

# Applications for authorisation:

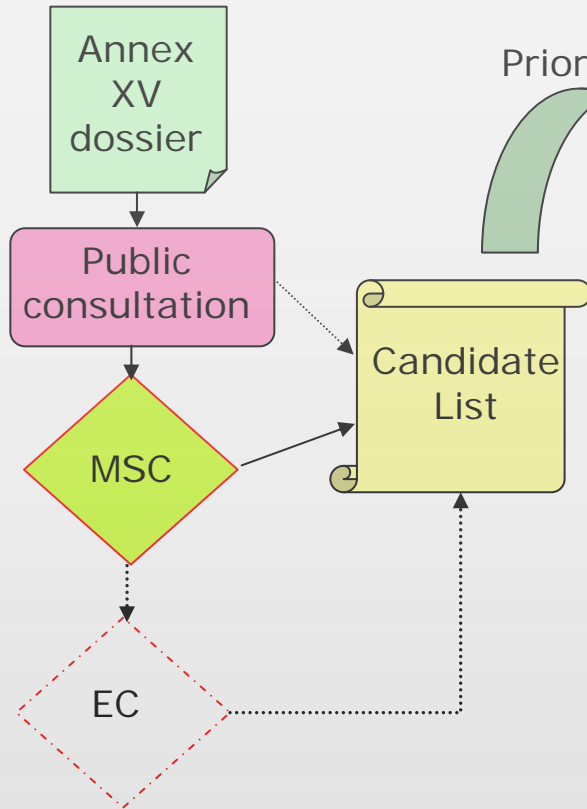
How can applicants and stakeholders  
best contribute to the process?

ECHA's seventh Stakeholders' Day  
23 May, 2012

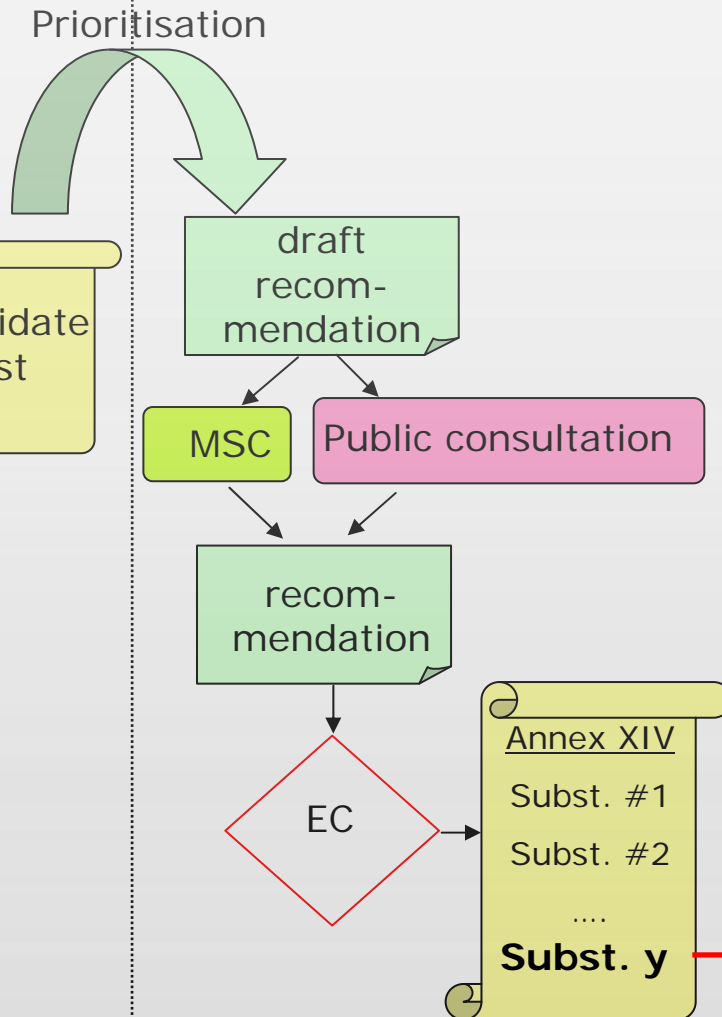
Matti Vainio  
Head of Unit – Risk Management  
Implementation  
ECHA



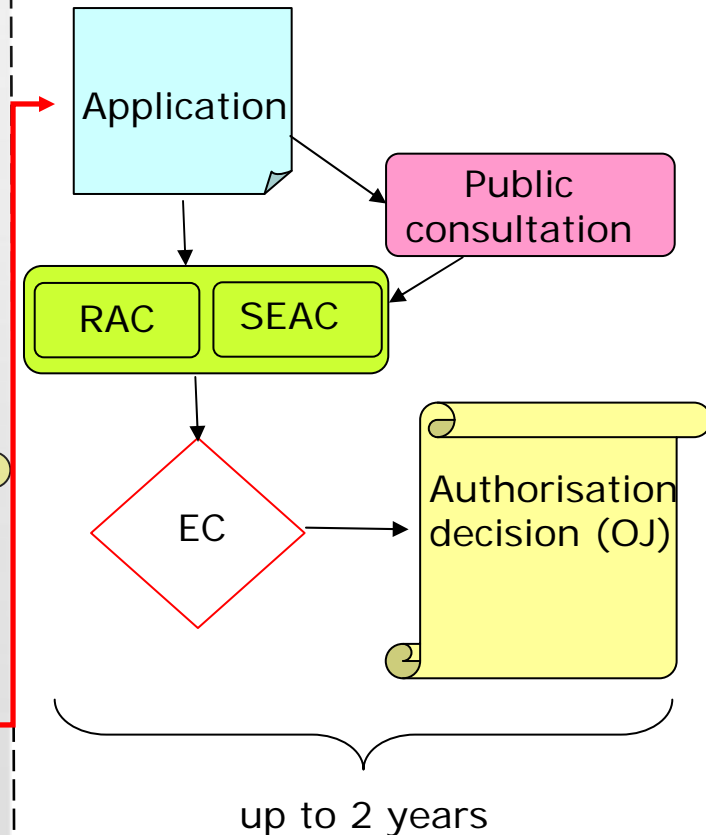
## Step 1.1: Identifying SVHCs



## Step 1.2: Subjecting priority substances to authorisation



## Step 2: Granting (or not) authorisation



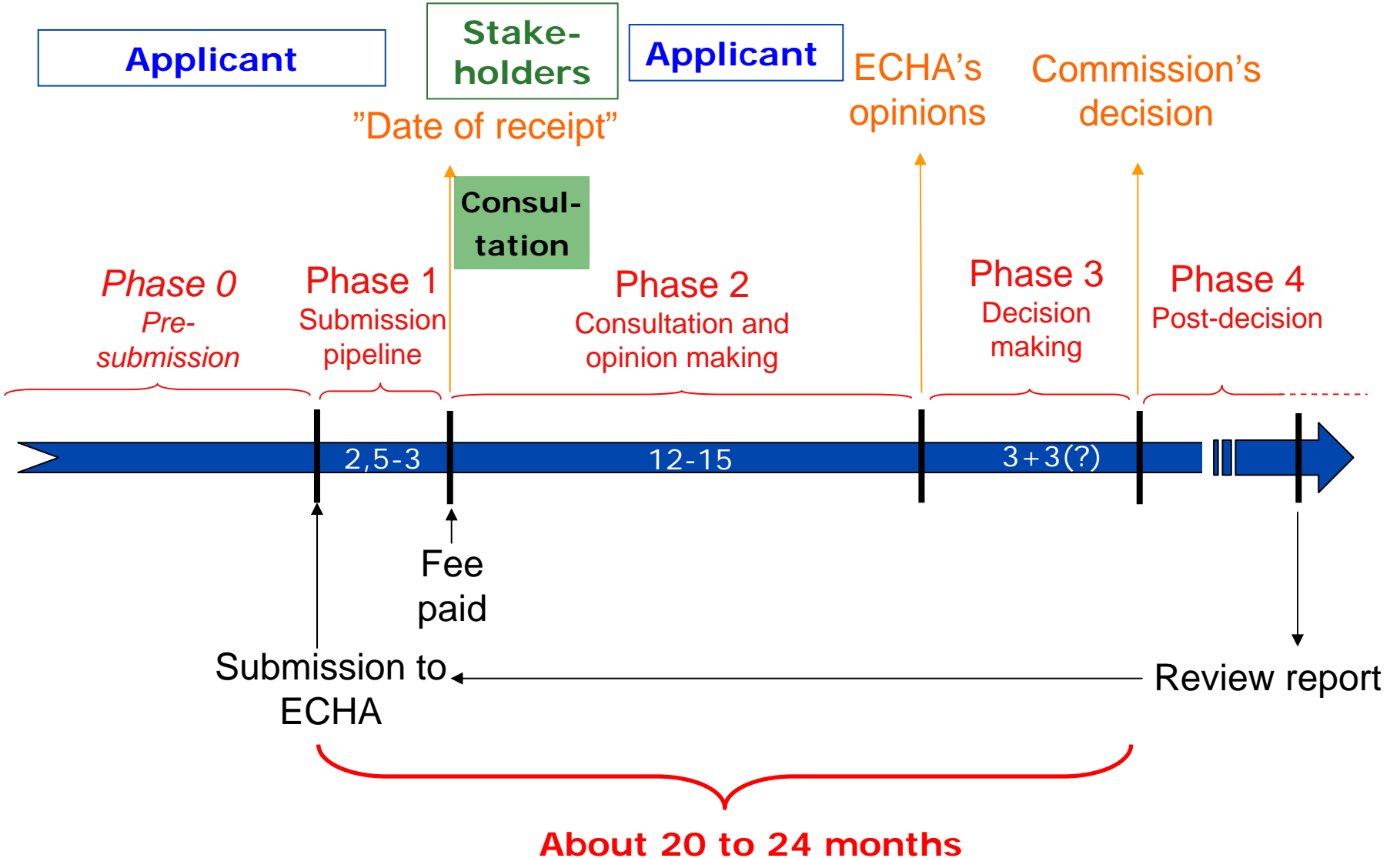
## Key messages

- Applicants: make a thorough application
- Stakeholders: give information on alternatives
- ECHA: run a transparent, meaningful and efficient public consultation process, based on:
  - Information on uses and functions
  - Public exposure scenario
  - Public version of Analysis of Alternatives
  - Name of the applicant

## Since Stakeholder Day 2011

- Updated webpages
  - More information to potential applicants
  - New Questions and Answers
  - Issued details of "pre-submission activities"
- Raised awareness
- Built ECHA's capacity
- Preparatory work to adapt IT tools, manuals and templates
- Clarified what will be made public at different phases

# Role of applicants and stakeholders in the process



## 8 week consultation on possible alternatives

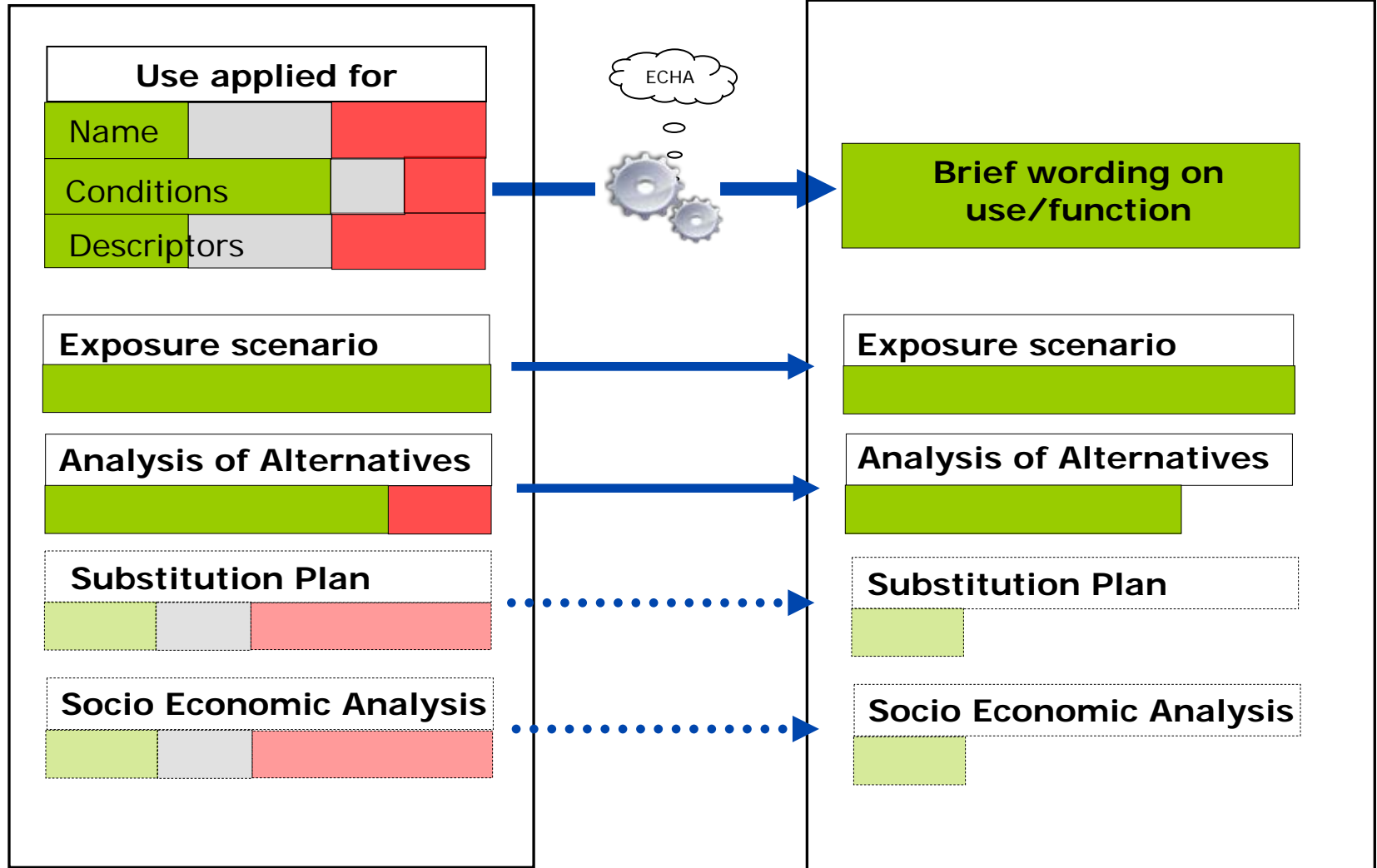
- Needs to be meaningful
  - for RAC's and SEAC's opinions and Commission's decision
- Based on the application
  - Include all relevant information
- During consultation: stakeholder information adds value
  - Description of alternative substance or technology
  - Technical and economic feasibility of the alternative
  - Availability of the alternative
  - Assessment of alternative's capacity to reduce overall risks
- ECHA (SEAC) may require further information

## ECHA intends to publish during consultation

- Brief wording on use and function
  - name of the use
  - conditions of use
  - use descriptors
- Additional information – public versions of:
  - exposure scenario
  - Analysis of Alternatives
  - summary of Substitution Plan
  - summary of Socio-economic Analysis
- Name of the applicant
- **Applicants' interest to make a thorough application!**

## Application

## Publication



CBI free
  Grey
  CBI



### C) Webform for submitting comments



#### Public Consultation on Alternatives for Application

##### I. Contact information

###### 1. Personal information

Note: Personal information is never disclosed to the public

First Name: \*

Family Name: \*

Email: \*

Confirm email: \*

Country: \*  Please select country..

###### 2. Organisation

Are you submitting information: \*  On behalf of an organisation or institution  As an Individual

Type of organisation/institution:  Please select organisation type..

Country where the organisation or institution is legally established:  Please select country..

Name of organisation / institution:

I do not wish the name of my organisation/institution be disclosed to the public.

Note: Type and country of your organisation/institution cannot be claimed confidential and will always be disclosed.

##### II. Comments

###### 1. Consultation selection

### A) Public consultation on alternatives webpage

Consultation #	Substance Name	EC Number	CAS Number	Consultation Deadline	Broad information on use applied for (title)	Details
001-01	4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	21 Apr 2012	Hardener in epoxy resins	<a href="#">Details</a>
001-02	4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	21 Apr 2012	Hardener in adhesives	<a href="#">Details</a>

### B) Information on “uses applied for” webpage

Substance name	4,4'-Diamino-diphenylmethane (MDA)
EC number	202-974-4
CAS number	101-77-9
Annex XIV identifier	2
Broad information on use applied for (title)	<b>Hardener in epoxy resins</b>
Broad information on use applied for (name, conditions of use)	Use as a hardener in epoxy resins under the following specific conditions...
Broad information on use applied for (Use descriptor system)	[text field that will contain the UDS codes]
Additional information:	
Exposure scenario (non-confidential)	
Analysis of Alternatives (non-confidential report)	
Substitution Plan (non-confidential summary)	
Socio-Economic Analysis (non-confidential summary)	
Consultation number	001-01
Consultation period	21 February 2012 - 21 April 2012
	<a href="#">Give Comments</a> <a href="#">View comments submitted to date</a>

### D) Comments submitted to date webpage

Broad information on use applied for (title)	<b>Hardener in epoxy resins</b>
Substance name	4,4'-Diamino-diphenylmethane (MDA)
Annex XIV identifier	2
EC number	202-974-4
CAS number	101-77-9
Consultation number	001-01
Consultation period	21 February 2012 - 21 April 2012

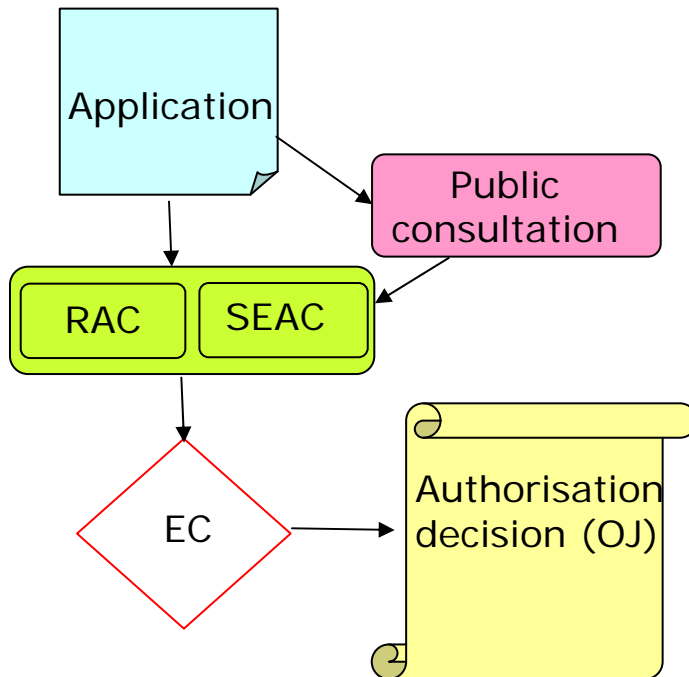
Organisation / Company / Individual	Type/ Role in sup chain	Name of org/company	Country	Submission Date	Alternative:					Classification & Labelling	GHS/ DSD- DPD	Non-confidential attachment
					Generic name	EC Number	CAS Number	IUPAC Name	Description of tech			

## Public elements of RAC/SEAC opinions

- RAC and SEAC opinions
- Justifications of the opinions
- Additional risk management measures/monitoring arrangements
- Recommended duration of the review period
- Details, such as
  - substance name and ID and brief wording of uses and functions
  - names of the rapporteurs
  - various dates
  - applicant's name

## Role of the applicant:

- well documented, clear and transparent application
- answer questions during opinion making
- comment draft opinion



## Role of stakeholders:

- added value on alternatives during consultation
- answer questions during opinion making

ECHA provides the framework

## Upcoming ECHA Seminars in October 2012

- General seminar: overview of the procedures, guidance, tools
- Specific seminar (if at preparatory stage):  
Analysis of Alternatives and Socio-economic Analysis

**Thank you.**

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