the size of your business:

following objectives? (1= not effective, 5= n the legislation.	very effective).	Please only consider	der chemical-rel	ated provisions
	1	2 3	4	5 I don't know
Protecting human health				
Protecting the environment				
Ensuring a well-functioning internal market				
Stimulating competitiveness and innovation				
11. If you think the EU chemical and cher effective, please indicate what you believ following table:				
	The legislation unclear	The legislation is is not adapted to the issues at stake	The legislation is not effectively implemented	No opinion or not applicable
Protecting human health				
Protecting the environment				
Ensuring a well-functioning internal market				
Stimulating competitiveness and innovation				
12. To what extent do you consider that E value above what could have been achie nigh added value)				
1	2	3 4	5	I don't know
EU-level legislation adds value to national level action		0 0		
Consultation on the regulatory fit	ness of chemi	icals legislation	(excluding RI	EACH)
Part III - Specific Questions				
This part contains more detailed gues	tiono voloto d to	the five evaluation		ulvim av 4lb a

* 10. Do you think the EU chemical and chemical-related legislation has been effective in achieving the

This part contains more detailed questions related to the five evaluation criteria underlying the fitness check: effectiveness, efficiency, relevance, coherence and EU added value.

13. <u>For businesses and industry associations</u> - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.

For	other stakeholders - Please sele	ect the legislation y	ou are familiar wit	h.	
	Classification, labelling and packaging (Regulation No (EC) 1272/2008)	Major-accident h	ances (Seveso)		Cosmetic products (Regulation (EC) No 1223/2009)
	Plant protection products (Regulation (EC) No 1107/2009)	(Directive 2012/1 Water Framewor	·		Detergents (Regulation (EC) No 648/2004)
	Biocidal products (Regulation (EU) No 528/2012)	2000/60/EC) Urban Waste Wa	iter (Directive		Drinking Water (Directive 98/83/EC)
	REACH, Annex XIII (Regulation (EC) No 1907/2006)	91/271/EEC) Marine Strategy	Framework (Directive		Fertilisers (Regulation (EC) No 2003/2003)
	Inland transport of dangerous goods	2008/56/EC)			Medical devices (Directive 93/42/EEC regarding medical devices, Directive
	(Directive 2008/68/EC) Chemical Agents (Directive 98/24/EC)	Restriction of the hazardous substate electronic equipn	ances in electrical and		90/385/EEC regarding active implantable medical devices, and
	Asbestos (Directive 2009/148/EC)	2011/65/EU)	ient (Directive		Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
	Carcinogens and mutagens at work (Directive 2004/37/EC)	End of life vehicle 2000/53/EC)	es (Directive		Aerosol dispensers (Directive
	Young people at work (Directive	Batteries (Directi	ve 2006/66/EC)		75/324/EEC) Explosives (Directive 93/15/EEC)
	1994/33/EC) Pregnant workers (Directive	Packaging and P (Directive 94/62/I	• •		Pressure equipment (Directive
	1992/85/EEC)	Export and import chemicals (Regu	t of hazardous lation No 649/2012)		2014/68/EU) Food contact materials (Regulation
	Signs at work (Directive 92/58/EEC) Industrial emissions (integrated	Persistent organi (Regulation (EC)			(EC) No 10/2011 and Regulation (EC) No 450/2009)
	pollution prevention and control) (Directive 2010/75/EU)	Contaminants in	food and feed		General Product Safety (Directive 2001/95/EC)
	Waste framework (Directive 2008/98/EC) and List of Waste	(Regulation (EEC Directive 2002/32	·		Test methods (Regulation (EC) No 440/2008)
	Waste shipments (Regulation (EC) No 1013/2006)	Residues of pest (EC) No 396/200	icides (Regulation 5)		Good Laboratory Practice (Directives
		EU Ecolabel (Re	gulation (EC) 66/2010)	2004/9/EC and 2004/10/EC) Protection of animals used for scientific
		Safety of toys (D	irective 2009/48/EC)		purposes (Directive 2010/63/EU)
					I am not familiar with any of the pieces of legislation listed above
Othe	er (please specify)		_		

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

The following questions explore the extent to which the objectives of the EU legislative framework for chemicals have been met, and any significant factors which may have contributed to or inhibited progress towards meeting those objectives.

14. In the EU legislative fra	mework for chemicals, risk ma	anagement measures are, in some cases,	
determined directly based	on the identified hazard using (generic risk considerations (e.g. widespread	
exposure or exposure of vi	ulnerable groups), which justify	the automatic adoption of such measures. In	
·	• . ,	ned by a specific risk assessment that assesse	es
	-	ts resulting from the specific exposure scenarion	
associated with the propos			
• •	• •	ited legislation should, in general:	
-	20 onormour and onormour rola	tod regionation enedia, in general.	
	s specific risk assessments (i.e. differe discussions and implementation delay	entiate more between chemicals depending on their use over so)	despite
	s generic risk considerations (i.e. take in the interest of society might be rest	e more cautious approaches, despite the possibility that contricted)	ertain
c. Remain as it is because to assessments and generic ri	= :	he legislation ensures appropriate application of specific	risk
d. I don't know			
If you answered a or b, please ex	cplain		
considerations taken into a will be combined effects of	ccount in regulatory decision n	nemical substance or mixture, are all relevant making on risk management (e.g. whether there certain vulnerable groups, whether there will be r, etc.)? Please explain your answer.	
Yes	No	I don't know	
If you answered no, please explain legislation you are referring to.	in which considerations are not (suffic	ciently) taken into account and, if relevant, explain which	

16. In your view, to what extent are the following elements of the overall EU legislative framework for
chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

1	2	3	4	5	I don't know
ou consider	relevant.	If you have spe	cific legislatio	n in mind, pl	ease specify it.
					1 2 3 4 5

	4	0	0	4	F	l -l 14 l
Hazard identification criteria	1	2	3	4	5	I don't kno
Risk assessment and characterisation						
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)						
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)						
Risk management measures restricting or banning the use of chemicals						
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)						
f you answered 1, 2 or 3 above and would like to provide explain your answers.	le further in	formation (in _l	oarticular on s	specific pieces	s of legislatio	n), please
18. Safety data for chemicals is subject to quaimed at ensuring the reliability and reproduct appropriate?			=		-	-
			=		-	-
aimed at ensuring the reliability and reproduce appropriate?			=	ider these ı	-	-

17. In your view, to what extent are the following elements of risk management satisfactory? (1= not

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

Efficiency

The following questions explore the costs and benefits of implementing the EU legislative framework for chemicals. The legislation was designed to deliver benefits in terms of protection of human health and the environment, better functioning of the EU internal market (e.g. facilitating exports and imports between EU member states) and fostering competitiveness and innovation (e.g. better and safer chemicals). Costs can relate to costs for businesses, public authorities and society as a whole.

In your view, what are the most significant benefits mical related legislation? (one or more answers per	s generated for EU society by the EU chemical and ossible)
Reducing the exposure of consumers and of citizens in gene productivity, etc.	ral to toxic chemicals and, therefore, avoiding healthcare costs, lost
Reducing the exposure of workers to toxic chemicals and, the	erefore, avoiding healthcare costs, lost productivity, etc.
Reducing the damage to the environment and to eco-system restoring impacted fisheries, cleaning-up of contaminated lar	s and, therefore, avoiding the costs of treating contaminated water, ad, compensating for reduced crop pollinisation, etc.
Encouraging research and innovation, generating new jobs, encouraging/supporting a shift towards green, sustainable ch	and improving the competitiveness of the EU chemicals industry by nemistry and a circular economy
Stimulating competition and trade within the EU single market	et
Stimulating international trade between the EU and other cou	untries
I don't know	
In your view, what are the most significant costs in mical related legislation? (one or more answers pe	
Costs for authorities at EU level	Costs for consumers
Costs for authorities at national level	Costs for society in general
Costs for small and medium sized enterprises	I don't know
Costs for large enterprises	

	In your view, do any of the following requiremen companies?	ts in the legislative framework lead to significant costs
	Classification requirements for substances and mixtures	Training staff to ensure compliance with legal requirements
	Chemical labelling and packaging requirements	Inspections and administrative requirements
	Risk management measures under the different legislation. Understanding and keeping up-to-date with changes in leg requirements	legislation to be significant
	Other (please specify)	
		icals legislative framework which lead to particularly
	Are there specific requirements in the EU cheminificant costs for authorities?	
sigr	res No	icals legislative framework which lead to particularly
sigr	nificant costs for authorities?	
sigr If yo	Yes No ou answered yes, please indicate what these are.	

The following questions explore the extent to which the EU legislative framework for chemicals is consistent with current needs.

a large contribution)				safer alternative	33. (1 110 00	mandadon, o		
	1	2	3	4	5	I don't know		
Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	0				0	0		
24. To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)								
	1	2	3	4	5	I don't know		
Novel areas of concern sufficiently addressed by framework						0		
Please comment								
Consultation on the	regulatory	fitness of c	hemicals le	gislation (ex	cluding RE	ACH)		
Consultation on the	regulatory	fitness of c	hemicals le	gislation (ex	cluding RE	EACH)		

23. To what extent has the EU legislative framework for chemicals contributed to a reduction in the number

This section explores whether the chemical-related provisions in the various pieces of legislation within the scope of this fitness check are consistent with each other, whether they are complementary or if there are significant gaps, overlaps and inconsistencies that stand in the way of their effective implementation.

chemicals legislation framework overall								
	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree			
The EU chemicals legislation framework contains gaps and missing links								
The EU chemicals legislation framework has overlaps			\bigcirc		\bigcirc			
The EU chemicals legislation framework is internally inconsistent								
the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here . Gaps or missing links								
Overlaps Inconsistencies								
27. Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and <u>any other legislation</u> you consider relevant as regards the regulation and risk management of chemicals.								
Consultation on the regulatory fitness of chemicals legislation (excluding REACH)								

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation') governs the identification and classification of the health, environmental and physical hazards of chemicals, as well as the communication of these hazards to workers and consumers.

Part IV: Specific questions on the CLP Regulation

effective)						
		1	2	3	4	5 I don't know
To what extent are CLP labe communicating hazards to v		C				
To what extent are CLP labe communicating hazards to c						
29. Do the hazard classe	es in the CLF	Regulation o	cover all relev	vant hazards?		
	Y	es		No	10	don't know
Environmental						
Physical						
Human health						
Please list any hazard classes	s that are not co	overed				
30. How effective is the (1= not effective; 5= ver	y effective)					
Cuidanas dasumants	1	2	3	4	5	No experience
Guidance documents Helpdesks						
Industry association						
guidance and materials						
Other (training, conferences, etc.)						
Please add further details as	necessary					

28. CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very

Enforcement is harmonised across all Member St Enforcement is harmonised across most Member Please add further details as necessary		Enforcement is not harmonised across most Member Star I don't know						
Ticase and further details as necessary								
32. To what extent are the current elements a satisfactory; 5= very satisfactory)	relating to	the CLP cl	assification	criteria sa	tisfactory'	? (1= not		
	1	2	3	4	5	l don't know		
Ease of implementation for duty holders								
Appropriateness of classification criteria and methods for substances								
Appropriateness of classification criteria and methods for mixtures								
International harmonisation through the Globally Harmonised System (GHS)								
If you answered 1, 2 or 3 and would like to provide furth	her informa	tion, please ex	plain your an	swer				
33. CLP is revised on a regular basis through allow sufficient time to implement new or rev	-			ess. Do tra	ınsitional	periods		
Transition period is sufficient		Transtio	n period is to	o long				
Transition period is too short	I don't know or have no opinion							
Please elaborate if you answered that the transition pe	riod is too s	short or too lon	g.					

34. To what extent are the current elements of the procedures for harmonised classification & labelling