Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction - Industry

1. Introduction

Introduction

The European Commission is currently revising the REACH Regulation ((EC) No 1907/2006). The overall objective of the revision is to ensure that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market, as provided for in the Chemicals Strategy for Sustainability. Further information on the REACH revision is available here.

Thank you for taking the time to participate in this survey for the '**Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses, and to reform REACH authorisation and restriction**', carried out by the VVA Consortium for the European Commission (DG GROW). This is one of the studies supporting the European Commission's impact assessment for the REACH revision.

In line with the scope of the study, this survey focusses **ONLY** on the potential reforms to authorisations and restrictions, as well as the extension of the Generic Risk management Approach (GRA). Other related changes to REACH processes are currently being considered – such as the possible implementation of the concept of essential use – these are captured in the current survey where they are relevant to specific questions. A wider Public Consultation (PC) on all the measures considered for the REACH revision was open until the 15th April.

Due to the nature of the questions, **this survey is aimed at industry stakeholders only. It is designed to supplement technical consultation via the CARACAL meetings that occurred on the 27th January (on authorisation and restriction reform) and on 23rd March 2022 on the generic risk management approach, as well as the public consultation. This survey also supplements a workshop held on the 21st March 2022, which focussed on obtaining further detail on "use maps" of substances/application that may be affected by the extension of the GRA.**

If it is easier to attach (or refer to) your responses to the CARACAL papers (CA/03/2022 and CA/19/2022) to supplement your answers to this survey, please do so. Similarly, if your company or association took part in the CEFIC study "Economic analysis of the impacts of the Chemical Strategy for sustainability study (Phase 1)", then it may be useful to refer to these data, where possible.

An overview of the four options being considered is presented in the table below and these are discussed in more detail in the section *Options for the revision of authorisation and restriction processes.*

- **Option 1 Keep authorisation (with clarifications and simplifications) and restriction processes separate**

- **Option 2: Merge the authorisation and restriction processes**
- **Option 2A (variation of option 2): Keep SVHC and restriction Titles separate, but introduce the possibility for derogation requests**
- **Option 3: Remove the authorisation title from REACH**

Step	Substances	Baseline (No changes to REACH)	Option 1	Option 2A	Option 2	Option 3
Candidate List		CMR, PBT, vPvB substances + ELoC for other substances	Add ED, PMT, vPvM to hazard classes where no ELoC is necessary; Add requirements for downstream users to provide information on use, exposure, alternatives and waste management Add fees linked to this notification obligation linked to the SVHC use			
Type of restriction applying by default (i.e., unless there is a derogation or authorisation)	SVHC on Annex XIV	Authorisation requirement/ Annex XIV	Authorisation requirement/ Annex XIV	Restriction/ Annex XIV bis[1]	Restriction/ Annex XVII (integration of ex-Annex XIV)	None
	Other substances	Restriction/ Annex XVII	Restriction/ Annex XVII	Restriction/ Annex XVII		Restriction/ Annex XVII
Derogation proposed by authorities	SVHC on Annex XIV	Art 58(2) Only for uses where risks are properly controlled by other legislation	Art 58(2) Only for uses where risks are properly controlled by other legislation	Part of restriction proposal	Part of restriction proposal	n/a
	Other substances	Part of restriction proposal	Part of restriction proposal	Part of restriction proposal		Part of restriction proposal
Derogation of general applicability[2] on industry request		None	None	Possible where foreseen in restriction	Possible where foreseen in restriction	none
Authorisation	SVHC on Annex XIV	For substances in Annex XIV	For substances in Annex XIV	Possible where foreseen in Annex XIV bis, no upstream applications	Possible where foreseen in Annex XVII, no upstream applications	none
	Other substances	none	none	Possible where foreseen in Annex XVII		none

At this stage, no decision has been taken on which, if any of the potential options may be adopted, however, elements from different options may be combined. These options should not be interpreted as the proposal of the European Commission.

It must also be noted that two possibilities for granting authorisations and/or derogations from restrictions will also **apply to the options** being considered here.

- Firstly the "**essential use**" concept (being developed under another study), where derogations from restrictions and/or authorisations are only granted if the use is proven necessary for health and/or safety or critical for the functioning of society, AND there are no suitable alternatives that are acceptable from the standpoint of environment and health.
- Secondly, the "**minimal exposure**" route for uses of substances in articles and for industrial uses of substances in mixtures, in exceptional cases, a derogation and/or authorisation may be granted if industry proves that the exposure/emissions throughout the whole life cycle of

the substance are absent or minimal[1] AND there are no suitable alternatives that are acceptable from the standpoint of environment and health.

General information on the survey

Through this survey, **we are seeking your views on the effectiveness and efficiency[2] of both the current REACH regulation processes and how this may change – for better or worse – under the options discussed in more detail in the section *Options for the revision of authorisation and restriction processes*. These options seek a balance between five aims, and we will be asking questions on whether and how the options might achieve them:**

- Reduce the administrative burden on companies and authorities;
- Free authority resources to tackle a wider range of chemical risks;
- Make the authorisation processes more efficient and effective;
- Achieve a higher level of protection of human health and the environment from the risks of the most harmful substances;
- Give clearer market signals and greater planning security for companies.

The survey is structured of two main parts, the first one dedicated to the extension of the use of the generic risk management approach and the second one dedicated to the revision of authorisation and restrictions processes. The survey contains a series of open and closed questions and should not take longer than 45 - 60 minutes to complete. You may select which part(s) of the questionnaire to complete to reduce the length of time required to complete it, if you prefer (see question 6). Please note that you have the possibility to **save your answers and continue the survey later on. If you wish to return to a previous page or question, please use the software navigation button at the bottom of each page rather than the browser's button, as answers might be lost otherwise.**

Protecting confidential information

All the information provided, including your personal details, will be treated confidentially, respecting the European Commission's data protection rules, including the rules of the General Data Protection Regulation. Confidential information will not be provided to any third party and the study report will contain data only in an aggregated format. The report will not mention specific companies by name and will exclude confidential information (e.g., by use of ranges and aggregated values).

1) Please consult the privacy statement.*

(x) I read and agree with the privacy statement.

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2. Introductory questions

2) Please provide your name and the contact details of your organisation:*

Name: _____

Email or telephone number (please include country code):

_____

Company/organisation: AmCham EU

Role in the company/organisation: _____

3) Which of the following options best reflects your organisation and its operations in the EU (please select all that apply):
*

[ ] Manufacturer of substance(s)

[ ] Formulator of mixtures (including downstream users formulating mixtures, usually supplying them further down the supply chain or directly to consumers)

[ ] Importers of substances or mixtures

[ ] Distributor/wholesaler/retailer of substances or mixtures

[ ] Supplier of articles (Producer/importer/distributor of articles)

[ ] Downstream user (Companies using chemicals, including operators where chemicals are not the main business, such as food, construction or cleaning companies)

[ ] End user(s) (using substances or mixtures but not supplying them further)

[x] Trade association (made up of multiple members and operations)

[ ] Other - Write In: _____

4) Which economic sector best represents your organisations activities (please select the option(s) that best describes your activity)?*

[ ] Agriculture, forestry and fishing

[] Mining and quarrying

[X] Manufacture of food products

[X] Manufacture of beverages

[ ] Manufacture of tobacco products

[X] Manufacture of textiles

[X] Manufacture of wearing apparel

[ ] Manufacture of leather and related products

[ ] Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials

[ ] Manufacture of paper and paper products

[ ] Printing and reproduction of recorded media

[ ] Manufacture of coke and refined petroleum products

[X] Manufacture of chemicals and chemical products

[X] Manufacture of basic pharmaceutical products and pharmaceutical preparations

[X] Manufacture of rubber and plastic products

[] Manufacture of other non-metallic mineral products

[] Manufacture of basic metals

[ ] Manufacture of fabricated metal products, except machinery and equipment

[X] Manufacture of computer, electronic and optical products

[X] Manufacture of electrical equipment

[X] Manufacture of machinery and equipment n.e.c.

[X] Manufacturer of medical devices/ instruments

[X] Manufacture of motor vehicles, trailers and semi-trailers

[X] Manufacture of other transport equipment

[ ] Manufacture of furniture

[ ] Other manufacturing (please explain)

[ ] Repair and installation of machinery and equipment

[ ] Electricity, gas, steam and air conditioning supply

[ ] Water supply; sewerage; waste management and remediation activities

[ ] Construction

[ ] Wholesale and retail trade; repair of motor vehicles and motorcycles

[ ] Transporting and storage

[ ] Accommodation and food service activities

[ ] Information and communication

[ ] Financial and insurance activities

[ ] Real estate activities

[ ] Professional, scientific and technical activities

[ ] Administrative and support service activities

[ ] Public administration and defence; compulsory social security

[ ] Education

[ ] Human health and social work activities

[ ] Arts, entertainment and recreation

[ ] Other services activities

[ ] Activities of households as employers; undifferentiated goods – and services – producing activities of households for own use

[ ] Activities of extraterritorial organisations and bodies

[ ] Other - Write In: _____Defence Industry _____

5) In which country/countries is your company based (please select all that apply)*

[ ] All EU27 Member States

[ ] Austria

[x] Belgium

[ ] Bulgaria

[ ] Croatia

[ ] Cyprus

[ ] Czech Republic

[ ] Denmark

[ ] Estonia

[ ] Finland

[ ] France

[ ] Germany

[ ] Greece

[ ] Hungary

[ ] Ireland

[ ] Italy

[ ] Latvia

[ ] Lithuania

[ ] Luxembourg

[ ] Malta

[ ] Netherlands

[ ] Poland

[ ] Portugal

[ ] Romania

[ ] Slovakia

[ ] Slovenia

[ ] Spain

[ ] Sweden

[ ] United Kingdom

[x] United States

[ ] China

[ ] Japan

[ ] South Korea

[ ] India

[ ] Other - Write In: ___AmCham members are based in the US, with various site locations in the EU._____

6) Which category best describes the size of your organisation:*

[x] Larger Enterprise (More than 250 employees and more than or equal to €50 million turnover)

[ ] Medium-sized enterprise (50 – 249 employees and ≤ € 50 m turnover or €43 million balance sheet)

[ ] Small enterprise (10 - 49 employees and ≤ € 10 m turnover or balance sheet)

[ ] Micro Enterprise (0 – 9 employees and ≤ € 2 million turnover or balance sheet)

[] Not applicable

[ ] I do not know

7) Please state approximate turnover and staff numbers.

8) Which parts of the questionnaire do you wish to complete?
*

( ) I will answer questions on the extension of the generic approach to risk management only [stop after section 3. Extending the use of the generic risk management approach (GRA)]

( ) I will answer questions on the reforms to authorisation and restriction only [skip to section 4. Options for the revision of authorisation and restriction processes]

(x) I will answer the whole questionnaire

3. Extending the use of the generic risk management approach (GRA)

9) Has your organisation been affected by a restriction under REACH to date?
*

(X) Yes

() No

10) If yes, please briefly describe whether this was under Article 68 (1) or 68 (2) and how you were affected.

AmCham EU members have been affected by a number of REACH restriction processes (including cadmium, formaldehyde, diisocyanates, NMP, DMAC and DMF) over the years, and most recently on microplastics, bisphenols, and PFAS.

11) Has your organisation encountered any of the following challenges during the CURRENT REACH restriction procedure (Article 68 (1)[1]). If yes, how significant where these? Please tick all those that apply. (1 being not important at all, and 5 being very important).

Please provide an answer for each row. If you do not have an answer, please select "I do not know/no opinion".

[1] Article 68(1) of REACH applies the standard restriction procedure of Articles 69 to 73, which requires the preparation of an Annex XV dossier to initiate the restriction process, public consultation, opinions by RAC and SEAC and the consultation of the forum. Under Article 68(2) the procedures of Articles 69 to 73 do not apply. Article 68(2) instead provides a simplified procedure which the Commission may use in relation to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers.

	1 (not important at all)	2 (rather not important)	3 (neutral)	4 (rather important)	5 (very important)	I do not know/no opinion
Uncertainty of the timing of the outcome of the restriction process	( )	( )	( )	( )	X	( )
The overall duration of the entire restriction process is too slow	X	( )	( )	( )	( )	( )
Challenges in data collection to reply to calls for evidence and/or consultations on restriction dossiers	( )	( )	( )		(X)	( )
Administrative burden associated with responding to consultations on restriction dossiers	( )	( )	( )		(X)	( )

Overlap, duplication or inefficiencies between REACH and other related legislations	( )	( )	( )	X	( )	( )
Risk of regrettable substitution	( )	( )		( )	(X)	( )

12) Concerning "overlap, duplication or inefficiencies between REACH and other related legislations" Please note the key legislation where you consider there to be overlaps.

Occupational safety legislation, CMD, CAD, Ecodesign, RoHS, Food Contact Materials. There are also overlaps and inconsistencies between regulatory approaches proposed for the same substances under REACH e.g. restriction vs. authorisation.

13) In your opinion, what are the most significant potential advantages and disadvantages of moving to a broader application of the generic risk management approach to further hazard classes (mentioned in the introduction) and to professional uses? (1 being significant disadvantages, 3 being no significant advantage nor disadvantage, and 5 being significant advantages)

Please provide an answer for each row. If you do not have an answer, please select "I do not know/no opinion".

	1	**2**	**3**	**4**	**5**	**I do not know/no opinion**
Achieve a higher level of	(x)	( )	( )	( )	( )	( )

protection to human health and the environment						
Promotion of alternative methods for assessment of hazards of substances	(X)	( )	()	( )	( )	( )
Free circulation of substances on the internal market	(x)	( )	( )	( )	( )	( )
Drives substitution of substances of very high concern with safer alternative substances or technologies	(x)	( )	( )	( )	( )	( )
Enhance competitiveness amongst by industry	(x)	( )	( )	( )	( )	( )
Provides clear and predictable market signals to industry	(X)	( )	()	( )	( )	( )
Limiting administrative burdens on companies	(x)	( )	( )	( )	( )	( )

Limiting administrative burdens on competent authorities that are responsible for proposing restrictions	(X)	()	( )	( )	( )	( )
An opportunity to increase innovative/ R&D activities in my company	(x)	( )	( )	( )	( )	( )
An opportunity to enhance the global appeal of our products	(x)	( )	( )	( )	( )	( )
Limiting administrative burdens on enforcement authorities	(X)	( )	()	( )	( )	( )
Enabling authority resources to be prioritised on the most serious chemical risks	(X)	( )	( )	( )	( )	( )
An opportunity to gain market share via development of new safer alternatives	(X)	( )	()	( )	( )	( )

An opportunity to gain market share via increased sales of existing safer alternatives	(X)	( )	()	( )	( )	( )
Making the REACH restriction processes more efficient for competent authorities	(X)	()	( )	( )	( )	( )
Making the REACH restriction processes more efficient for industry	(X)	( )	( )	( )	( )	( )
Making the REACH authorisation processes more efficient for competent authorities	(X)	()	( )	( )	( )	( )
Making the REACH authorisation processes more efficient for industry	(x)	( )	( )	( )	( )	( )

14) What do you consider to be the most significant advantages and disadvantages of extending application of the generic risk management approach to further hazard classes for uses by consumers?

Response optional

	Advantages	**Disadvantages**
1	_____	Removal of scientific and socio-economic assessment from the restriction process
2	_____	Severe risk of unintended consequences, incl. regrettable substitution of hazardous substances that can be used safety and that provide important sustainability benefits
3	_____	Significant increase in regulatory burden and administrative congestion
4		AmCham members who do not manufacture or sell consumer goods are concerned that this may drive unintended

		material obsolescence in the industrial sector.

15) What do you consider to be the most significant advantages and disadvantages of extending application of the generic risk management approach for uses by professionals?

Response optional

	Advantages	**Disadvantages**
1	_____	Undermining of OSH and disregarding the role of professional training in promoting safe use
2	_____	Removal of scientific and socio-economic assessment from the restriction process
3	_____	Severe risk of unintended consequences, incl. regrettable substitution of hazardous substances that can be used safety and that provide important sustainability benefits
4		AmCham members who do not manufacture or sell consumer goods are concerned that this may drive unintended material obsolescence in the industrial sector.

16) What you consider to be the most significant advantages and disadvantages of moving to a broader application of the generic risk management approach for substances in articles?

Response optional

	Advantages	**Disadvantages**
1	_____	Ignores potential safe uses of substances in articles
2	_____	Severe risk of unintended consequences, incl. regrettable substitution of hazardous substances that can be used safety and that provide important sustainability benefits
3	_____	Significant burdens in terms of enforcement, which is already a weak point in REACH

17) Please can you provide an estimate of typical annual turnover/revenue to your company from its sales of all chemicals substances, mixtures or articles manufactured or sold in the EU/EEA?
Note: you may wish to report the last financial year before the COVID-19 pandemic given the abnormal market conditions. Please state the year.

*If you do not know the response, please indicate "I do not know" or "N/A" in the given text box.**
Typical annual revenue € annual: NA

Year(s): _____

18) Based on your current activities, please can you provide an estimate of the typical proportion (%) of your portfolio that is undergoing reformulation in any one year?
Note this proportion should be expressed as a % of your annual turnover/revenue to your company from its sales of all chemical substances, mixtures or articles manufactured or sold in the EU/EEA in the previous question.

*If you do not know the response, please indicate "I do not know" or "N/A" in the given text box.**

	Low range (%)	**High range (%)**
Extent of portfolio affected by minor reformulations (I,e a change in an ingredient) in any one year	_____ _____	_____ _____
Extent of portfolio affected by major reformulation (I,e redesign of substance and/or change in several ingredients) in any one year	_____ _____	_____ _____

19) Based on your current activities, please can you provide an estimate of the approximate duration of a typical reformulation effort? Please provide the average duration of reformulation where technically and economically feasible.

*Please provide an answer for each row. If you do not have an answer, please select "I do not know/not relevant".**

	Years
Extent of portfolio affected by minor reformulations (I,e a change in an ingredient) in any one year	_____
Extent of portfolio affected by major reformulation (I,e redesign of substance and/or change in several ingredients) in any one year	_____

20) Are you manufacturing, using in mixtures or using in articles, substances in the following hazard classes?

Please select "Yes", "No" or "N/A" in each cell.

	Manufacturing substances with these hazard classes	**Using in mixtures**	**Using in articles**	**I do not know if substances display these properties**

Endocrine disruptors (ED) with effects for human health				
Endocrine disruptors (ED) with effects on the environment				
Persistent, bioaccumulative and toxic substances (PBT)				
Very persistent and very bioaccumulative substances (vPvB)[1]				
Substances with specific target organ toxicity, single exposure (STOT SE)				
Substances with specific target organ toxicity, repeated exposure (STOT RE)				
Immunotoxic substances				
Neurotoxic substances				

Respiratory sensitisers				

21) Are you able to estimate any of the following information for your current portfolio, based on the hazard classes of the substances involved in their manufacture or their uses?

*Please select an answer for each item.**

	Yes	**No**	**I do not know/no opinion**
Approx. share of current product portfolio (by volume and/or value) used for consumer uses or professional uses			
Approx. Number of substances manufactured and/or used for consumer uses or professional uses			
Approx. share of current product portfolio (by volume and/or value)			

by hazard class			

22) You indicated you may be able to estimate some of the information below. Please provide whatever information you are able to. If you do not know the answers, please leave it blank.
What number of registered substances are you using, per hazard class that could be affected by the extension of the generic risk management approach? *Note approximate answers and/or answers in ranges would still be helpful.*

Wherever possible:

- Provide an indication of the share of the product portfolio by volume, share of profit affected by the extension of the generic risk management approach.
- Please estimate a total and if possible, an approximate proportion that may be used in professional and/or consumer uses.
- If you can only estimate some of the information, please do so, leaving the rest blank.

If you do not know or wish to reply "not applicable", please leave blank or indicate "N/A" in the given text box.

	Number of substances affected	**Share of product portfolio by volume (%)**	**Share of profit affected (%)**
Endocrine disruptors (ED) with effects for human health - Total No.	_____ _____ _____	_____ _____ _____	_____ _____ _____
Endocrine disruptors (ED) with effects for human	_____ _____ _____	_____ _____ _____	_____ _____ _____

health - Approx. Prof. %			
Endocrine disruptors (ED) with effects for human health - Approx. Consumer %	_____	_____	_____
Endocrine disruptors (ED) with effects on the environment - Total No.	_____	_____	_____
Endocrine disruptors (ED) with effects on the environment - Approx. Prof. %	_____	_____	_____

Endocrine disruptors (ED) with effects on the environment - Approx. Consumer %	_____	_____	_____
Persistent, bioaccumulative and toxic substances (PBT) - Total No	_____	_____	_____
Persistent, bioaccumulative and toxic substances (PBT) - Approx. Prof. %	_____	_____	_____
Persistent, bioaccumulative and toxic	_____	_____	_____

substances (PBT) - Approx. Consumer %			
Very persistent and very bioaccumulative substances (vPvB) - Total No	_____	_____	_____
Very persistent and very bioaccumulative substances (vPvB) - Approx. Prof. %	_____	_____	_____
Very persistent and very bioaccumulative substances (vPvB) -	_____	_____	_____

Approx. Consumer %			
Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ - Total No	_____	_____	_____
Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ -	_____	_____	_____

Approx. Prof. %			
Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ - Approx. Consumer %	_____ _____ _____	_____ _____ _____	_____ _____ _____
Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target	_____ _____ _____	_____ _____ _____	_____ _____ _____

organ - Total No			
Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ - Approx. Prof. %	_____	_____	_____
Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on	_____	_____	_____

target organ - Approx. Consumer %			
Immunotoxic substances - Total No	_____	_____	_____
Immunotoxic substances - Approx. Prof. %	_____	_____	_____
Immunotoxic substances - Approx. Consumer %	_____	_____	_____
Neurotoxic substances - Total No	_____	_____	_____
Neurotoxic substances - Approx. Prof. %	_____	_____	_____

Neurotoxic substances - Approx. Consumer %	_____ _____ _____	_____ _____ _____	_____ _____ _____
Respiratory sensitisers - Total No	_____ _____ _____	_____ _____ _____	_____ _____ _____
Respiratory sensitisers - Approx. Prof. %	_____ _____ _____	_____ _____ _____	_____ _____ _____
Respiratory sensitisers - Approx. Consumer %	_____ _____ _____	_____ _____ _____	_____ _____ _____

23) The extension of the GRA may result in further restrictions to substances, mixtures or articles. To the best of your current knowledge, what proportion of your existing portfolio do you consider it likely that substitution, reformulation would occur or where you might expect to cease manufacture or supply?

Please scroll to the right for all categories.

	Endocrine disruptors	**Endocrine disruptor**	**Persistent, bioa**	**Very persistent and**	**Substances with**	**Substances with**	**Immunotoxic subs**	**Neurotoxic subs**	**Respiratory sensi**

	(ED) with effects for human health	s (ED) with effects on the environment	ccumulative and toxic substances (PBT)	very bioaccumulative substances (vPvB)	specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ	specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ	tances	tances	tisers
Substitute with an alternative substance or technology?	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ _____ ____

Reformulate substance/mixture or redesign article(s)									
Cease manufacture/supply of substance/mixture/ article in the EU									

24) If you have answered “Cease supply of the substances/mixture/articles” in the previous question, please give the main reasons why substitution or reformulation is not likely to be possible? Otherwise, please leave this question blank.

Please scroll to the right for all categories.

	Endocrine disruptors (ED) with effects for human health	**Endocrine disruptors (ED) with effects on the environment**	**Persistent, bioaccumulative and toxic substances (PBT)**	**Very persistent and very bioaccumulative substances (vPvB)**	**Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ**	**Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ**	**Immunotoxic substances**	**Neurotoxic substances**	**Respiratory sensitisers**
No alternatives for the required func	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____	_____ _____ _____ _____ _____ _____ _____ _____ ____

tionalities									
Alternatives also affected by other hazard class(es) under GRA (Please state which one(s)									
Not economically feasible to substitute/reformu									

late /red esig n									

25) If you replied “No alternatives for the required functionalities” in your answer above, please could you indicate the key functionalities in question and the key products groups that might be affected, per hazard class?

If you do not know, please leave this blank.

	Key functionality(ies) affected	**Key product/ product groups affected**
Endocrine disruptors (ED) with effects for human health	_____ _____	_____ _____
Endocrine disruptors (ED) with effects on the environme nt	_____ _____	_____ _____
Persistent, bioaccumu lative and toxic substances (PBT)	_____ _____	_____ _____
Very persistent and very bioaccumu	_____ _____	_____ _____

lative substances (vPvB)		
Substances with specific target organ toxicity, single exposure (STOT SE), differentiated based on target organ	_____ _____	_____ _____
Substances with specific target organ toxicity, repeated exposure (STOT RE), differentiated based on target organ	_____ _____	_____ _____
Immunotoxic substances	_____ _____	_____ _____
Neurotoxic substances	_____ _____	_____ _____
Respiratory sensitisers	_____ _____	_____ _____

4. Options for the revision of authorisation and restriction processes

26) Has your organisation submitted an application for authorisation under REACH to date?*

(x) Yes

() No

27) Has your organisation encountered any challenges concerning the following aspects during the CURRENT REACH authorisation procedure? If yes, how significant where these? Please tick all those that apply. (1 being not at all problematic and 5 being a major problem)

Please provide an answer for each row. If you do not have an answer, please select "I do not know/no opinion".

	Relevant to your role/application(s)	**1 (not a problem at all)**	**2 (rather not a problem)**	**3 (neutral)**	**4 (rather a problem)**	**5 (major problem)**	**I do not know /no opinion**
Request for additional information by RAC and SEAC, as part of the conformity check	[ ]	[X]	[ ]	[]	[ ]	[ ]	[ ]

Clarity of legal definitions and what uses were affected and/or exempted	[ ]	[ ]	[ ]	[]	[ ]	[X]	[ ]
Availability of data on e.g. uses, risk management measures, suitable alternatives for applications	[ ]	[ ]	[ ]	[]	[ ]	[X]	[ ]
Data on alternatives including technical feasibility or hazard/risk	[ ]	[ ]	[ ]	[X]	[ ]	[ ]	[ ]
The overall costs of preparing an authorisation application	[ ]	[ ]	[ ]	[ ]	[X]	[ ]	[ ]
Delays in the	[ ]	[ ]	[ ]	[ ]	[]	[X]	[ ]

authorisation process and decision making							
Uncertainty about the outcome of the authorisation process	[ ]	[ ]	[ ]	[ ]	[ ]	[X]	[ ]
Time between decision by the European Commission and sunset date	[ ]	[ ]	[ ]	[ ]	[X]	[ ]	[ ]
Proportionality of data needed, taking into account volume of use and/or company size	[ ]	[ ]	[ ]	[ ]	[]	[X]	[ ]
Additional burdens, complexity or uncertainty due to overlap in legislation	[ ]	[ ]	[ ]	[ ]	[ ]	[X]	[ ]

between REACH and OSH							
Additional burdens, complexity or uncertainty due to overlap in legislation between REACH and IED	[ ]	[ ]	[ ]	[]	[ ]	[ ]	[X]

28) If you added an answer in "other" in the previous question, please describe the specific problem or issue faced in relation to the authorisation process.

Authorisation is not necessarily the best risk management measure for all SVHCs. Risks from certain SVHCs are best managed through targeted restrictions or occupational safety. AmCham EU supports decoupling the Candidate List from the Authorisation Chapter of REACH, to ensure other risk management options can be prioritised vs. authorisation where appropriate.

29) What do you consider to be the greatest advantage(s) of the current authorisation procedure?

Risk assessment and socio-economic analysis are included as part of the process.

Safe uses can be authorised.

_____

30) In your opinion, what do you see as the main potential disadvantages of each option, for your organisation, compared to the CURRENT REACH process? Under each option please rank your top 5 disadvantages by adding a number between 1 and 5 in each column (1 being the biggest disadvantage).

Please provide an answer for each row. If you do not have an answer, please write an X in "I do not

know/no opinion".

	Option 1: Keeping the authorisation process, with clarifications and simplifications	**Option 2: Merge the authorisation and restriction processes and introduce possibility for derogation requests**	**Option 2A: keep Annex XIV and Annex XVII separate but introduce possibility for derogation requests**	**Option 3: Remove the authorisation title from REACH**	**I do not know/no opinion**
Additional administrative burden for Authorities					X
Additional administrative burden for companies					X
Additional costs linked to data collection					X
Additional costs linked to substitution / reformulati3on					X
Additional costs linked to Risk Management					X

Measures for companies					
Lower protection of human health					X
Lower protection of the environment					X
Longer and/or more uncertain regulatory processes					X
Free-riding behaviour of some companies covered by the same use applied for					X
Adverse effects on international competitiveness					X

31) In your opinion, what do you see as the main potential advantages of each option compared to the CURRENT REACH process? Under each option please rank your top 5 advantages by adding a number between 1 and 5 in each column (1 being the biggest advantage).

Please provide an answer for each row. If you do not have an answer, please write an X in "I do not know/no opinion".

	Option 1: Keeping the authorisation process, with clarifications and simplifications	Option 2: Merge the authorisation and restriction processes and introduce possibility for derogation requests	Option 2A: keep Annex XIV and Annex XVII separate but introduce possibility for derogation requests	Option 3: Remove the authorisation title from REACH	I do not know/no opinion
More effective protection of human health					X
More effective protection of the environment					X
More legal certainty and predictability for companies					X
Reduced administrative burdens for Authorities					X
Free up authority resources to focus on the most					X

significant chemical risks					
Reduced administrative burdens to companies					X
Cost savings in data collection to my company					X
Cost savings in substitution / reformulation to my company					X
Cost savings in Risk Management Measures to my company					X
The possibility for joint requests for authorisations/ derogations to reduce costs and provide certainty for companies	1	2	3		X
Faster decision	1	2	3	4	X

making by authorities					

32) Option 1 includes a list of potential clarifications and simplifications to the authorisation process. Compared to the current system, in your view, would these changes be positive or negative (-3 being strongly negative and +3 strongly positive)?

*Please provide an answer for each row. If you do not have an answer, please select "I do not know" or "no opinion".**

	-3	**-2**	**-1**	**0**	**+1**	**+2**	**+3**	**I do not know**	**No opinion**
Notification obligations for downstream users (DUs) of substance on the candidate list: to gather information in advance for more efficient regulatory actions (and more complete applications for authorisations) industry should regularly (e.g., annually) notify ECHA with certain information on e.g., uses, tonnages and exposure/ emission patterns, waste management, possible alternatives (note this is a horizontal option being considered under both option 1 and 2)	(x)	( )	( )	( )	( )	( )	( )	( )	( )
Annual “fee” for SVHCs in the Candidate List to incentivise substitution. All	(x)	( )	( )	( )	( )	( )	( )	( )	( )

substances in the Candidate List would be subject to the SVHC notification fee and to annual fees.									
Impact of such an annual fee on substitution of substances in the candidate list	(x)	( )	( )	()	( )	( )	( )	( )	( )
Redefining the legal conditions that need to be fulfilled in order to grant an authorisation, including a clearer definition of the suitability of alternatives (e.g., the requirement to submit a substitution plan and minimisation of exposure/emissions in all applications whether or not a safe threshold can be demonstrated).	()	( )	( )	(x)	( )	( )	( )	( )	( )
Clarification of criteria and possible extension of exempted uses (e.g. research and development, intermediates)	( )	( )	( )	( )	(x)	( )	()	( )	( )
Clarification of the information requirements: use description, technical function, level of granularity required and representativeness of DUs information	( )	( )	( )	( )	(x)	( )	( )	( )	( )
Clarify substitution plan requirement: substitution	( )	( )	( )	()	(x)	( )	( )	( )	( )

plan required if there are suitable alternatives in the Union to implement one or more of those identified alternatives (art. 62(4f))									
Where an application for authorisation is refused, introduce the possibility for the Commission to set out a transitional period up to 18 months and ad-hoc arrangements for allowing the affected companies a smooth cease of the use (e.g., also avoiding problems of disposal of the unused substance).	( )	( )	( )	( )	( )	( )	(x)	( )	( )
Facilitation of submission of subsequent applications for authorisation in accordance with Article 63 (relying on existing applications/authorisations).	( )	( )	( )	( )	( )	()	( )	(x)	( )
Clarify procedure for changes during the validity of an authorisation (the authorisation holder should have the obligation to notify the relevant authorities (ECHA or national authorities) of any relevant changes e.g., legal entity, increase in tonnage, new RMMs) for a potential review of the authorisation by the Commission.	( )	( )	( )	(x)	( )	( )	( )	( )	( )
Interested parties (NGOs, alternatives providers,	(x)	( )	( )	()	( )	( )	( )	( )	( )

etc.) may submit new evidence on suitable alternatives as regards authorised uses to ECHA for subsequent assessment and ultimately a potential review of the authorisation by the Commission.									

33) Option 2 (and 2A) involve more substantial changes to the authorisation and restriction procedures, compared to the current process. In your view, would these changes be positive or negative (-3 being strongly negative and +3 strongly positive)?

Please provide an answer for each row. If you do not have an answer, please select "I do not know" or "no opinion".
*

	-3	**-2**	**-1**	**0**	**+1**	**+2**	**+3**	**I do not know**	**No opinion**
Integrating Substances of Very High Concern into Annex XVII. Move the substances listed in Annex XIV to Annex XVII (i.e. total ban except for authorised/derogated uses until the end of the review period and exempted uses	()	( )	( )	(x)	( )	( )	( )	( )	( )
Include presence in articles in authorisation scope to address risk arising from SVHC in articles (note this is a horizontal option being considered under both option 1 and 2)	(x)	( )	( )	( )	( )	( )	( )	( )	( )

Adding in Article 58(3) the following prioritisation criterion: [priority shall be given to substances with:] (d) substitution potential for other substances already included in Annex XIV. This would aim to prevent regrettable substitution.	( )	( )	( )	( )	(x)	( )	( )	( )	( )
Removing the Member State Committee (MSC) opinion on the ECHA proposal for inclusion in AXIV	(x)	( )	( )	( )	( )	( )	( )	( )	( )
Derogations of general applicability would be included as part of the restriction as proposed and adopted by authorities (as in the existing restriction system)	( )	( )	( )	( )	( )	( )	(x)	( )	( )
Joint derogations of general applicability requested by companies (a new element), with the burden of proof to remain on industry	( )	( )	( )	( )	( )	()	(x)	( )	( )
Individual derogations/authorisations requested by companies (similar to existing REACH authorisation system), with the burden of proof on industry	( )	( )	( )		(x)	( )	( )	( )	( )

Derogations from restrictions and/or authorisations granted if the use is proven essential. “Essential Use” route	( )	( )	( )	()	(x)	( )	( )	( )	( )
Derogations from restrictions and/or authorisations granted if it is proven that emissions/exposure for uses of substances in articles and for industrial uses of substances in mixtures are absent/minimal throughout the lifecycle AND there are no suitable alternatives. “Minimal exposure” route	( )	( )	( )	( )	( )	( )	(x)	( )	( )
Option 2A variation: keep Annex XIV and Annex XVII separate, Annex XIV bis would include general bans for SVHC. Annex XVII would include general bans for restricted substances (both under art. 68(1) and 68(2))	( )		( )	()	()	( )	( )	(x)	( )

34) In option 2A, an authorisation in its current form would cease to exist and current authorisation decisions are replaced by derogations of individual applicability from restrictions. However Annex XIV and Annex XVII would be kept separate - Annex XIV bis would include general bans for SVHC. Annex XVII would include general bans for restricted substances (both under art. 68(1) and 68(2)). What do you consider to be the most significant *advantages and disadvantages* of keeping Annex XIV and Annex XVII separate (option 2A)?

	Advantages	**Disadvantages**

1	Retains ability to apply for Authorisation if a derogation is not granted.	. Unclear exactly how this will be implemented and what Authorisations will look like in this future model.
2	Provides a more formal means for requesting derogations.	In AmCham EU's view, the future REACH should still include a simplified Authorisation Chapter. One important remark is that Authorisation should not be automatically be considered to be the most appropriate risk management option for all SVHCs. We support a more formal use of screenings for SVHCs, based on which the most appropriate RMO can be selected (Authorisation, Restriction, OSH, etc).

3	_____	It appears that Upstream AfAs will not be allowed in this option. For industries such as Aerospace and Defence, who have very complex supply chains and onerous processes for switching suppliers, this could be devastating. In many instances, the entities (e.g. downstream suppliers building to OEM and Airworthiness requirements) that would need to apply for Authorisation do not have the resources (funding and technical knowledge) required for an AfA.

5. Closing questions

35) Do you have any other quantitative evidence on costs and benefits to MS of the current authorisation and restriction processes?

_____

_____

_____

_____

36) Are there any other issues or topics not covered in this questionnaire that you would like the study to consider?

In line with the findings of the 2018 REACH review, we encourage the Commission to pursue improvements that are targeted and incremental, avoiding the severe uncertainty that would stem from an unjustified overhaul of EU chemicals legislation. It would be best to simplify the Authorisation process and add a formal derogation process to Restrictions, rather than completing overhauling the regulation. As previously stated, the removal of Upstream AfAs would be extremely detrimental to industries such as aerospace and defence with complex supply chain and safety related regulatory requirements controlling these supply chains. Options 2, 2A and 3 would result in major changes to the way REACH works today, which in our view are not justified and will introduce significant uncertainties.

Generally speaking, the reform of authorisation and restriction cannot be adequately discussed without taking into account parallel work on generic risk assessment (GRA) and essential use criteria (EUC), as both elements carry the potential to radically impact the framework for risk management under REACH. The rationale to reform authorisation and restriction is partially driven by a willingness to alleviate unjustified burdens on authorities and stakeholders. While some proposals (such as a merger of restriction and authorisation based on GRA and EUC) may appear simple in principle, there is a high probability that in practice these could result in extremely burdensome regulatory procedures. As an example, industry would need to prepare (and authorities would need to assess) significant numbers of EUC derogation requests for professional and consumer uses that may not pose an actual risk but may nevertheless be restricted automatically based on hazard classification under GRA. We agree that the Candidate List should be decoupled from the Authorisation Chapter of REACH. Inclusion in Annex XIV is not necessarily the most appropriate risk management option for all SVHCs, particularly in cases where uses are primarily industrial (including intermediate uses). Once new substances are included in the Candidate List, ECHA could be tasked to conduct a screening to determine the most appropriate regulatory pathway to address potential risks (where this has not already been done earlier in the process eg through the Public Activities Coordination Tool, PACT). This would also allow for a more comprehensive assessment of the interface between risk management measures under REACH and other legislation, such as OSH. As regards options 2, 2A and 3 (merging authorisation with restriction or removing authorisation altogether), we would note that authorisation currently exempts certain uses and applications,

including intermediate uses which are safely managed and contained on manufacturing sites. These exemptions are fully justified and should be maintained.

As regards the reform of restriction and the extension of GRA to professional and consumer uses, AmCham EU continues to support the requirement under REACH Art. 68(1) that restrictions should be initiated where there are unacceptable risks that need to be addressed on a Community-wide basis. These unacceptable risks should be well documented in Annex XV dossiers and thoroughly reviewed by ECHA's committees. We are concerned that the extension of GRA proposed in the CSS will weaken this principle by simply assuming that a risk is present based on hazard classification and shortcutting scientific and socio-economic assessments by RAC and SEAC. In the absence of safeguards for uses that are proven to be safe, we strongly believe this would be to the detriment of EU competitiveness and innovation. In principle, AmCham EU supports the introduction of a "concept of safe use" a, however, we are concerned that the definition of EUC and how it will be implemented is still undefined, should the Commission proceed with the extension of GRA t as announced in the CSS.

Another key issue is the future role of ECHA committees. While AmCham EU agrees that there are areas where improvements can be made (e.g. more resources to ensure committees are equipped to thoroughly review the scientific and technical details of specific proposals), we also believe the answer is to strengthen the role of ECHA committees, rather than remove them from regulatory processes. The latter option can only result in weaker, less thorough decision-making. In a recent CARACAL paper, for example, the Commission indicates that RAC and SEAC may not be included in the restriction process under the planned GRA extension. We find these proposals to be extremely concerning, particularly when it comes to the EU's ability to assess derogations based on essentiality or safe use under GRA. The paper indicates that, in such cases, the burden of proof for justifying and assessing derogations and review periods (including potentially complex joint derogation requests by industry) would be with the Commission. We would strongly advise that the Commission includes a role for RAC and SEAC in delivering expert opinions as part of this critical process. We also believe derogations should be assessed by ECHA committees during the restriction adoption process (as opposed to after adoption). This would help avoid unintended consequences and allow for regulatory decisions that are based on a comprehensive understanding of how potential restrictions are likely to impact EU industry, technology and overall competitiveness. We particularly disagree that GRA should be applied indiscriminately to the wide range of current and future hazard classes presented above (e.g. sensitisers, neurotoxic/immunotoxic substances, STOT) as well as to articles and professional uses where users are well trained on the safe use of substances.

AmCham EU aligns with ASMoR's additional views on derogations for minimal exposure. We support the notion that safe uses should be derogated from risk management measures, but disagree with the framework for minimal exposure route presented in this questionnaire. This relates to two points, i.e. (1) the part of the life-cycle for which minimal exposure needs to be demonstrated and (2) the additional condition that there must not be any alternative available.

Regarding 1: We emphasise that the scope of having to demonstrate minimal exposure should be focused on the regulatory objective, which is to ensure (1) for HH the safety of consumers (and – particularly still under discussion – of (some) professionals (2) for ENV the prevention of risks arising from consumer (and possibly some professional) uses. In order to obtain a derogation based on

demonstrated minimal exposure, it should be decisive whether the minimal exposure can be demonstrated for the scope of the restriction under consideration. E.g. for a substance in an article, it should be demonstrated that the consumer using the article only faces minimal exposure to the substance and that there is no relevant exposure of the environment to the substance arising from the use of the article.

Extending the scope of having to demonstrate such minimal exposure to workplaces would significantly undermine OSH and would lead to bans of materials that are safe to use for consumers and that the derogation route is meant to prevent. We strongly object to a broadening of the GRA and EUC concept to uses that are covered by OSH.

Regarding 2: Where the consumer use of a substance is actually safe for both HH and ENV (due to minimal exposure), the derogation should be granted regardless of alternatives that may or may not be available. Otherwise, a complex Analysis of Alternatives would need to be conducted for many uses for which authorities have already assessed the safety of the continued use of substances with certain hazard profiles. Simply pushing for the use of substances that do not have the hazard classification of a 'most harmful chemical' could lead to cases where substances with perceived 'lower' hazard classifications (e.g. acute toxicity) would lead to actual risks, where the substance with the 'higher' classification was safe to use. Also, articles containing substances with a 'lower' hazard classification may not provide the same durability / environmental performance (higher CO2-footprint, lesser recyclability, etc.). Not permitting the continued safe uses of substances will lead to regrettable substitution and to the needless lowering of performance of articles.

Regarding question 26. AmCham EU did not submit an application for authorization but AmCham EU members did.

Regarding questions 30 and 31 – the ranking of the options was done in order of preference.

37) Do you consent to being contacted for a follow-up call with the VVA Consortium to clarify some of your answers and/or provide additional input?
*

(x) Yes

( ) No

38) If so, please provide contact details if different form your answer in the introduction.

x_____

_____

_____

_____

39) Please use the button below to upload any document you would like to share with the study team.

Thank You!