

A close-up photograph of a microscope's objective lenses and eyepiece, rendered in a blue-tinted, semi-transparent style. The text is overlaid on the top left of this image.

STEPTOE & JOHNSON LLP

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Restrictions On Use

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OVERVIEW

Main *horizontal* legal instruments governing chemicals *was* Directive 76/769/EEC on **restrictions** on the marketing and use of certain **dangerous substances and preparations**: repealed by REACH and replaced.

New restriction procedures introduced by REACH.

Certain *vertical* legal instruments whose prohibitions and restrictions remain e.g. Cosmetics Directive (76/768/EEC), RoHS Directive (2002/95/EC) POPs Regulation ((EC) No 850/2004).

OVERVIEW

Cut and paste of all restrictions in Directive 76/769/EEC into Annex XVII of REACH Regulation (e.g. asbestos and certain azo-dyes) .
Covers substances on own, in a preparation or in an article.

Substance cannot be:

- manufactured
- used
- placed on the market

unless complies with the conditions of the restriction.

Not linked to duty to register a substance - **no tonnage thresholds** apply (unless otherwise specified in the restriction).

OVERVIEW

Some **exemptions** from restrictions process:

- process orientated research and development (“PORD”)
<1t/y
- wastes being treated as waste
- on site isolated intermediated
- lab. scale research or uses as a reference standard (for Annex XVII substances)

OVERVIEW

Transitional procedure applies from 1 June 2007.

New procedure applies from 1 June 2009.

Stricter Member State measures can be maintained until 1 June 2013 if notified according to EC Treaty. (Inventory of such measures to be published by Commission by 1 June 2009.)

TRANSITIONAL PROCEDURE

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Applies 1 June 2007 – 31 May 2010

“To take full advantage of the work performed under Directive 76/769/EEC and to avoid such work being lost, the Commission should be empowered during the start-up period to initiate restrictions based on that work without following the full restrictions procedure laid down in this Regulation. All those elements should be used, as soon as this Regulation enters into force, to support risk reduction measures.”

(Recital 126)

TRANSITIONAL PROCEDURE

By 1 June 2010 draft amendments to Annex XVII (if necessary) prepared by Commission in accordance with:

- a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII of this Regulation but for which a decision under Directive 76/769/EEC has not yet been taken; or
- (b) any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction or the amendment of restrictions under Directive 76/769/EEC.

Any amendment to the restrictions adopted under Directive 76/769/EEC from 1 June 2007 shall be incorporated in Annex XVII with effect from 1 June 2009.

REACH does not wipe the slate clean.

NEW PROCEDURES

NEW PROCEDURES

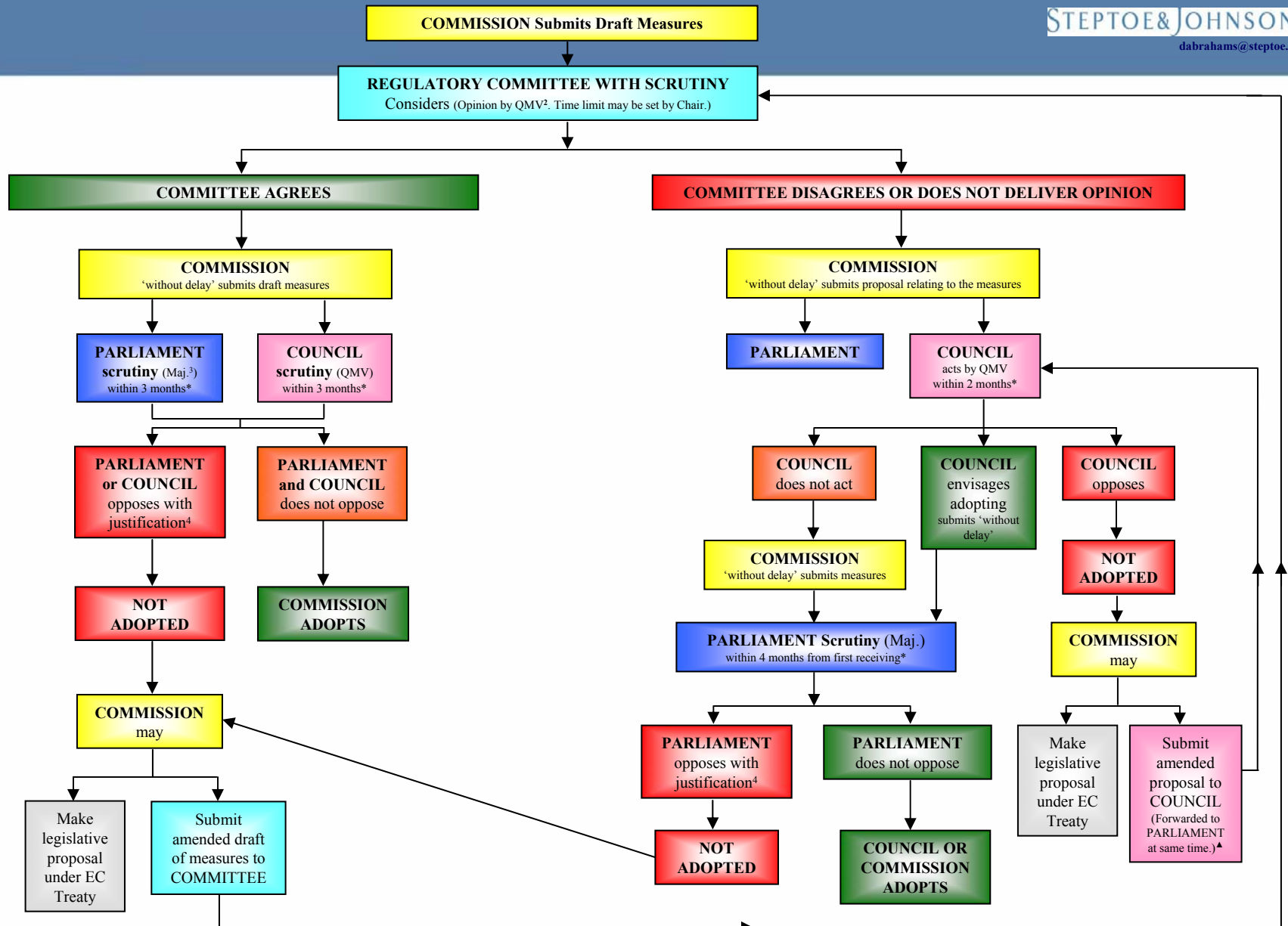
Two variants (to amend current restriction or entirely adopt new one):

- Longer version
- Shorter version

Preliminary Stages are different.

Both require final adoption under “regulatory procedure with scrutiny”.

REGULATORY PROCEDURE WITH SCRUTINY¹



REGULATORY PROCEDURE WITH SCRUTINY

Key to regulatory Procedure with Scrutiny Diagram

1. Council Decision 2006/512/EC of 17 July 2006.
 2. Qualified Majority Voting under Art. 205(2) EC Treaty. Committee members may also invoke Article 205(4). It is not clear if this applies in the Council.
 3. Majority of its component members.
 4. Justification: draft measures (i) exceed implementing powers provided for in the basic instrument; (ii) are not compatible with the aim/content of the basic instrument; or (iii) do not respect subsidiarity or proportionality.
- * May be extended by 1 month if complex or curtailed if efficient. An abbreviated procedure may be provided for in situations of imperative urgency.
- ▲ This is not expressly stated but is implicit.

NEW PROCEDURES

Longer version is for:

- (unacceptable) risk to human health or the environment
- and not adequately controlled
- and needs to be addressed on a Community-wide basis

(Any decision must “take into account the socio-economic impact of the restrictions, including the availability of alternatives”.)

Art. 68(1)

Shorter version is for:

- substances meeting criteria for classification as carcinogenic, mutagenic or toxic to reproduction (Cat.1 or 2)
- and *could* be used by consumers
- and restriction proposed by Commission (rather than a Member State).

Art. 68(2)

NEW PROCEDURE: LONGER VERSION

Commission *or* Member State can *initiate* restrictions process.

Commission

- **Commission asks Agency to prepare restriction dossier** conforming with Annex XV. (For substances subject to Authorisation, Agency prepares dossier after the “sunset date” if considers risk not adequately controlled.)
- **Agency suggests restrictions within 12 months** of initial Commission request (if Community-wide action necessary).

Member State

- **Member State notifies Agency that it proposes to prepare a dossier** conforming with Annex XV.
- **Member State prepares dossier within 12 months of its notification** if substance not already on proposed restrictions list (maintained by Agency).
- **Member State submits dossier** (if Community-wide action necessary).

NEW PROCEDURE: LONGER VERSION

Key Aspects

- **Reference can be made to any dossier**, CSR, or risk assessment submitted to the Agency or Member State under REACH and any risk assessment under any *other* EU legislation. EU Agencies holding such information must provide it.
- **Conformity check** of dossier by Committees on (1) Risk Assessment and (2) Socio-economic Analysis. List of those conforming will be publicly available along with dossier.
- **No duplication** of dossiers once a complete dossier submitted.
- **Interested parties** have 6 months from date of publication to **comment** to Agency on proposed restriction and/or socio-economic analysis aspects.
- **Committees** for Risk Assessment and Socio-economic Analysis will issue **opinions** (interested parties have 60 days to comment on latter).

PRACTICAL STEPS

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Questions to ask yourself:

- Do I use any currently restricted substances at any volume? (moment to check)
- Are restrictions *pending* for substances I use?
- Do I use substances which pose a *risk* to health or the environment? Are there alternatives? How strong is the socio-economic benefits case?
- Do I use substances which are carcinogenic, mutagenic or toxic to reproduction (Cat. 1 or 2) and have exposure to consumers? (candidate for shorter procedure)

PRACTICAL STEPS

Questions to ask yourself:

- Do substances I use (especially in articles) meet the criteria for Authorisation and therefore face greater even greater potential scrutiny? (if so should I consider defensive phase out?)
- Do substances I use face potential ‘political’ attack by Member States?
- What material has been submitted in other contexts which might support further restrictions?
