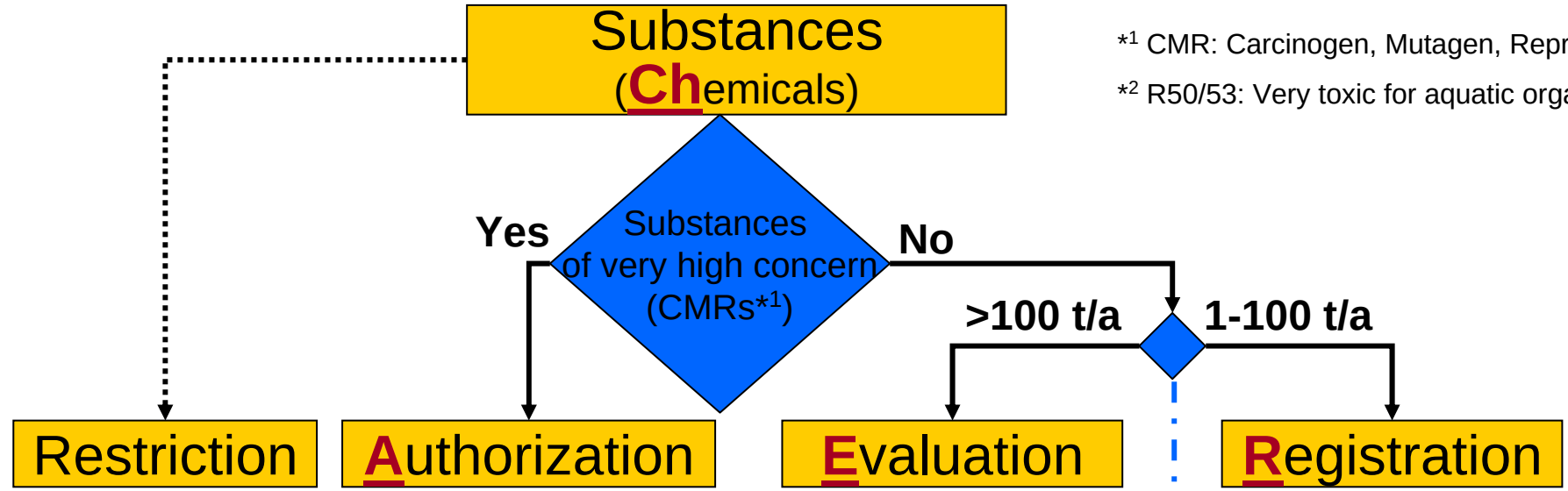
Idea to use IMDS & GADSL

for Authorization & Restriction tracking

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

REACH - General Rules



*1 CMR: Carcinogen, Mutagen, Reprotoxic

*2 R50/53: Very toxic for aquatic organisms

Transition Period (only for Pre-Registered Substances):

Deadline for Pre-Registration
(Pre-Reg =12-18 month after entry into force)

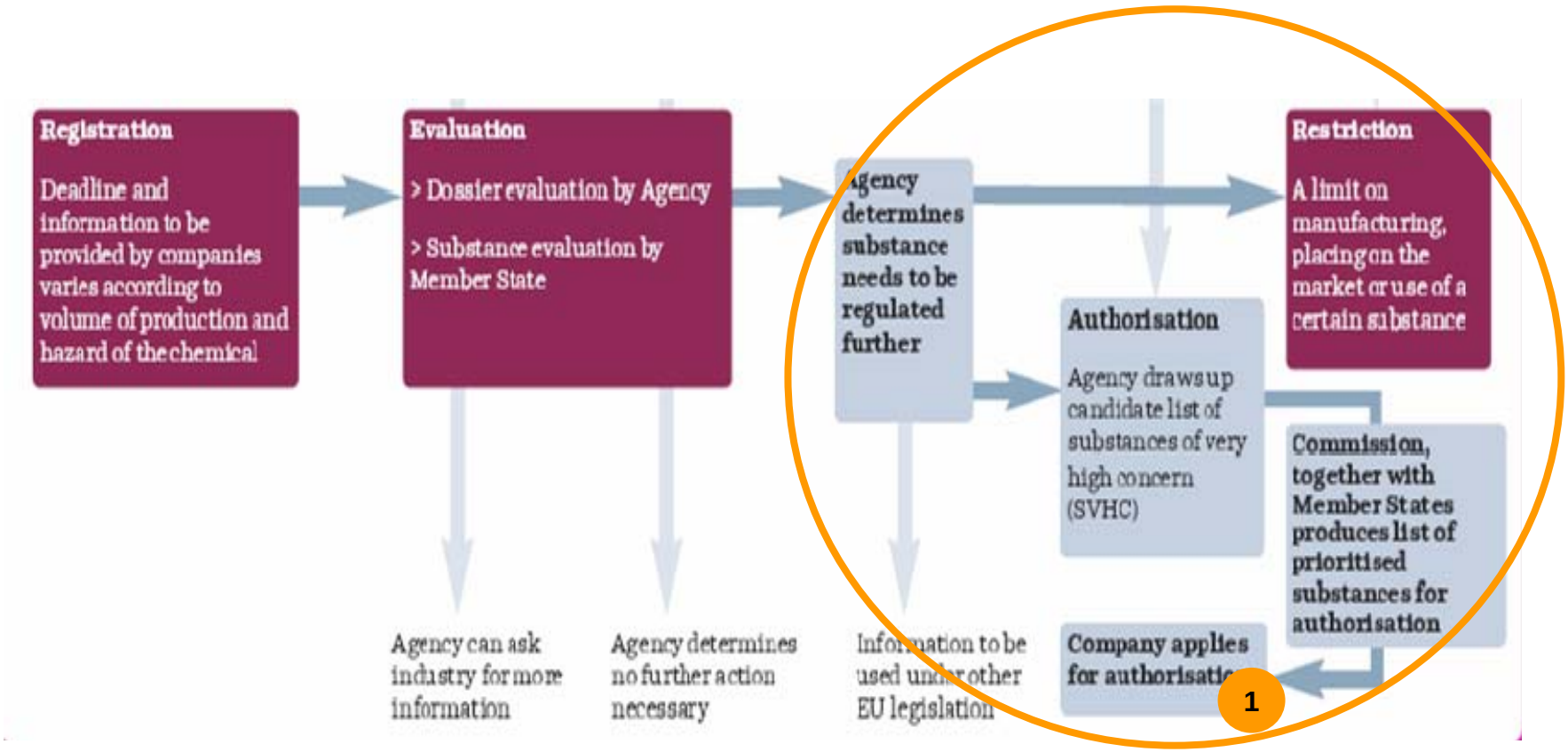
06/2007	2008	12/2010	06/2013	06/2018
REACH enters into force		Registration & Evaluation - of Substances>1000t/a - of Substances>100t/a which are classified as R50/53*2 +Substances for Authorization	Registration & Evaluation of Substances 100-1000t/a	Registration of Substances 1-100t/a

Registration for all substances > 1t/a, NOT been pre-registered!

optional — mandatory

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

REACH …after Evaluation



1 Authorization for use is given to producer/importer/user of a substance who applies for Authorization of use for a substance contained in Annex XIV. You need to make sure that they include your 'use' and your customers.

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

Objectives of Authorization & Restriction

Under Authorisation, every use of a substance is prohibited if not explicitly allowed

Under Restriction every use of a substance is allowed if not explicitly prohibited.

Aim of Authorization:

Goal is to ensure the good functioning of the internal market while assuring that the **risks** from substances of very high concern **(SVHCs)** are properly **controlled** and that these **substances** are progressively **replaced** by suitable **alternative** substances or technologies where these are economically and technically viable.

- Exemptions: R&D, pesticides, biocides, medicinal products, food additives, flavourings in food, fuels…
- Will affect around **1.500 substances!!!**

Aim of Restriction:

Goal is to address at EC level unacceptable risks to human health or the environment, arising from the manufacture, use or placing on the market of substances.

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

Restriction and / or Authorisation

Annex XV Dossier MS or ECHA (at COM´s request)

Candidate List Substances

Prioritisation

Comitology Process

Annex XIV (Authorisation)

After sunset date, Industry is not allowed to place on the market or use a substance included in Annex XIV unless industry has an authorization granted by the COM

- Annex XIV
  "LIST OF SUBSTANCES SUBJECT TO AUTHORISATION"
- Necessary for each use of SVHCs (only) in an industrial / professional application without tonnage threshold
- Periodic review (twice a year)
- Authorization process may not lead to a relaxation of a restriction.
- Substitution principle

Annex XV Dossier MS or ECHA (at COM´s request)

ECHA is required to assess, for every substance in Annex XIV, whether there are risks related to articles that must be addressed. If so, ECHA is to prepare an Annex XV dossier with a view to introduce a restriction.

Comitology Process

Annex XVII (Restriction)

Industry has to comply with the conditions of the restriction in Annex XVII for the substance (including, if relevant, manufacturing and uses in articles)

- Annex XVII Former 76/769/EEC (and others)
  "RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES
- Groups of chemicals (not only SVHCs)
- Total bans are possible but rare in practice
- Review on request
- *Cannot fall under Authorization*

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

But what does this means for articles?

- If you use Annex XIV substance to produce Articles within the EU, Authorization is required
- If you use Annex XIV substance to produce Articles outside the EU, Authorization is **not** required
- If you import articles containing Annex XIV substance, Authorization is **not** required

➡ **If you use non-EU articles, you don´t need to worry about Authorisation**

➡ **However, those Articles might be effected by a Restriction:**

- Risks arising from substances contained in articles can only be addressed through a restriction (not through authorization).
- Restrictions can be introduced even though the substance is listed in Annex XIV, if its presence in articles poses an unacceptable risk for man or the environment and this risk

Timelines for Candidate List -> Annex XIV

Candidate List

Agency prepares draft recommendation dossier

MS Committee consultation

Agency revises draft recommendation dossier

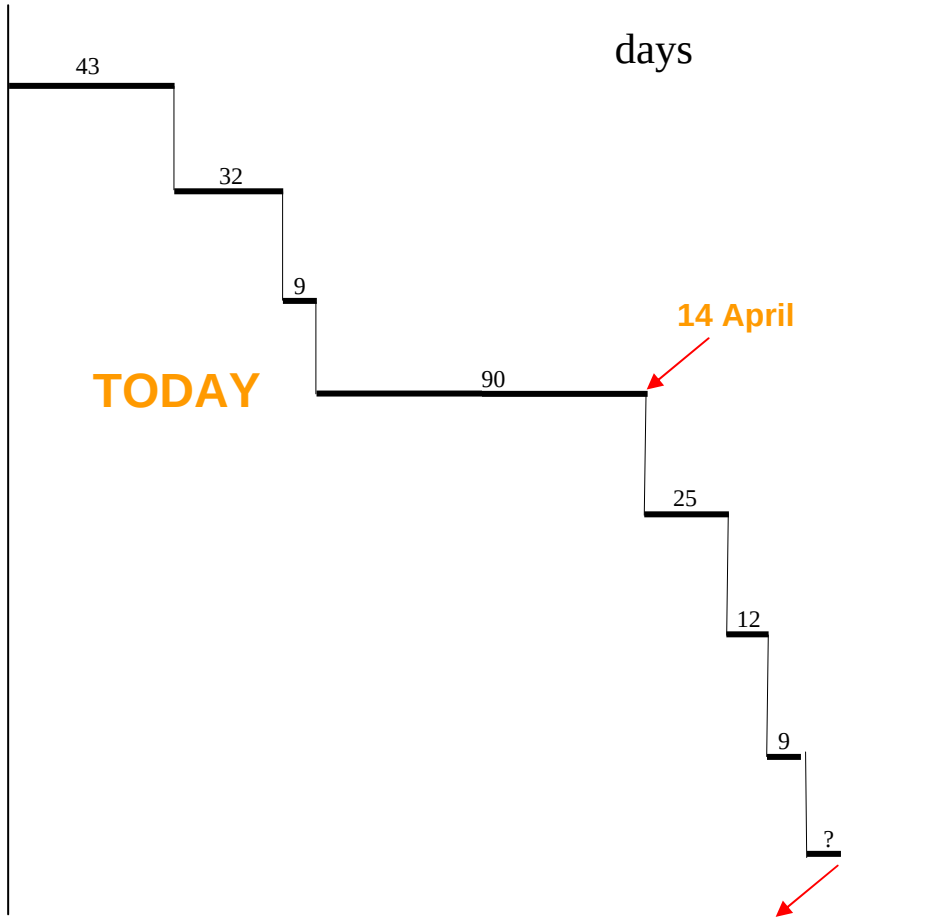
Commenting period all stakeholders

Agency revises draft recommendation dossier

MS Committee consultation

Agency sends recommendation to commission

Commission publishes priority list



Frequency: 2 x per year; First: 1 June 2009 ?

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

Proposal of Annex XIV – Prioritisation & Authorization Timeline

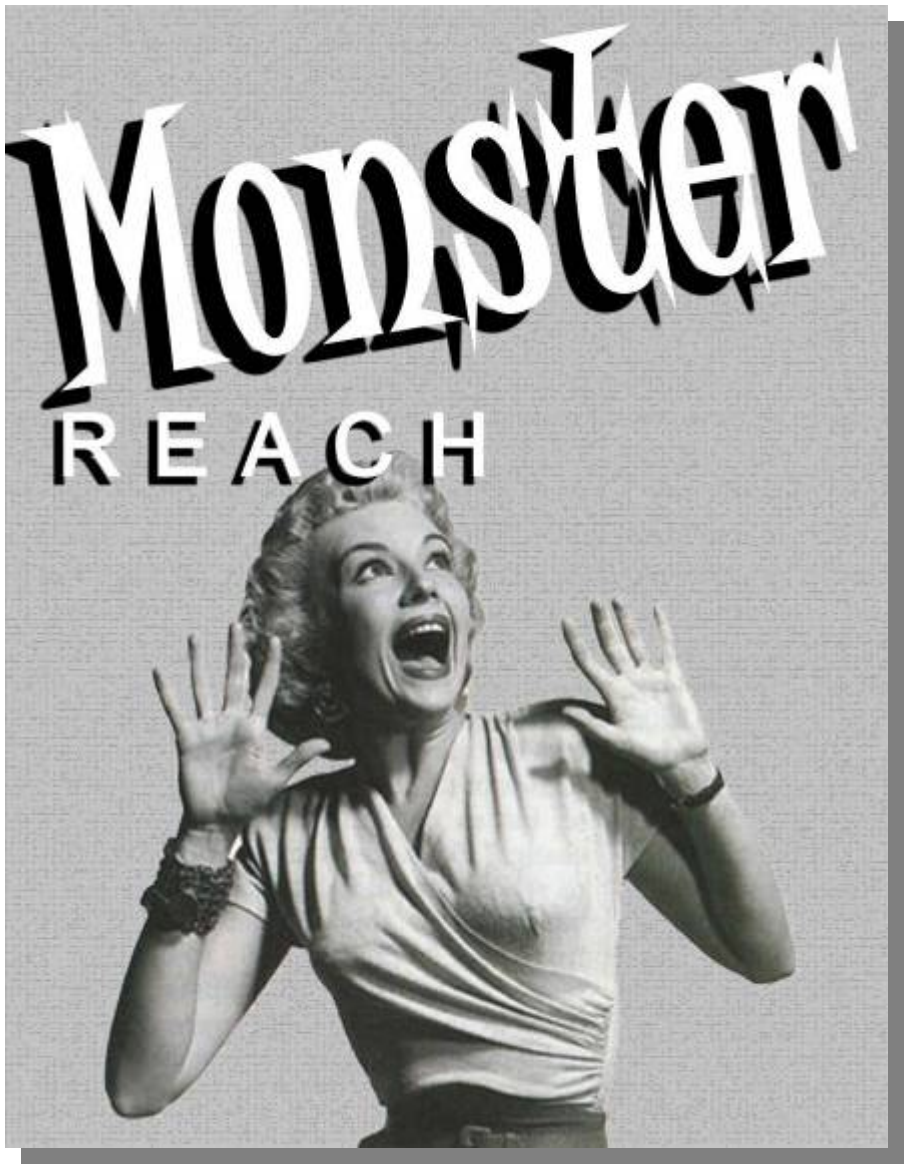
- After the sunset date, it can only be used or placed on the market by any manufacturer, importer or downstream user for any use of the substance on its own, in a preparation or the incorporation into an article (not for import) if:
  - the use has been Authorized to himself or an immediate downstream user or his supplier, or
  - the use is exempted from the Authorization requirement, or
  - the sunset date has not yet been reached or
  - an application has been made at least 18 months before the sunset date and no decision has been taken yet.
- Request for Authorization must be applied latest 18 Month before the sunset date!

Draft recommendation dossiers (likely to end up on Annex XIV):

Substance	GADSL Category	# of references in 2,8M MDS (# of MDS)	Latest application Date		Sunset Date
Musk xylene	None	No usage	1 June 2011		1 Dec. 2012
MDA	P	277	1 June 2011		1 Dec. 2012
SCCP	P	235	1 Sept. 2011		1 March 2013
HBCDD	D	10 K	1 Sept. 2011	+18=	1 March 2013
DEHP	D	1.3 M (170 K)	1 Dec. 2011		1 June 2013
BBP	D	21 K	1 Dec. 2011		1 June 2013
DBP	D	45 K	1 Dec. 2011		1 June 2013

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

How to tame the Authorization Monster?



We can expect that in future more and more substances (which are used within the Automotive Industry) will be added to Annex XIV

- For some of them, no authorization will be granted by the Commission
- For others, the substance producer / importer/user will not apply for authorization due to cost reasons

→ **Substances will disappear**

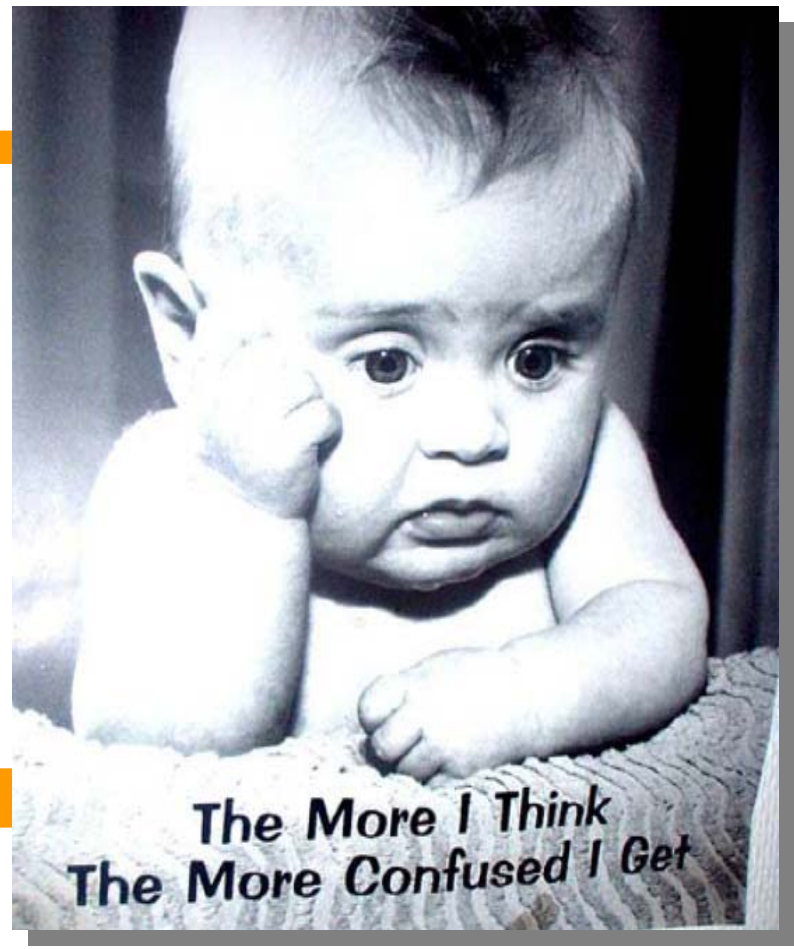
→ **Our products / productions definitely are affected**

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

The basic question

The basic question:

How can we control, whether our substances have been Authorized by our suppliers (Annex XIV) or whether a restricted one has been used (Annex XVII)?



The idea / suggestion

- IMDS & GADSL can be used to track the Authorization activities of the supply chain – ONLY FOR PARTS BUT NOT PROCESSES!
- To do so, some minor enhancements of the GADSL list as well as of the IMDS needs to be done.
  - New GADSL Classifications & new IMDS Application Codes:

	(**New**) GADSL-Classifications	IMDS-Application Codes (on substance level?) 1st Level	2nd Level	
Substances on the Candidate List	**D** (if applicable for AI)	-	-	
Substances on Annex XIV (Authorization)	**D/P** (if applicable for AI)	Authorized	Expiration Data	(Formatted Text Field)
			Authorization Number	(Formatted Text Field)
		Not Authorized		
		Authorization in progress	Applied on:	(Formatted Text Field)
		Not applicable	Use exempted	(Tick Box)
			Produced outside EU	(Tick Box)
			Others	(Contact your customer)
Substances on Annex XVII (Restriction)	**P** (if applicable for AI)	-	-	

What else…?

What else:

- The REACH TF is considering the Authorization & Restriction Process under REACH as of very critical for our all business.
- Compared to the ELV Annex II (4 Substances), the Authorization challenge (>X00(0)? Substances) is expected to be much more time and cost consuming.
- If Authorization for use is not granted and substitution becomes necessary it will involve companies in an alternative substance search and new validation
- Similar to the Annex II activities, the TF is therefore currently discussing to start common activities for lobbying and stakeholder consultation replies.
  - As we well know from our ELV experience, the secret of success is a good coordination of our sector specific information and strategies.
  - Coordination can be done by an AI internal volunteer or an external consultant (Budget needed!)
  - The discussion will be continued…

➡ **For successful lobbying, the supplier input is key!**

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group

Last but not least

IMPORTANT TO NOTE!!!

- **The discussion just has started and no decision has been made**
- **Your input is highly appreciated**
- **Don´t forget...**

…Together we are stronger!!!

REACh

Backup

Summary of authorization lists

1 Pre-Candidate list

- Purpose: identifying substances which meet the criteria (CMR 1/2, PBT/vP SVHC)
- As per 59 (4) ECHA publishes a note that an Annex XV dossier for a substa happened shortly after 1 June 2008
- Comments possible but timeframe limited 60-90 days
- Only Member States can stop the process, it will then go into a Committee p
- No possibility to remove substances from candidate lists foreseen!

2 Candidate list

- As per Art 59 (6), in case of no comments from the Member States committee included in the candidate list.
- The candidate list was published for the first time in November 2008. With ever tion communication will be required.
- Art 33 applies as of (2) is published (August - September 2008) communication sumers.

3 Pre-Annex XIV list

- Purpose: identify substances intended for authorization
- As per Art. 58 (4), ECHA shall make publicly available a recommendation to inclu n Annex XIV. This happened on 1 March 2009 (3 month period for comments)
- Recommendation from Agency to Commission, taking into account handling capab ll only contain a handful of substances)

4 Annex XIV (Authorization Priority List)

– Purpose: contains the substances which are under authorization, specific timeline e r sunset date & application for authorization of use

- As per Art. 58 (3), ECHA makes a first recommendation of priority substance to be in Annex XIV. Art. 58 (3) defines this to happen on 1 June 2009.

– Expected maximum capacity: 25 / year

– Polymers not exempt

Hyundai Motor Europe Technical Center
Regulation•Vehicle-Safety•Environment
European Environmental Strategy Group