

The European Position on Human Embryonic Stem Cells

Dr David Coles
Enhance International

Europe:

“A rich cultural tapestry”

- Differing cultural backgrounds
- Different underlying values affecting attitudes to some applications of Science and Technology
- However finding consensus despite diversity is usually a strength of Europe
- Not so in the case of hESC!

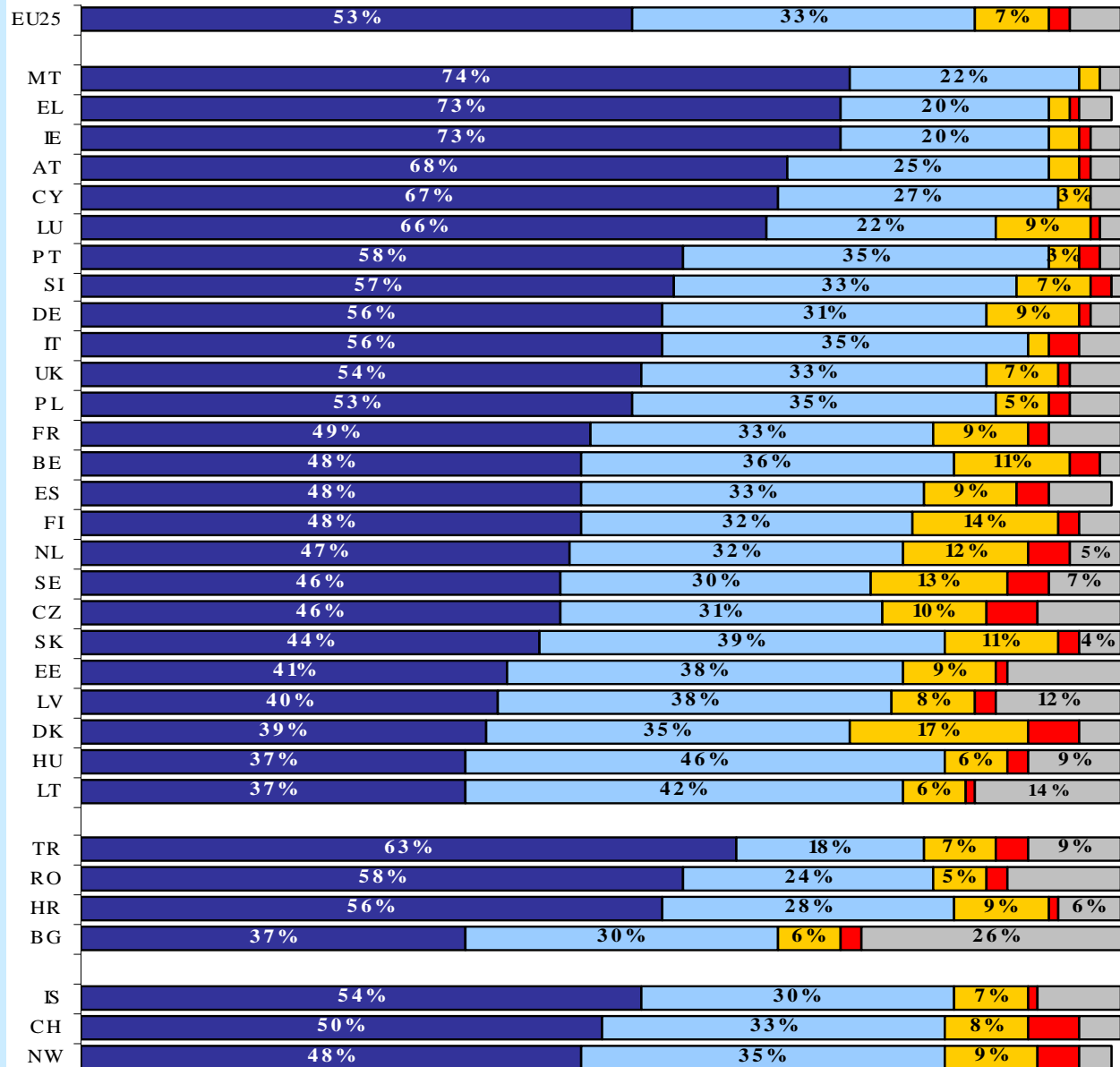
“Values” Eurobarometer - 2005

- 31 countries surveyed
- - Range of perceptions across European countries with regard to protecting the dignity of any human unborn life

Q15a.2 For each of the following, how important do you think it will be for our society in ten years time?

Protecting the dignity of any human unborn life

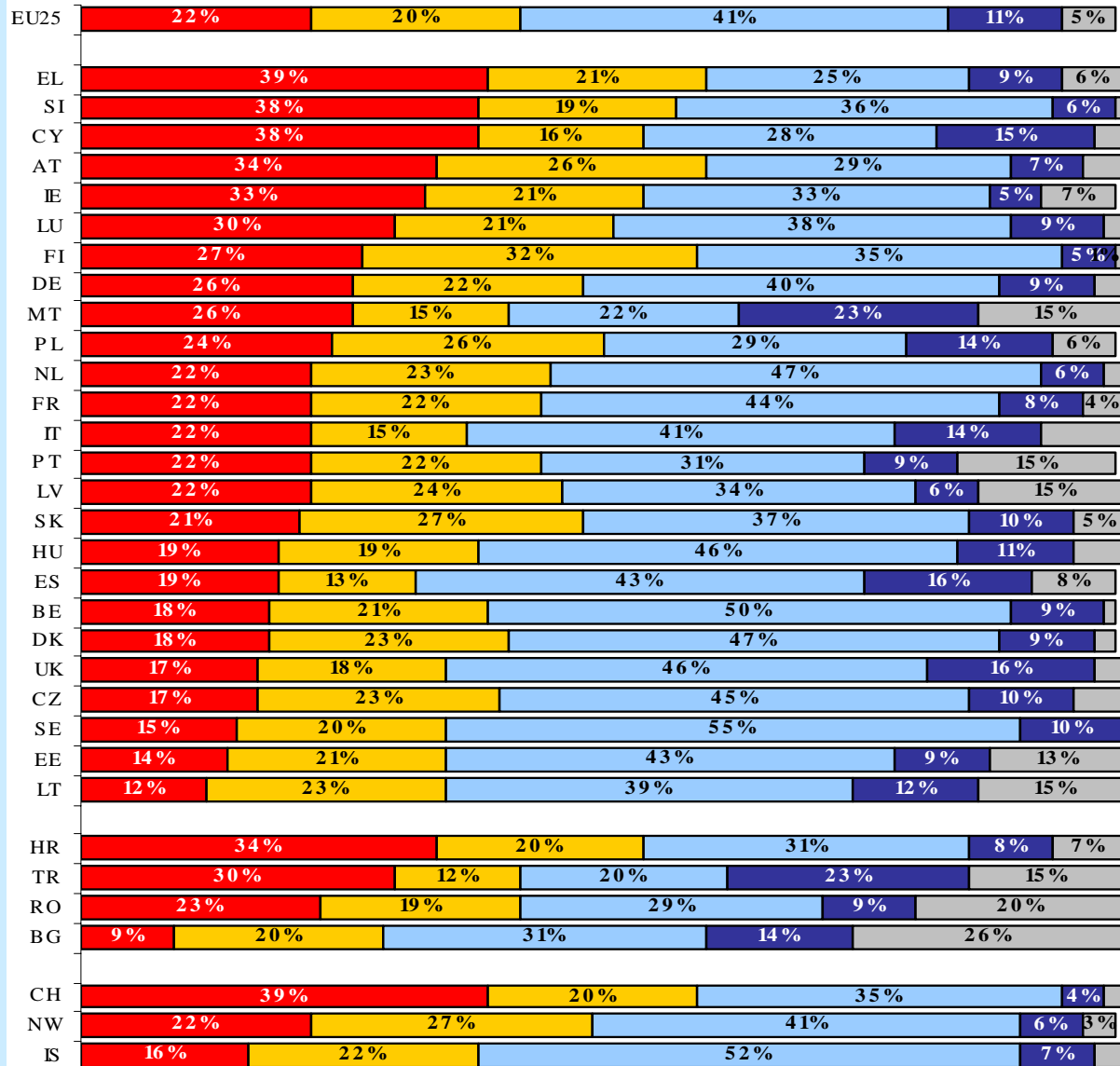
■ Very important
 ■ Fairly important
 ■ Not very important
 ■ Not at all important
 ■ DK



Q17b.1 ...please tell me to what extent, if at all, you approve of its use.

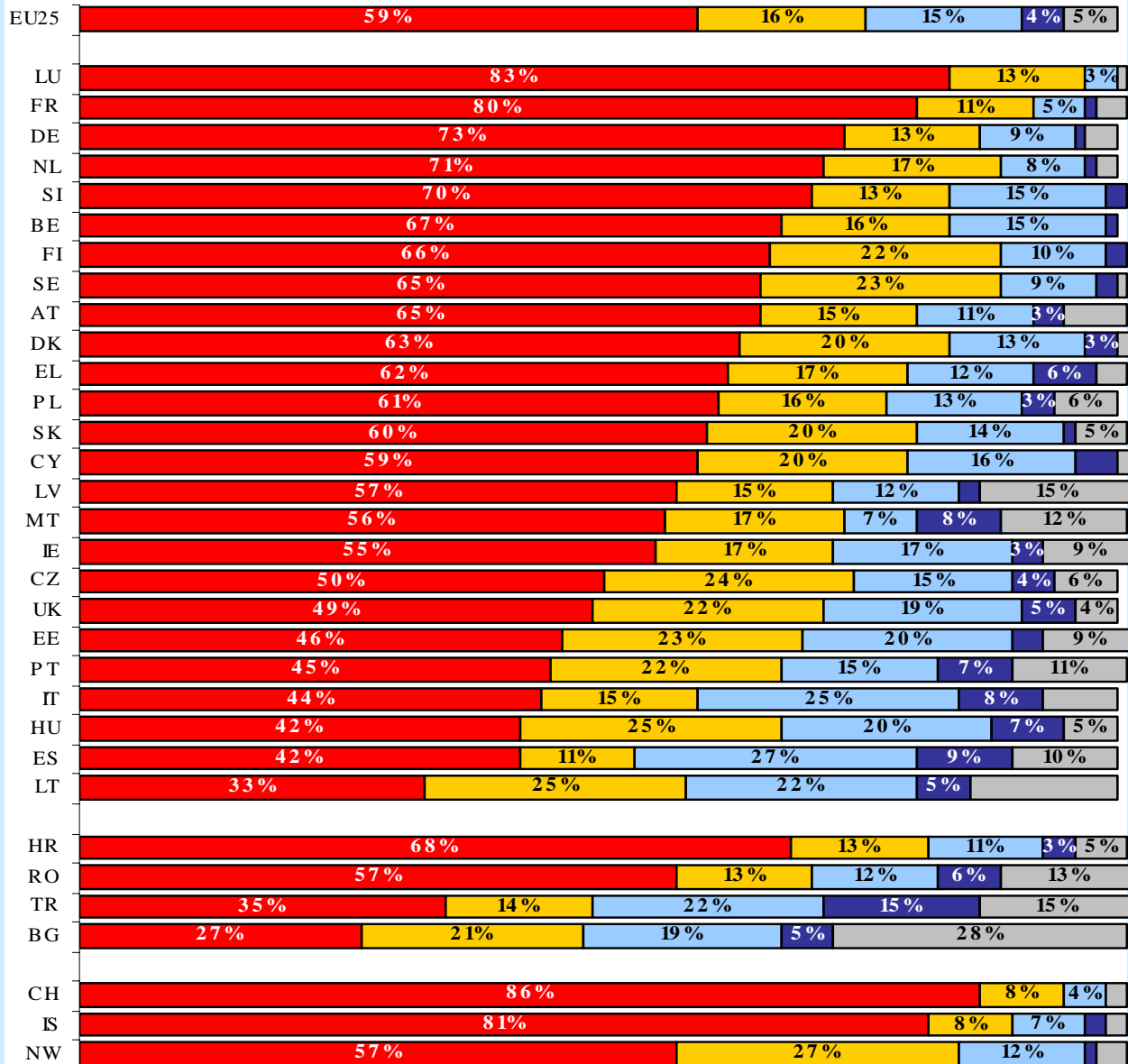
Cloning human stem cells from embryos to make cells and organs that can be transplanted into people with diseases

- Never
- Only in exceptional circumstances
- Only if it is highly regulated and controlled
- In all circumstances
- DK



Q17a.2 ...please tell me to what extent, if at all, you approve of its use. **Cloning human beings so that couples can have a baby even when one partner has a genetic disease**

- Never
- Only in exceptional circumstances
- Only if it is highly regulated and controlled
- In all circumstances
- DK



EC 6th Framework Programme

- 2001–2002: Discussions between the Commission, the 15 Member States of the European Council and the European Parliament to establish the 6th Framework programme of research.
- Research on embryos and human embryonic stem cells proved an intractable problem for the negotiations.

Human Embryonic Stem Cells in FP6

- Threatened implementation of FP6. Still no agreement by mid 2002 although FP6 due to start 1 Jan 2003
- To enable FP6 to start a “European compromise” was agreed.

The FP6 Compromise

- Legal text of Main 6th Framework document was agreed without direct reference to hESCs.
- Discussion on hESCs was moved to the Specific Programme.
- Several countries (DE, IT, AT, PT, ES) opposed use of hESC in SP1*
- “Moratorium” agreed on research involving embryos and human embryonic stem cells until 31 December 2003 to enable Commission to develop and propose “implementing provisions” for use of hESCs
- Exception: “except for banked or isolated hESCs in culture”

“Procedural Modalities”

- Developed by the Commission for interim period to cover banked hESCs.
- Scientific assessment of “necessity”
- Ethical review
 - Source
 - Consent
 - No payment
- EC regulatory committee approval

Implementing Provisions

- Commission proposal for “implementing provisions”
 - Use only of supernumerary embryos created before June 2002
 - Necessity
 - Consent
 - Compliance with national legislation

November 2003 - No agreement at Council

- Council split
- Against: DE, IT, AT, LUX, PT
- For: UK, SE, FR, BE, NL, DK, FI
- No clear position: IE, ES, GR
- Italian presidency left proposal on the table for the next Presidency – Ireland (who, unsurprisingly did not wish to pick it up)

Outcome for FP6

- EU Comitology rules – If Council makes no decision on a Commission proposal, the Commission can implement it.
- Commission decided to continue to use the principles of the “procedural modalities” – but removing the moratorium condition of “only for hESC cells banked or in culture” as this expired on 31 December 2003.
- Busquin “assurance” to the College of Commissioners

FP6 in Practice

- All hESC projects have an EU ethical review.
- All have to be approved on case by case basis by regulatory committee of MS.
- FP6 regulations do not exclude derivation of hESCs from supernumerary embryos (or other research on such embryos).
- In practice only proposals using existing hESCs have been submitted and funded.

Ethical review

- Effective EU level ethical review is an essential validation
- Most hESC proposals reviewed by EC ethical review are non-problematic.
- Key issue at EU level is ensuring compliance with national regulations – which are still changing.

What about FP7?

- Commission proposal – Treatment of ethics to be same as for FP6
- Including treatment of hESC research.
- However, some MS do not accept this particularly for hESC.
- Negotiations have included proposals for:
 - Detailed guidelines for all ethical issues
 - No use of hESCs derived after 2005
 - No EU level ethical assessment – leave it to each MS
 - Complete ban of all hESC research

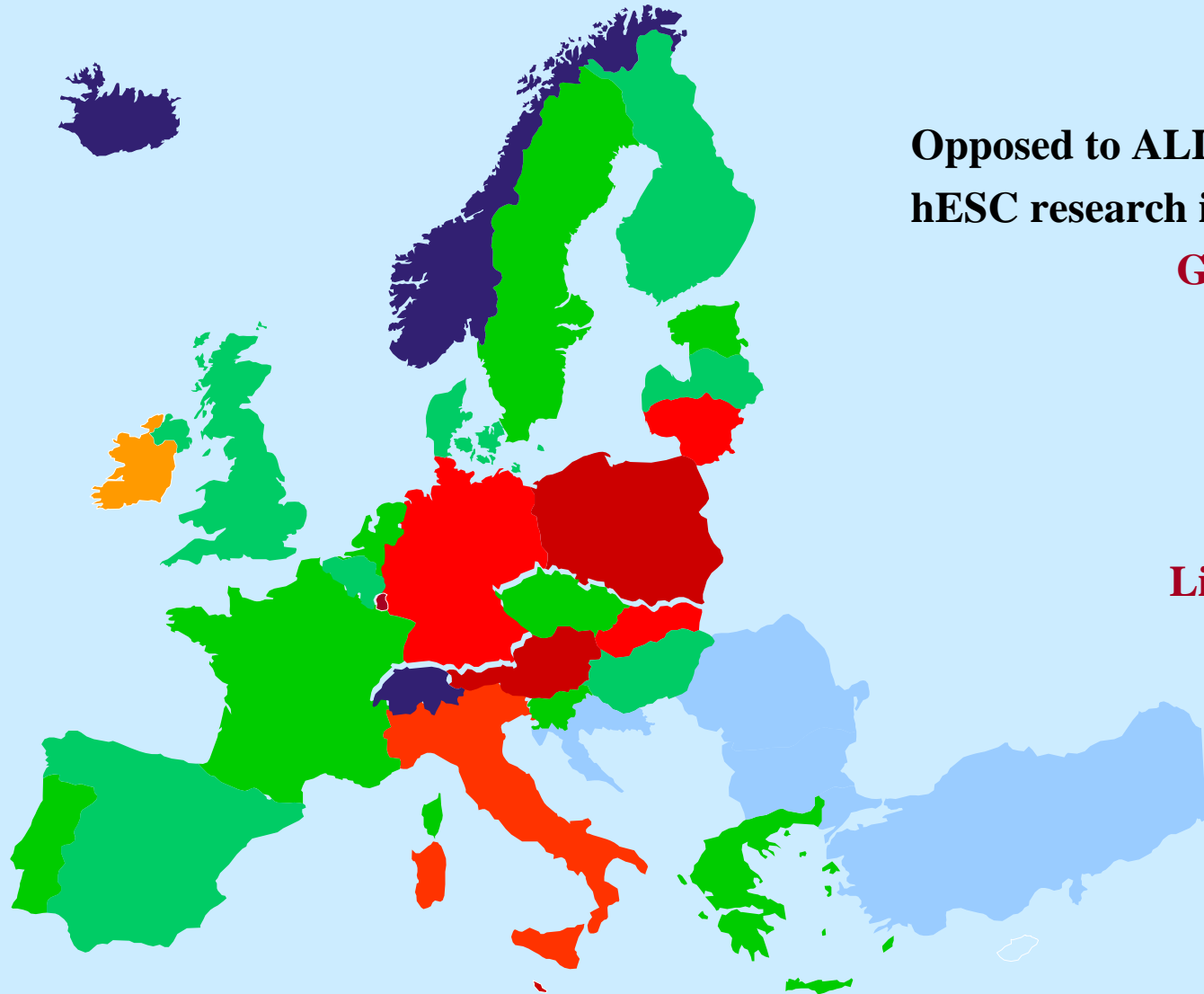
National Positions

- Austria, Ireland, Lithuania, Poland and the Slovak Republic have prohibited procurement of stem cells from embryos,
- Germany and Italy(?) allow the import of stem cell lines, but not their creation.
- The UK, Sweden and Belgium allow the creation of human embryos for the procurement of embryonic stem cells.

National Positions

- **Belgium, UK and Sweden** allow therapeutic cloning, (expressly excluded from FP6).
- **Denmark, Finland, France, Greece, Spain, Netherlands** have regulations allowing the derivation of new hESC from supernumerary IVF embryos.
- **Estonia, Hungary, Latvia and Slovenia** have no specific regulations on hESC, but allow some research on supernumerary IVF embryos.
- **Germany and Italy** have regulations which restrict hESC research. These regulations mean that scientists in these countries cannot derive new hESC, but can import them. In Germany, these cells have to have been derived before 1 January 2002.
- **Ireland and Slovakia** prohibit procurement of hESCs from human embryos
- **Austria, Lithuania and Poland** have legislation prohibiting hESC research.
- **Portugal, Luxembourg, Malta, Cyprus** have no specific legislation

hESC Research in FP7



**Opposed to ALL
hESC research in FP7:**

- Germany**
- Poland**
- Austria**
- Italy**
- Malta**
- Lithuania**

- This forms a “blocking minority”
- Could exclude hESC research from FP7
- Final decision on FP7 is still subject to further negotiation.

To be continued.....