REACH

REACH and Worker protection legislation Conference:

Two complementary pieces of law for improved worker protection ?

The place of substitution in the REACH authorisation

19 September 2006
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Authorisation of substances

- Contents:
  - The basics
    - REACH
    - Authorisation
    - Substitution
  - Issues:
    - How do the procedures work
    - Guidance on the authorisation procedure
    - Benefits of authorisation!
  - Conclusions

Basics:
WHY do we need REACH?

Current chemicals management system is inefficient

- Difficult to identify risks + difficult to address risks:
  - Lack of information about most chemicals on the market
  - Burden of proof lies on public authorities
  - No efficient instrument is in place to deal with problematic substances
- Lack of incentives for innovation
- Lack of confidence in chemicals

Basics:
Workplace issues

REACH benefits for occupational health

(according to RPA study of March 2003, based on EU-15):

- Estimation of 6500 occupational cancer deaths per year due to unidentified chemical hazards
- REACH may help to reduce between 1/3 and 2/3 of these deaths, plus additional non-fatal cancer cases
- Estimation of total economic benefits of REACH concerning occupational health 17-28 bio € over 30 years

Basics: REACH - key elements

- Registration of substances ≥ 1 tonne/yr
- Increased information and communication throughout the supply chain
- Evaluation of some substances
- Authorisation only for substances of very high concern
- Restrictions - the safety net (Community wide action)
- Agency to efficiently manage system

Focus on priorities:

Substances with high volumes and those of greatest concern!

Basics: authorisation

Ensure risks from substances of very high concern are properly controlled and eventually substituted.

- Substances of very high concern (estimated 1500):
  - CMR[1], PBT, vPvB
  - 'equivalent concern substances with scientific evidence of probable serious effects';
- Prioritised and progressively authorised as resources allow (25-30/year):
  - High volumes
  - PBTs and vPvBs
  - Dispersive uses
- Commission grants authorisations if applicants demonstrate:
  - Adequate control, or
  - Socioeconomic benefits are greater than the risk and no substitutes exist.
- DU can use suppliers' authorisation

[1] Category 1 and 2 only

Basics: substitution (1)

- Always an aim of REACH as a whole (strengthened in CP):
  - Recital (7): An important objective of the new system … is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.
- Safe and well-tested alternatives will replace potentially problematic substances to improve health and environment and save Registration costs;
- Information down the supply chain will empower workers, downstream users, the retail sector and consumers to demand safer alternatives.

Basics: substitution (2)

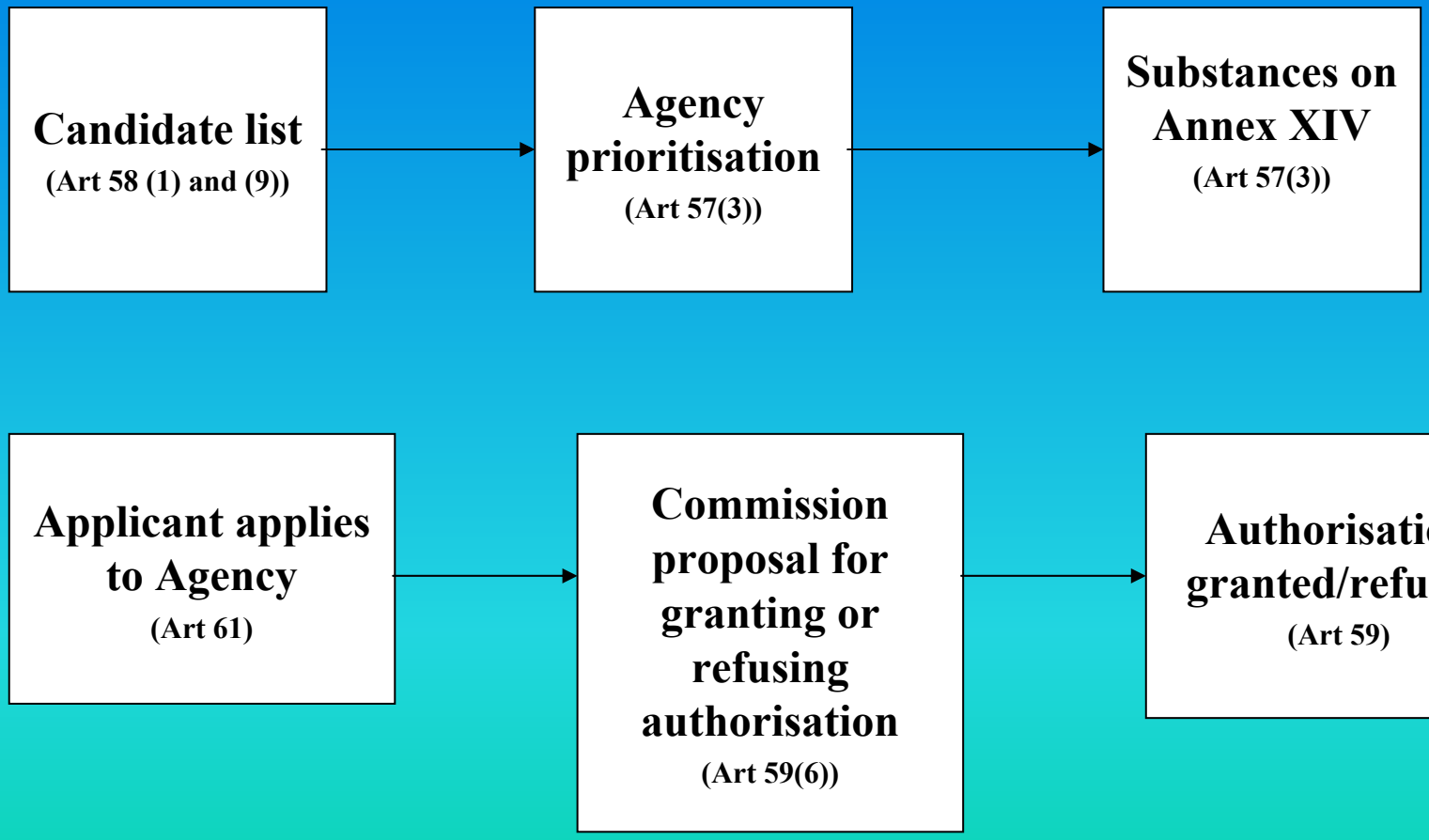
- Authorisation - companies encouraged to invest in research to find safer substitutes:
  - Applications will be costly;
  - If the risks cannot be adequately controlled (non-threshold substances, PBTs and vPvBs), the authorisation may only be granted even if it is shown socio-economic advantages outweigh risks and there are no suitable substitutes;
  - All authorisations require an analysis of alternatives to be provided and have a time-limited review.

Basics: substitution (3)

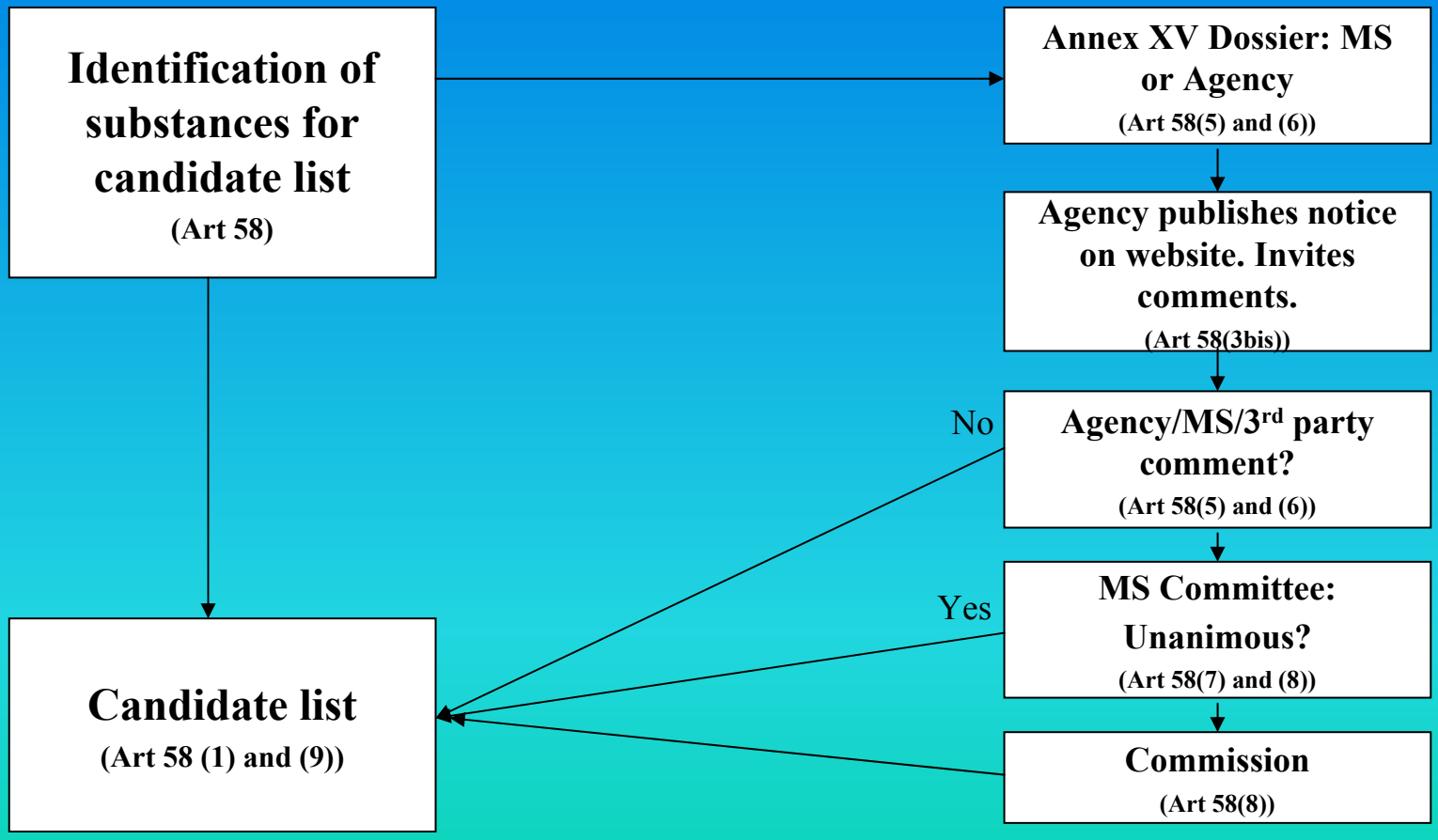
- Substances subject to authorisation and eventual substitution are substances of very high concern (CMR, PBT, vPvB, equivalent concern) causing costs to society as a whole;
- Applicant may provide a substitution plan (non-mandatory, will influence length of review period) where:
  - suitable substitute is not currently available,
  - more research needs to be done on their comparative risks
  - substitution can only be done at very high cost.
- Substitution can trigger innovation and prepare new market opportunities.

Authorisation procedure

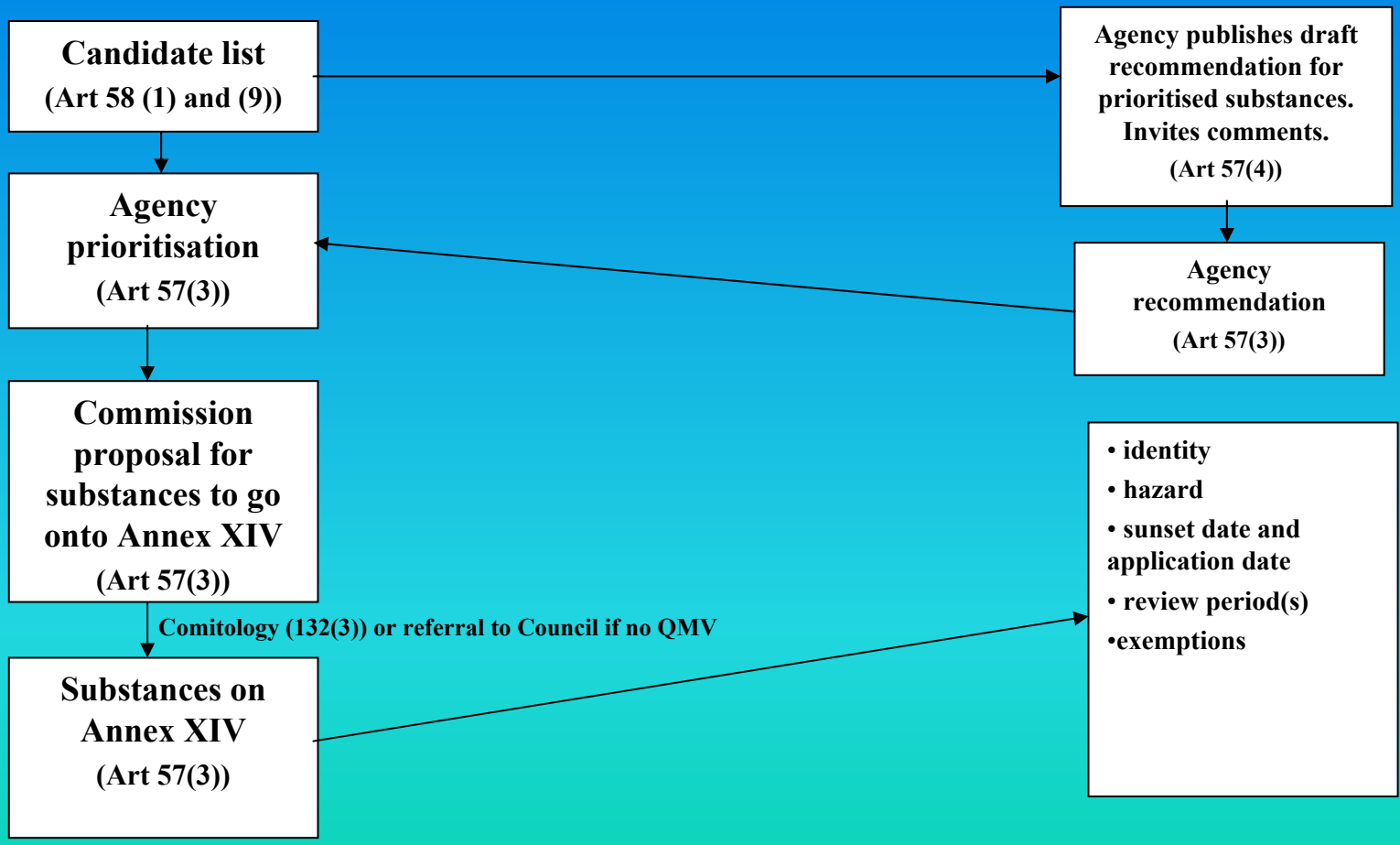
Overview


Candidate list
(Art 58 (1) and (9))
Agency prioritisation
(Art 57(3))
Substances on Annex XIV
(Art 57(3))
Applicant applies to Agency
(Art 61)
Commission proposal for granting or refusing authorisation
(Art 59(6))
Authorisation granted/refused
(Art 59)

Candidate list



Annex XIV


Candidate list
(Art 58 (1) and (9))
Agency prioritisation
(Art 57(3))
Commission proposal for substances to go onto Annex XIV
(Art 57(3))
Comitology (132(3)) or referral to Council if no QMV
Substances on Annex XIV
(Art 57(3))
Agency publishes draft recommendation for prioritised substances. Invites comments.
(Art 57(4))
Agency recommendation
(Art 57(3))
• identity
• hazard
• sunset date and application date
• review period(s)
•exemptions

Application and granting

Applicant applies to Agency
(Art 61)

Application contains:
- identity of substance
- applicants details
- uses applied for
- CSR (unless already registered)
- analysis of alternatives

Optional:
- socio-economic assessment
- substitution plan

(Art 61(4) and (5))

Risk Assessment Committee and Socio-Economic Assessment Committee deliver opinions
(Art 61)

Applicant comments on draft opinions and **3rd party** comments on substitutes
(Art 63 (2) and (5))

Commission proposal for granting or refusing authorisation
(Art 59(6))

Authorisation granted/refused
(Art 59)

Authorisation contains:
- identity of holder
- identity of substance
- uses for which authorisation granted
- conditions
- review date (case-by case)
- any monitoring arrangements
- exemptions

Reviews

Commission reviews
(Art 58)

Triggering review:

- **review period(s) expire**
- **circumstances change to affect risk or socio-economic impact**
- **new information on substitutes**
- **quality standard breached**

(Art 60)

2nd reading and authorisation

Progress in co-decision

Parliament:	**First reading**	**17 November 2005**
Council:	**Political agreement by unanimity**	**13 December 2005**
	Common Position by unanimity	**27 June 2006**

- 2006:
  - 2nd reading in Parliament (September start)
    - Amendments (11 September)
    - ENV Committee vote (10 October)
    - Plenary vote (October/November/December)
  - 2nd reading agreement (by end of the year)
- 2007
  - Entry into force

Authorisation (1)

- Public list of substances to be (eventually) authorised :
  - Council
    - Candidate list: substances meeting criteria
    - Annex XIV (substances prioritised and picked for authorisation within set timeframe)
    - CMRs with harmonised classifications to be proposed via an Annex XV dossier with limited justification, others with a more detailed justification.
    - Unanimity to agree substances on list
  - Parliament
    - Annex XIVa (candidate list: substances meeting criteria)
    - Annex XIVb (substances prioritised and picked for authorisation within set timeframe).
    - CMRs with harmonised classifications automatically on list
    - QMV to agree other substances on list.

Authorisation (2)

- Article 56(f): substances of equivalent concern:
  - Council: ..scientific evidence of probable serious effects to human health or the environment that give rise to an equivalent level of concern…
  - Parliament: ..identified as giving rise to a similar level of concern….
- Review periods/time-limited authorisations:
  - Council: time-limited review periods set on a case-by-case basis.
  - Parliament: time-limited authorisations – maximum 5 years.

Authorisation (3)

- Criteria for granting authorisations:
  - Analysis of substitutes in all cases.
  - Council:
    - Authorisation granted if adequate control
      - ➔ Not possible for PBT, vPvBs or CMRs/substances of equivalent concern if a safe threshold cannot be determined.
    - Still possible to grant authorisation if socio-economic benefits outweigh the risks and no alternatives available.
  - EP
    - 3 cumulative criteria for granting:
      - ➔ No suitable alternatives (= mandatory substitution), AND
      - ➔ Socio-economic advantages outweigh the risks, AND
      - ➔ The risk is adequately controlled.
    - Substitution plans in all cases

Next steps

After entry into force

- 2007 Entry into force
  - **Fees** and test methods regulations
  - Review of **Annex I** (i.e. CSA – relevant for adequate control and authorisation applications), and Annexes IV-V; possible commitology proposals
- 2008 Agency commences (in Helsinki, FIN);
  - Titles II, III, V, VI, **VII (Authorisation)**, X and XI commence (existing legislation ceases)
- **2009 First Agency recommendation of priority substances (expected start of authorisation).**
- 2010 First Registration deadline (1000 tonnes+)

Commission's Interim Strategy

- Commission's practical preparations
  - Before REACH coming into force: 2004 – 2007
  - In co-operation with industry and MS
- REACH Implementation Projects (RIPs):
  - RIP 1: Process descriptions (available on ENV website)
  - RIP 2: Development of IT systems (REACH-IT)
  - RIP 3/4: Guidance Documents (industry/authorities)
  - RIP 5/6: Preparation for start-up of Agency
  - RIP 7: Commission preparations
- Strategic partnerships – SPORT and PRODUCE

Commission's Interim Strategy (authorisation)

- RIP 3: Guidance Documents (industry)
  - **RIP 3.7: Preparing an Application Dossier for Authorisation.**

    Guidance on the process to be followed in applying for an authorisation.

    Commences Autumn 2006.
- RIP 4: Guidance Documents (authorities)
  - **RIP 4.3: Inclusion of Substances into Annex XIV (list of substances subject to Authorisation).**

    Procedures and methodology to be used by the Agency when developing its proposals for adaptation of Annex XIV.

    Commences Autumn 2006.
  - **RIP 4.4: Preparation of Annex XV Dossiers.**

    Justification of proposals for restrictions, harmonised classifications, and for substances of the candidate list.

    Finalised.

Conclusions

- REACH is on the horizon and expect agreement by the end of the year.
- Good correlation between Council and Parliament:
  - What for Second Reading?
    - Authorisation and substitution
- REACH Implementation Projects ongoing, technical guidance being prepared.
- REACH opportunity to rebuild confidence in chemicals.

Information

EUROPA

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://europa.eu.int/comm/enterprise/chemicals/index.htm