

Revision of Directive EC86/609

Update

18 April 2009

The European Commission Proposal - Origins

- 2002: European Commission announces review of EC86/609
- June 2003: Technical Expert Working Group (TEWG) established by Commission (reported Nov 2003)
- July 2004: EFSA Panel on Animal Health and Welfare asked to advise on certain points (report published December 2005)
- July-Aug 2006: Public consultation on impact assessment (results published early 2007)
- Jan 2007: Commission meeting for Member States and key stakeholders
- Nov 2007: Interservices consultation begins
- May 2008: SCHER report on use of NHPs (in response to EP Written Declaration in Sept 2007)
- Nov 2008: European Commission formally adopts their proposal for a new Directive – sent to European Parliament and Council of Ministers and so enters the [co-decision procedure](#)

The Co-decision Procedure

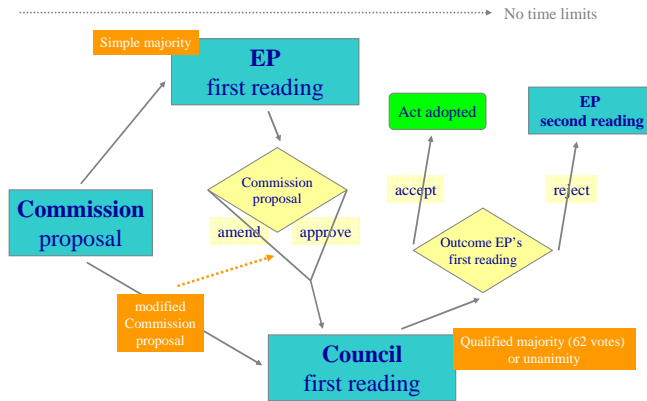
Requires consideration by the “Institutional Triangle” -

- The Council of the European Union (Council of Ministers)
- The European Parliament
- The European Commission

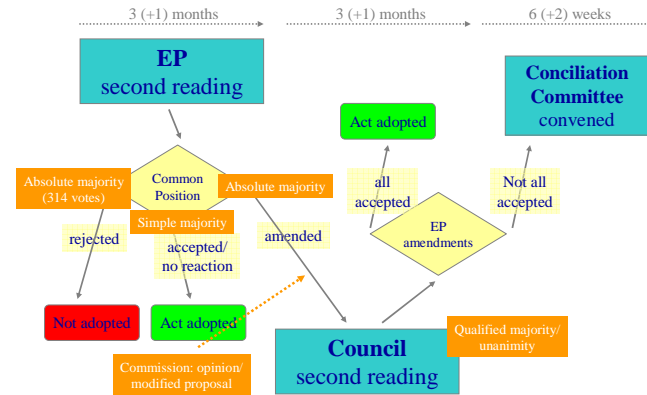
Co-decision is complicated!



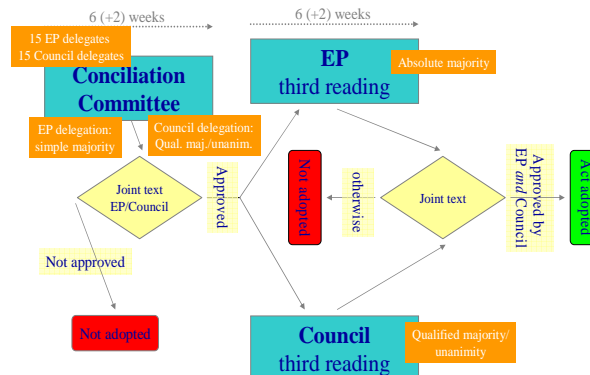
Co-decision: first phase



Co-decision: second phase



Co-decision: third phase



European Parliament – First Reading

- Agriculture Committee (Agri)
 - Lead committee
 - Neil Parish MEP, Chair and Rapporteur
- FELASA comments submitted
- Report with amendments to Commission proposal agreed by Agri on March 31st

Agriculture Committee Report

- Some major changes to Commission text
 - Larval/embryonic/foetal forms of non-mammals not to be included
 - Cyclostomes not to be included in scope
 - Not all decapod crustaceans included in scope
 - Re-use clarified and permitted where first procedure is up to “moderate”
 - “Severe” procedures with prolonged pain to be allowed under special scrutiny
 - Annual review by ethical review body only to be required for projects classified as “severe” or on NHPs
 - Projects classified as “severe” or involving NHPs require prior authorisation by competent authority, but others only require notification after ethical review
 - Projects involving procedures up to “moderate” to be exempt from requirement for retrospective assessment
 - Deadlines for use of only F2 NHPs dependent on result of feasibility study
 - Member States to ensure mutual recognition of education and training qualifications and authorisation to conduct designated procedures
 - Severity classification criteria to be compiled within 12 months of the Directive entering into force
- Overall favourably received by research community, not by animal protectionists

European Parliament – First Reading

- Agriculture Committee report will be forwarded to plenary session of Parliament (May 4th – 7th)
- Amendments can also be proposed by ITRE, Environment Committee, political groups, MEPs (if signed to by at least 37)
- Commission will provide comments on the amendments

European Parliament – First Reading

- Amendments adopted by plenary session represent the **Parliament's opinion**
- Sent to Commission (to amend proposal if it wishes)
- Sent to Council of Ministers (for its first reading)
- Assuming Parliament's first reading is completed, work will continue after the June elections and the new Parliament has been formed

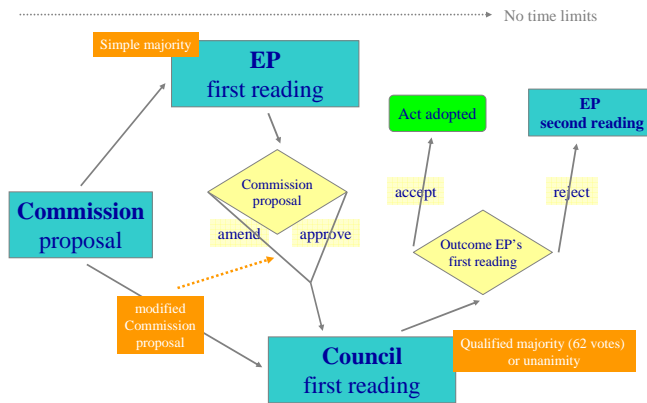
Council of Ministers – First reading

- Considers the Commission's proposal and Parliament's opinion
- Work done by working group of officials from Member States and COREPER (committee of permanent national representatives based in Brussels)
- WG met on 25 March, further meetings in April and May, then detailed consideration at ~ monthly meetings
- If all Parliament's amendments are accepted, proposal becomes law
- If not (more likely), a **common position** is produced
- Common position plus a Commission statement on it are sent to Parliament for second reading
- Swedish Presidency likely to want to progress the second reading actively

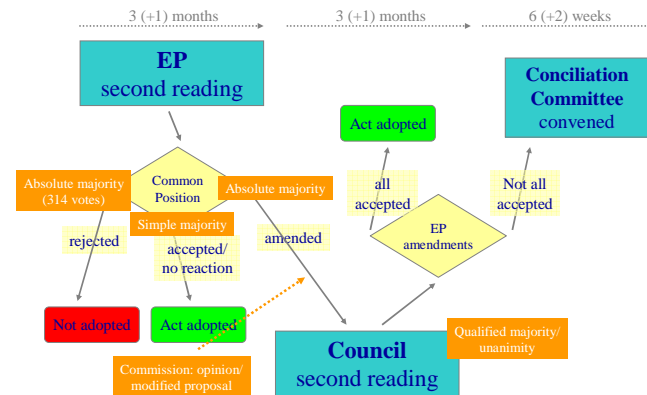
Co-decision can be very long!



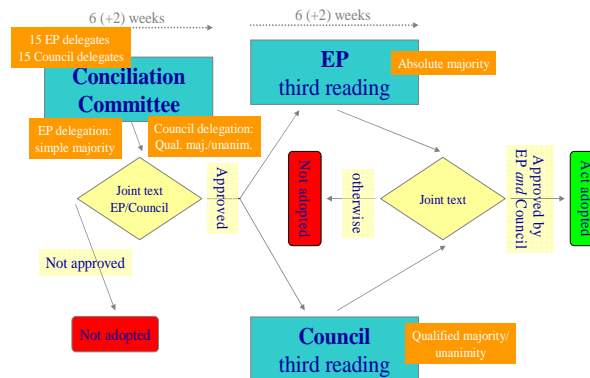
Co-decision: first phase



Co-decision: second phase



Co-decision: third phase



What to do?

- Study Commission text and amendments proposed by Agri
- Raise major concerns with national MEPs prior to the vote in May (using FELASA documents already circulated to GB members)
- Examine the outcome of the plenary session and provide comments to FELASA Task Force
- Raise concerns with representatives on the Council of Ministers working party (FELASA Task Force will prepare)
- Inform FELASA (Jan-Bas) of contacts

Have the Commission's key objectives been met?

- Level playing field for industry and researchers
- Significant increase in animal welfare
- Good legislative practice – red-tape, clarity, precision, i.e. not over-bureaucratic
- Ensure competitiveness of EU R&D
- Flexible wording setting objectives not methods