



What are the REACH duties of article suppliers ?

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A. Scope of this presentation

This presentation covers REACH duties of article producers and article importers

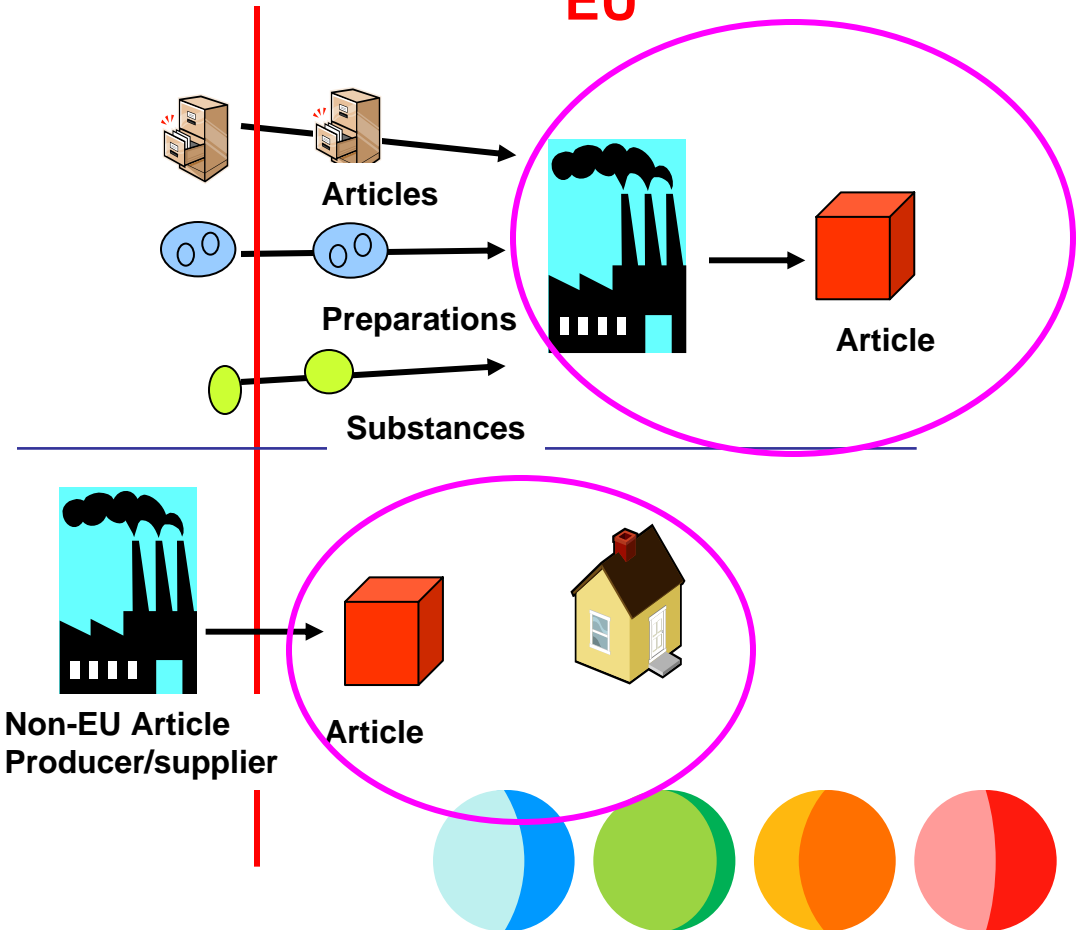
-> when they put an article on the market

Non-EU

EU

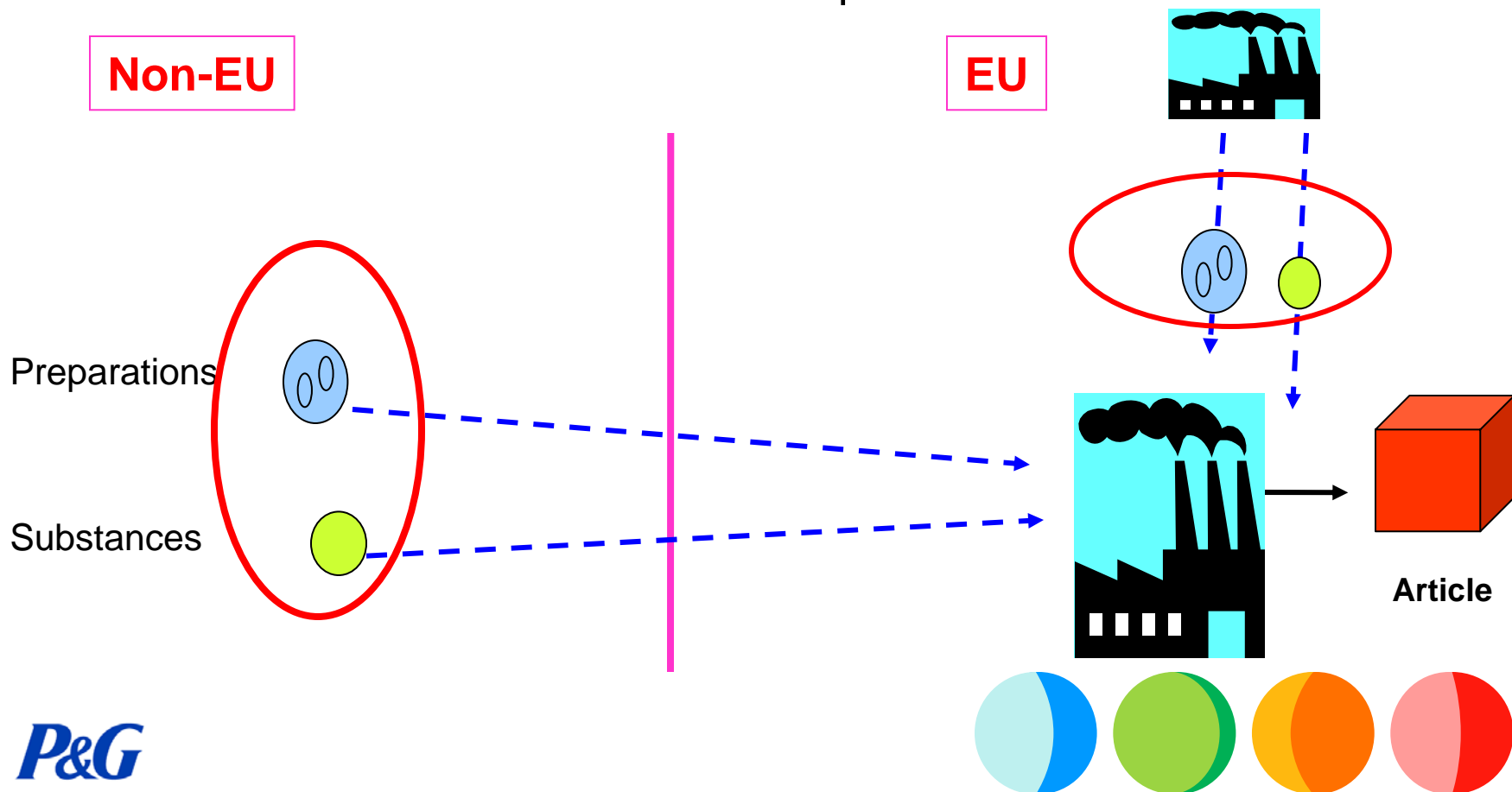
1. an article producer or

2. -an article importer or
-an only Representative of non-EU producer of article



This presentation **does not cover** REACH duties when article suppliers:

- -> import substances/preparations from non-EU suppliers
- -> buy substances/preparations from an EU supplier, i.e. downstream user requirements



B. Definition

Definition of Article:

means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”

Examples: Packaging, furniture, clothes, vehicles, books, toys, kitchen equipment and electronic equipment.

Is my product an article?

Look at Guidance: Substance in article (RIP 3-8) –

“Decision taking on the article definition” in Figures 2 and 3 (+ Appendixes 1 & 2)



C. What are the duties of article suppliers under REACH?

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1.1. When do I have to pre-register and register substances in articles ?

A **pre-registration and registration** of substances in article is obligatory for an article producer / importer only if all the following conditions are met (Art 7(1)):

- a) The substances are intended to be released from article(s) during normal and reasonable foreseeable conditions of use and
- b) The total amount of the substance present in the articles with intended releases produced and/or imported by that actor exceeds 1 tonne per year per producer or importer and
- c) the substance has not yet been registered for that specific use ^(a)



(a) What do they mean by “*the substance has not yet been registered for that specific use*”?

- This refers to any registration for that use of the substance up the same supply chain or any other supply chain.
- At the time of pre-registration, the supplier will not know yet whether his substance will be registered later on for that use.
- Therefore it is strongly recommended that article suppliers pre-register any substance in articles for which the conditions a) and b) mentioned in previous slide are met, as this is a pre-condition to be able to benefit from the extended phase-in deadlines for registration.



(a) **What do they mean by “*the substance has not yet been registered for that specific use*”? (con’t)**

- However, after pre-registration, you could do the following to avoid performing a Registration on those substances:
 - ➔ the easiest is to ask your own EU supplier to include your use in his registration dossier or
 - ➔ another option is that as you will part of SIEF, you could potentially find another supplier there who will register the substance for that use
 - ➔ you could also ask the Agency whether your specific use has been registered



1.2. How to assess the tonnage band of substance to be registered?

This is illustrated by the following example:

If a company X imports three articles A, B, and C with 60 tonnes of the substance present in each but:

- in article A, 0 out of 60 tonnes are released under normal conditions and
- in article B, 40 out of 60 tonnes are released under normal conditions and
- in article C, 10 out of 60 tonnes are released under normal conditions,

➔ the company X will need to register the total volume of the substance in article B and C: i.e $60 + 60 = \underline{120 \text{ tonnes}}$,
i.e. in the 100-1000 tonnes band.



1.2. How to assess the tonnage band of substance to be registered?

Rules

- The amounts intended to be released as well as the amounts which are not intended to be released have to be taken into account
- If more than one type of article with intended release is produced / imported, the quantities of that substance in all articles with intended releases have to be summed up.



1.3. When should I pre-register and register?

Pre-Registration

(June 1, 08- December 1, 08)

Registration
(Dec 2010)

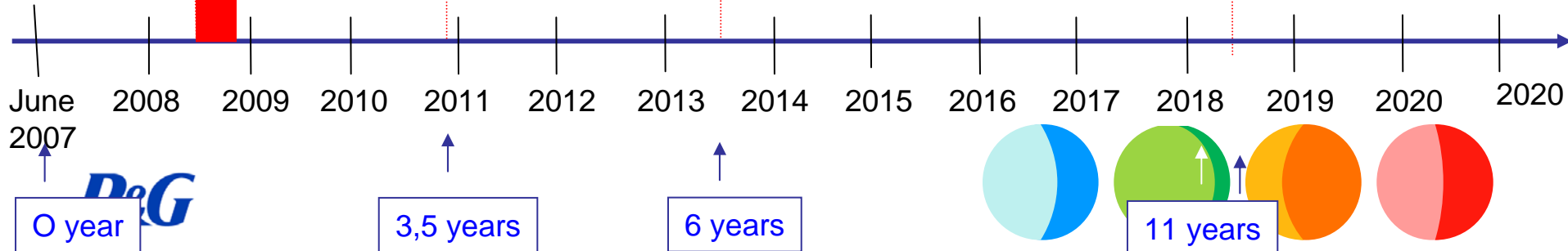
>1000t/y
or CMR 1&2 at >1t/y
or subst. classified R50/53 >100t/y

Registration (June 2013)

>100-1000t/y

Registration (June 2018)

>1-100t/y



1.4. How easy is to prepare a pre-registration dossier ?

- ✓ Yes, it is very easy to prepare
- ✓ Content of pre-registration dossier is very limited (only very few information to be provided)
- ✓ Pre-registration not followed by Registration later on will not be penalized
- ✓ Pre-registration made for a specific tonnage band could be followed by a Registration at a different tonnage band without leading to penalties



1.5. What are the drawbacks if I don't Pre-register within the deadlines?

*Pre-registration is by far the most urgent item right now

*No Pre-Registration of substance within pre-registration deadlines

i.e June 1, 2008 until December 1, 2008 will lead to

➔ No manufacturing or No import of the those substances after December 1, 08 !

*To re-manufacture or re-import the substance after that date:

- a registration dossier will have first to be prepared (this may take several months),
- then submit to ECHA (Chemical Agency), and only 3 weeks after this submission, the substance could be re-manufactured or re-imported

1.6. What happens if I produce or import an article with intended release for the first time after December 1, 08. Can I still pre-register?

Yes, if an article producer or importer :

- produces or imports an article with intended release of substances / preparations for the first time after 1 December 2008, or
- for the first time exceeds the threshold of 1 t/y for the substances intended to be released,

-> He could submit a pre-registration **in parallel** of his manuf. or import even though the deadline has expired,

....**BUT** provided that he submits the pre-registration within the following deadline:

- within six months of first manufacturing, importing or using of the substance at >1t/y and
- no later than 12 months before the relevant Registration deadlines i.e Dec 2010, June 2013, June 2018



1.7. What are the drawbacks if I don't Register within the deadlines?

*No Registration of substance within Registration deadlines
i.e Dec 2010 or June 2013 or June 2018 will lead to will lead to

➔ No manufacturing or No import of the those substances
after these deadlines !

*To re-manufacture or re-import the substance after that date:

- a registration dossier will have first to be prepared (this may take several months),
- then submit to ECHA (Chemical Agency), and only 3 weeks after this submission, the substance could be re-manufactured or re-imported



1.8. Can the Agency also ask for registration of other substances contained in the article and which are not intentionally released?

Yes, the Agency may decide that an article producer or importer must submit a registration for any substance contained in an article:

- if the amount of the substance exceeds 1 tonne per year and
- if there is a suspicion that it is released from the article resulting in risks to humans or the environment and
- if the substance has not yet been registered



C. What are the duties of article suppliers under REACH?

- 1) Pre-Registration and Registration of substances intentionally released from articles
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What are Substances of Very High concern (SVHC) ?

SVHC includes substances which are:

- Carcinogens, mutagens or toxic to reproduction (CMRs category 1 and 2), or
- Persistent, Bioaccumulative and Toxic (PBT) or
- Very Persistent and very Bioaccumulative (vPvB) or
- For which there is evidence for similar concern.

Watch out:

-SVHC present in articles at >0.1% includes intentional substances but also impurities!



Is a SVHC list already available today?

- No, a first candidate list of SVHC should be published by the Authorities around early 2009 on the ECHA website
- Inclusion of substances in the candidate list is preceded by a formal procedure detailed in Article 59 of the REACH Regulation, involving ECHA, Member States and interested parties
- This list will be dynamic and will be updated continuously when substances have been identified as meeting the criteria of SVHC
- Be aware that we expect current list of substances officially classified as CMR Cat. 1 & 2 (attached) to be part of this Candidate list of SVHC



Microsoft Excel
Worksheet



How do I calculate 0.1%(w/w) of SVHC in the article?

- The substance concentration threshold of 0.1 % (w/w) applies to the article as produced or imported.
- It does not relate to each homogeneous materials or parts of an article, as it may in some other legislation, but relates to the article as such (i.e. as produced or imported).

For example:

- If buttons for jackets are imported as such which contain a SVHC in concentrations of 0.5% (w/w), this will trigger the 0.1% limit.
- If now these buttons are imported as part of jackets the final concentration will probably be $> 0.1\%$ (w/w) and in that case no notification will have to be submitted
- However packaging should be considered as a separate article. E.g: if imported jackets are packaged in plastic packaging material, the content of SVHC in this packaging material would have to be assessed separately.



2.1. Notification to ECHA

2.1.1. What are the criteria for submitting a Notification of SVHC to ECHA?

When all the four following conditions are met:

- 1. The substance is included in the candidate list of SVHC for authorisation and
- 2. the substance is present in the article above a concentration of 0.1% (w/w) and
- 3. the substance is present in all articles produced or imported in an amount totalling over 1 tonne per year (per producer or importer) and
- 4. the substance has not yet been registered for that specific use

- However, no notification is required, if the following condition is met:
 - the producer or importer can exclude exposure of the substances to humans or the environment during normal or reasonable foreseeable conditions of use including disposal
- Be aware that this notification requirement does not apply retroactively i.e.

a notification is not required, if the article containing SVHC has been produced or imported before the substance has been included on the candidate list for authorisation.



2.1.2. By when should I submit the Notification?

The notification of SVHC in articles shall be submitted :

- > at the latest 6 months after it has been included on the candidate list for authorization
- > but only starting from 1st June 2011.



2.1.3. What is the content of Notification dossier?

- The information to be notified shall include the following:
 - (a) the identity of the producer or importer
 - (b) the registration number(s) of the substance if available;
 - (c) the identity of the substance .
 - (d) the classification of the substance(s)
 - (e) a brief description of the use(s) of the substance(s) in the article
 - (f) the tonnage range of the substance(s) contained in the article, such as 1 -10 tonnes, 10 -100 tonnes and so on.



2.1.4. How will I know from my supplier that my article contains SVHC at > 0.1% (w/w)?

- **A. If I receive substance and/or preparations from an EU supplier**, my supplier will have the duty to communicate the following information to me:
 - through SDS (if required): classification of the substance and information on the authorization if the substance is SVHC, and concentration range of SVHC in preparations
 - or through Art 32-information (if no SDS is required): if the substance is subject to authorization, and any details of any authorization granted or denied



2.1.4. How will I know from my supplier that my article contains SVHC at > 0.1% (w/w)? (con't)

B. If I received a an article from my supplier, he will have the duty to communicate presence of SVHC at >0.1% (w/w) through the supply chain (see next Section)

- If these information are not sufficient, you will have to ask this information to your supplier by other means
- For your information, Appendix 5 of the guidance provides list of information available on substances in articles
- However conducting chemical analysis on the article should only be used as “last resort”



2.2. . Communication of safety information down the supply chain if SVHC is present in article at >0.1%

2.2.1. Which information do I have to be provided to my customer i.e. the recipient of the article*?

You will have to provide the recipients of the articles with:

- > sufficient information, available to the supplier, to allow safe use of the article and
- > as a minimum the name of the substance.

➔ Please note that there is no tonnage trigger for this obligation (i.e. it also applies < 1 tonne/y)



*Recipient does not include consumers



2.2.2. Should I also provide information to consumers if my article contains SVHC at >0.1% (w/w)?

- Yes, but **only upon request**
- You will have to provide them with sufficient information, available to the supplier, to allow safe use of the article and as a minimum the name of the substance
- Consumers should receive the relevant information within 45 days of receipt of his request and free of charge



2.2.3. How should I communicate presence of SVHC in my articles to my customers or consumers?

- REACH Regulation does not specify any format /template
- Information on the same article can be different in information type, detail and format for consumers or professional users
- Some examples are provided in the guidance



2.2.4. As per when should I provide these information to my customers or consumers ?

- As soon as the substance is included on the candidate list of SVHC for Authorization (first list is expected early 2009).
- Be aware that this communication requirement does apply retroactively

The obligations apply also for articles which were produced or imported before the substance was included on the candidate list and are supplied after the inclusion. Thus, the date of supply of the article is relevant.



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3.1 When do I need to comply with Authorization?

If an EU producer of an article incorporates a SVHC as such or in preparation into the article at $>0.1\%$ (w/w), which is listed in Annex XIV of REACH “List of substances subject to Authorization”:

-> that use of a substance will be banned after a specific date unless authorized for a specific use

➤ If the SVHC is bought from an EU supplier:

-> the EU supplier has to give the authorization information to his Downstream User through SDS (Section 16) or via other means if SDS is not required

➤ If the SVHC is imported as such or in a preparation from a non-EU supplier:

-> the producer of article will have to apply for an Authorization for continued use



3.2. Who can apply for an Authorization application?

- ✓ -> the manufacturer(s), importer(s) and/or downstream user(s) of the substance
- ✓ -> one or several persons.

3.3. What should I do to apply to an Authorization?

Supplier will have:

- > to prepare an Authorization dossier and
- > will have to submitted it to the Agency **at the minimum 18 months before the sunset date** indicated in Annex XIV, date from which the placing on the market will be prohibited unless an authorization is granted



3.4. What are the criteria for Authorization granting?

-> For CMR Cat. 1 & 2, subst. of equivalent concern where safety threshold can be defined

-> Auth. **shall** be granted if Risk is adequately controlled.

-> For same than above for which no safety threshold cannot be defined +PBT, vPvB

-> Auth. **may** be granted if

- socio-economic benefits outweigh risk
- if no suitable alternatives

3.5. Once granted, is an Authorization valid forever?

-No, an Authorization shall be subject to time-limit review.

-> The duration will be determine on a case-by-case basis



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4.1 When do I need to comply with Restriction?

- The content of substances in articles can be restricted or banned under the restrictions procedure.
- Article producers and importers have to follow the conditions outlined in Annex XVII* of REACH from June 1, 2009.
- Until then, the Directive on Marketing and use of dangerous substances (76/769/EC) is still in force.
- Be aware that other legislation's concerning restrictions in articles still apply separately from REACH e.g. General Product Safety Directive (2001/95/EEC), RoHS (2002/95/EC) etc...
- More information on the subject on Appendixes 6,7 of RIP 3.8

**ANNEX XVII is the Annex on Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles*



4.2. Will my supplier have to communicate to me any information related to Restriction?

➤ If I receive substance and/or preparations from my EU supplier to make my article:

-> my supplier will have the duty to communicate the following information to me:

- **either through SDS** (if needed): information regarding restriction of substance or preparation , where applicable (in Section 2 or 3 of SDS)
- **or though Art 32-information** (if no SDS is required): details of any restriction imposed

➤ If I received a an article from my EU supplier, he will have **no duty** to communicate restrictions applicable to this article



Timelines: Summary

1. Pre-Registration

(June 1, 08- December 1, 08)

1.1.Registration
(Dec 2010)

>1000t/y or CMR 1&2 at >1t/y
or subst. classified R50/53 >100t/y

1.2.Registration (June 2013)

>100-1000t/y

1.3. Registration (June 2018)

>1-100t/y

2.1. Notification of SVHC in article

(to be submitted at the latest 6 months after it has been included on the candidate list for authorization but only starting from 1st June 2011)

2.2. Communication of SVHC in article down the supply chain

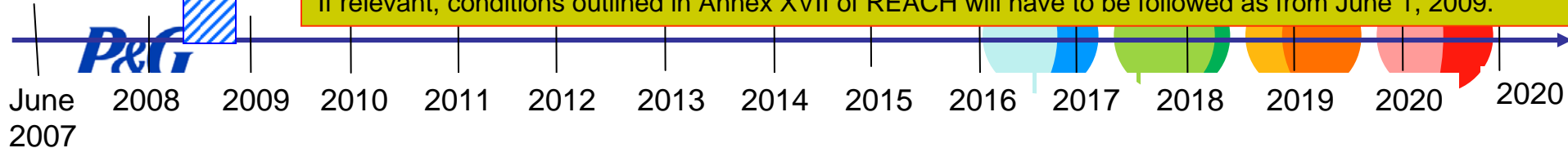
(As soon as the substance is included on the candidate list , which is expected early 09)

3. Authorization

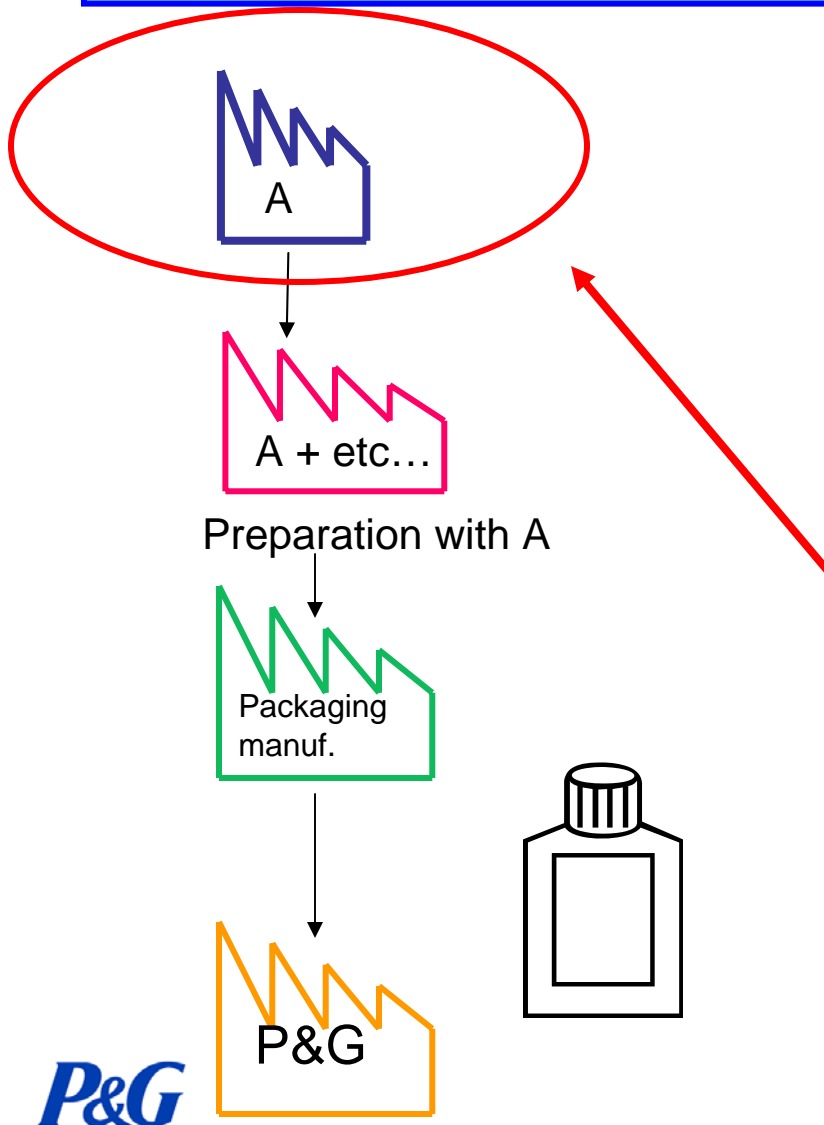
If relevant, ban of use of substance will be apply as per the sunset date provided in Annex XIV (first publication of this Annex planned in 2009). Otherwise authorization dossier will have to be submitted 18 months before the sunset date provided in Annex XIV.

4. Restriction

If relevant, conditions outlined in Annex XVII of REACH will have to be followed as from June 1, 2009.



D. What does P&G expect from their suppliers in the packaging supply chain?



1) Commitment from the original manufacturer /importer of the substances which end-up in our packaging, at the top of our supply chain in the EU, that they will be pre-registered and registered those substances



Why? This is critical to guarantee supply continuity

Recall If no pre-registration between June 1, 08 and Dec 1, 08
-> no supply continuity as per December 1, 2008!

How? P&G will:

- a) send letters to their direct suppliers on the topic and
- b) put new statement in specification sheets of materials

we buy to our direct suppliers

-> indicating that we expect them to pre-register & register if they are the manuf./importer of substances used in the articles and
-if not, to ensure that their own suppliers or suppliers above the supply chain will take over this responsibility

When? Very quickly as Pre-registration deadlines are very tight

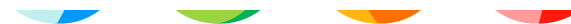
i.e June 1, 08 until December 1, 2008



2) Expect our suppliers and suppliers of our suppliers **not use any SVHC** which would end-up in articles at >0.1% (w/w).

Why?

- > Companies like us will be under high scrutiny by Authorities and other stakeholders as soon as Candidate list of SVHC will be published, early 2009
- > Absence of use of SVHC in the whole supply chain will lead to much less work for the whole supply chain i.e.
 - no notification,
 - no communication down the supply chain and
 - no authorization
 - no need to analyze what we import
- > If present at >0.1% , and REACH duties are not fulfilled, industry in supply chain will have sanctions



How? -P&G will put new statement on the topic in our specification sheets of products we buy to our suppliers as per mid 2008
i.e we will indicated that none of the products we buy should contain SVHC from the candidate list at >0.1%(w/w)

-We will also send a letter to our suppliers soon to inform them about the above



3) Expect our suppliers and suppliers of our suppliers to comply with Authorization and Restriction rules

How? P&G will:

- a) send letters to their direct suppliers on the topic and will ask them to do the same with their own suppliers and above the supply chain

- b) put a new statement in specification sheets of products we buy to our suppliers indicating this expectation





Thank you!