



Further expansion of NBS in European countries: horse carriages vs bullet trains



J.Gerard Loeber

APHL, Anaheim, USA, 301014



What is Europe?



EU



Cand EU



EU



Pot. cand EU



EU



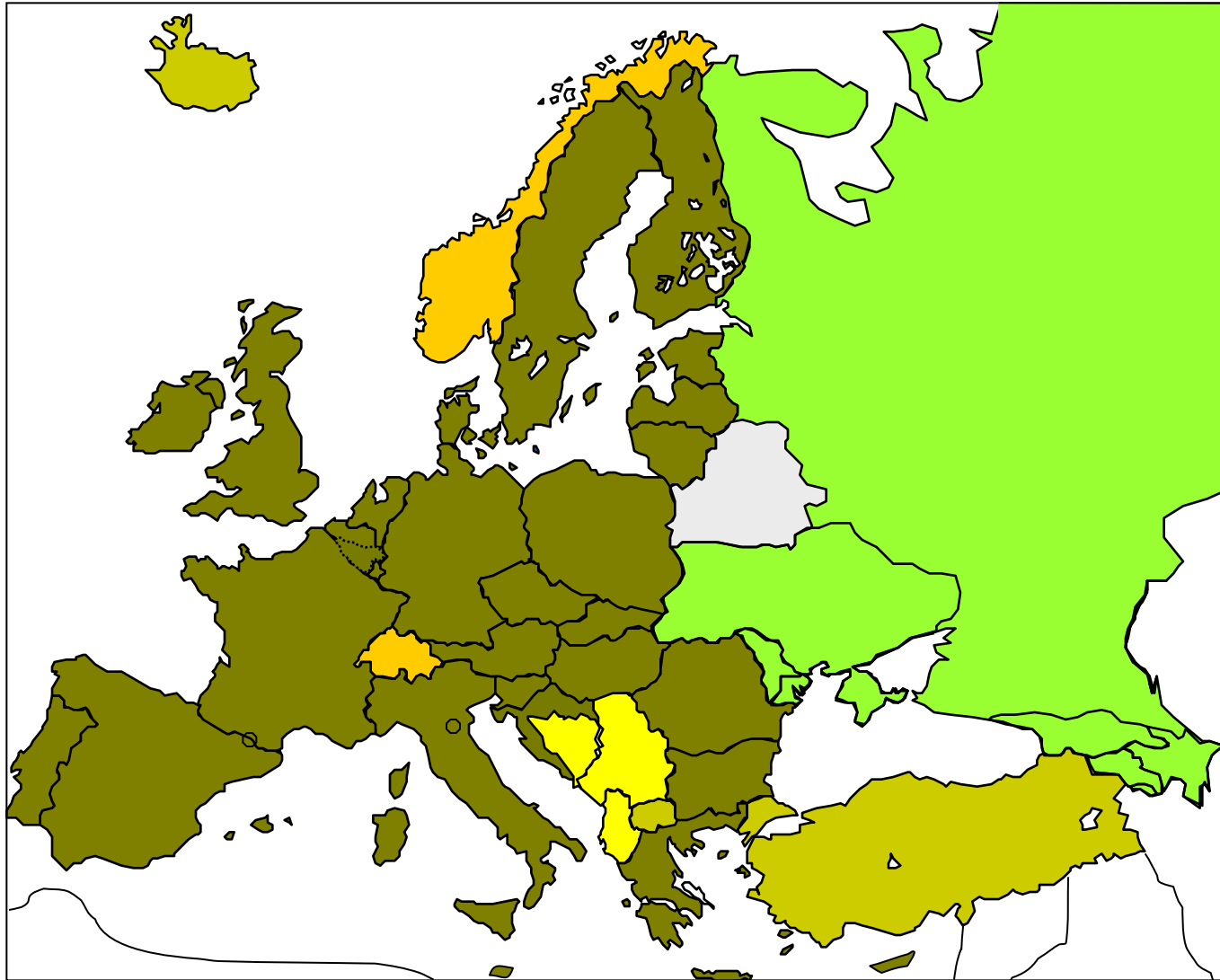
EFTA



Other



No memb



Council of Europe member countries



Europe versus USA

	Europe (C o E)	USA
Population	809 million	320 million
Births	9 million	4 million

Decisions in EU treaties

- Health care issues are in principle left to the member states
- EU is reluctant concerning health care policy making
- Consequently,
 - Every country has its own health care system
 - Every country has its own NBS policy
 - Every country has its own panel of conditions, sampling, treatment etc.
- Some countries are further subdivided in regions/provinces/länder with their own policies

COUNCIL RECOMMENDATION

of 8 June 2009

on an action in the field of rare diseases

(2009/C 151/02)

EU Council recommendations to EU Commission

- Rare disorders (prevalence < 1:2000)
- Make inventories of current situation
- Identify and stimulate research
- Create centres of expertise and reference networks
- Empower patients organisations
- Produce by end of 2013 an implementation report
- A European body for health technology assessment will be developed (EUnetHTA)



EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

Health Unit

EAHC
Executive Agency
for Health and Consumers

18 JUL. 2009

Luxembourg,

EAHC D (2009) D/LUXEMBOURG

Subject: Call for tender n EAHC/2009/Health/09 concerning evaluation of population newborn screening practices for rare disorders in Member States of the European Union

Contract notice 09/S 136-198073 of 18/07/2009

http://ec.europa.eu/eahc/documents/health/tenders/EAHC_2009_health_09_invitation_en-1.pdf

Newborn screening programmes in Europe; arguments and efforts regarding harmonization. Part 1 - From blood spot to screening result

**J. Gerard Loeber • Peter Burgard • Martina C. Cornel •
Tessel Rigter • Stephanie S. Weinreich • Kathrin Rupp •
Georg F. Hoffmann • Luciano Vittozzi**

Newborn screening programmes in Europe; arguments and efforts regarding harmonization. Part 2 – From screening laboratory results to treatment, follow-up and quality assurance

**Peter Burgard • Kathrin Rupp • Martin Lindner •
Gisela Haegi • Tessel Rigter • Stephanie S. Weinreich •
J. Gerard Loeber • Domenica Taruscio •
Luciano Vittozzi • Martina C. Cornel •
Georg F. Hoffmann**



EU Tender

“Evaluation of population newborn screening practices for rare disorders in Member States of the European Union”

Newborn screening in Europe Expert Opinion document

Authors:

Martina Cornel¹, Tessel Rigter¹, Stephanie Weinreich¹, Peter Burgard², Georg F. Hoffmann²,
Martin Lindner², J. Gerard Loeber³, Kathrin Rupp², Domenica Taruscio⁴, Luciano Vittozzi⁴

Documents available

- All project documents are on the internet:

<http://www.iss.it/cnrmr/prog/cont.php?id=1621&lang=1&tipo=64>

- Or see the ISNS website:

www.isns-neoscreening.org News section

Outline of this presentation

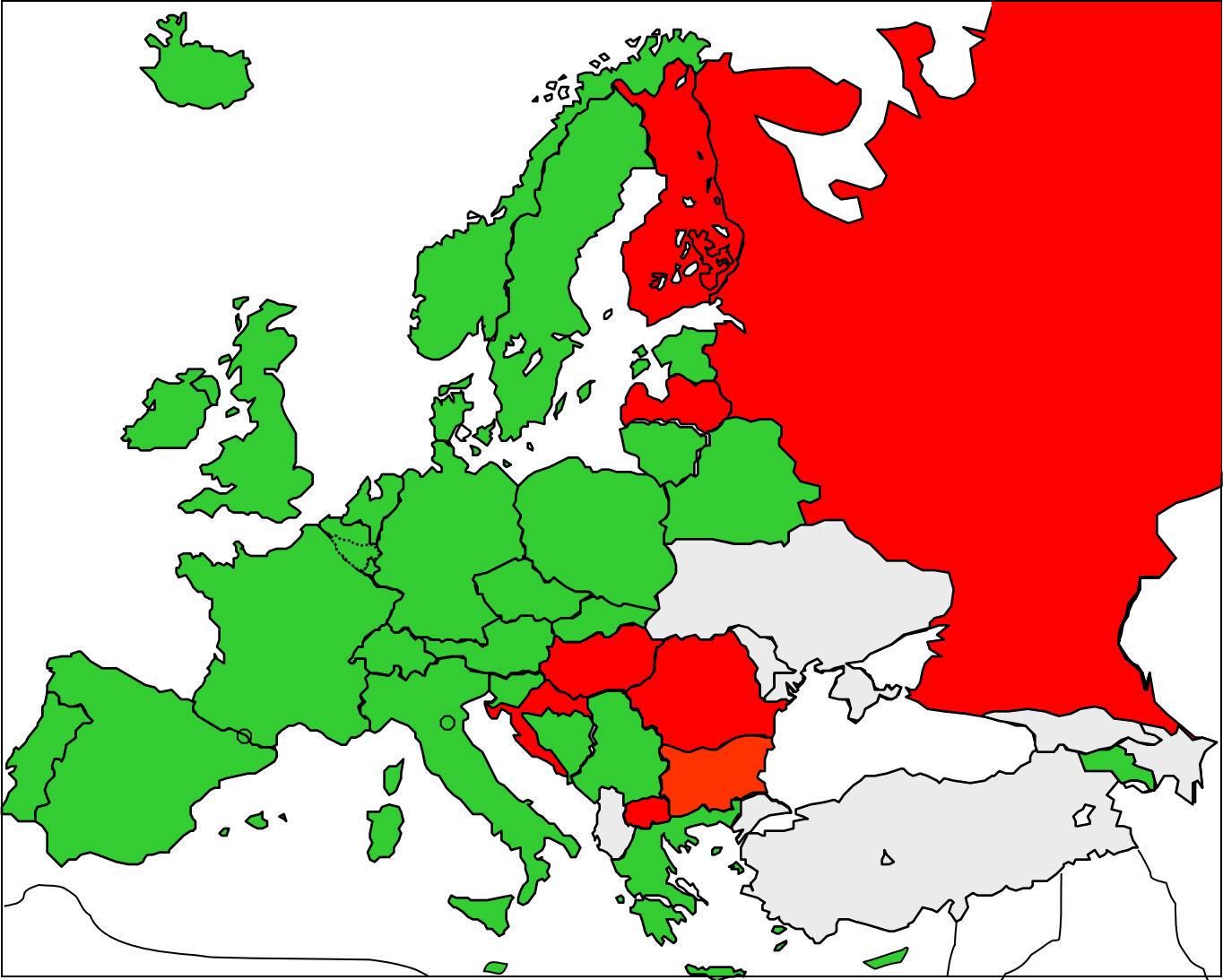
- Study results
- 2014 update results, also from Eastern European countries

Acknowledgement for data contribution

D. Kasper	Austria	L. Franszon	Iceland
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V. Sinigerska	Bulgaria	P. Borde	Luxembourg
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E. Karg	Hungary	U. von Döbeln	Sweden
L. Szonyi	Hungary	R. Fingerhut	Switzerland
		K. Hall	United Kingdom

Part 1 Governance, Information, Informed Consent

Information material for prospective parents



yes

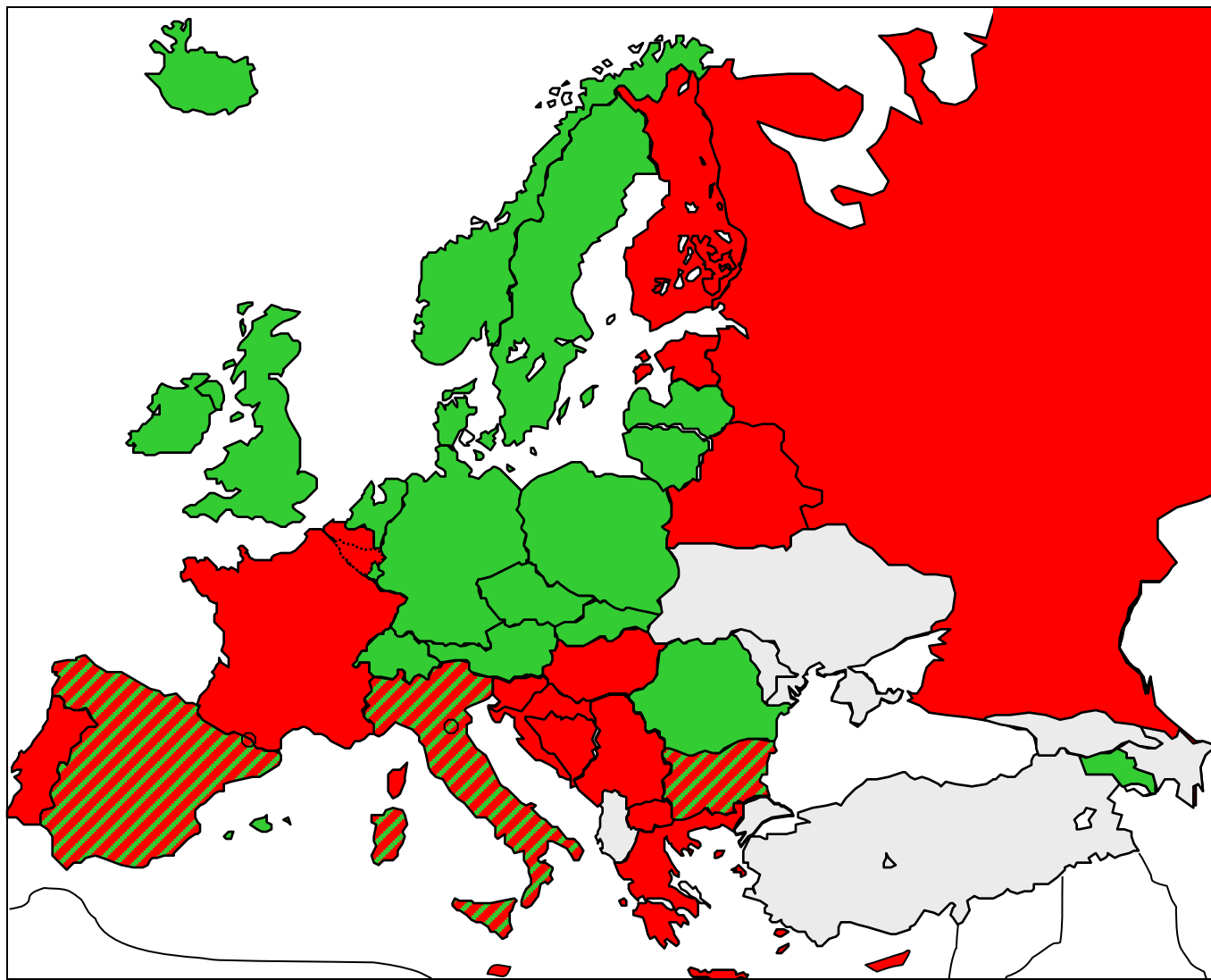


no



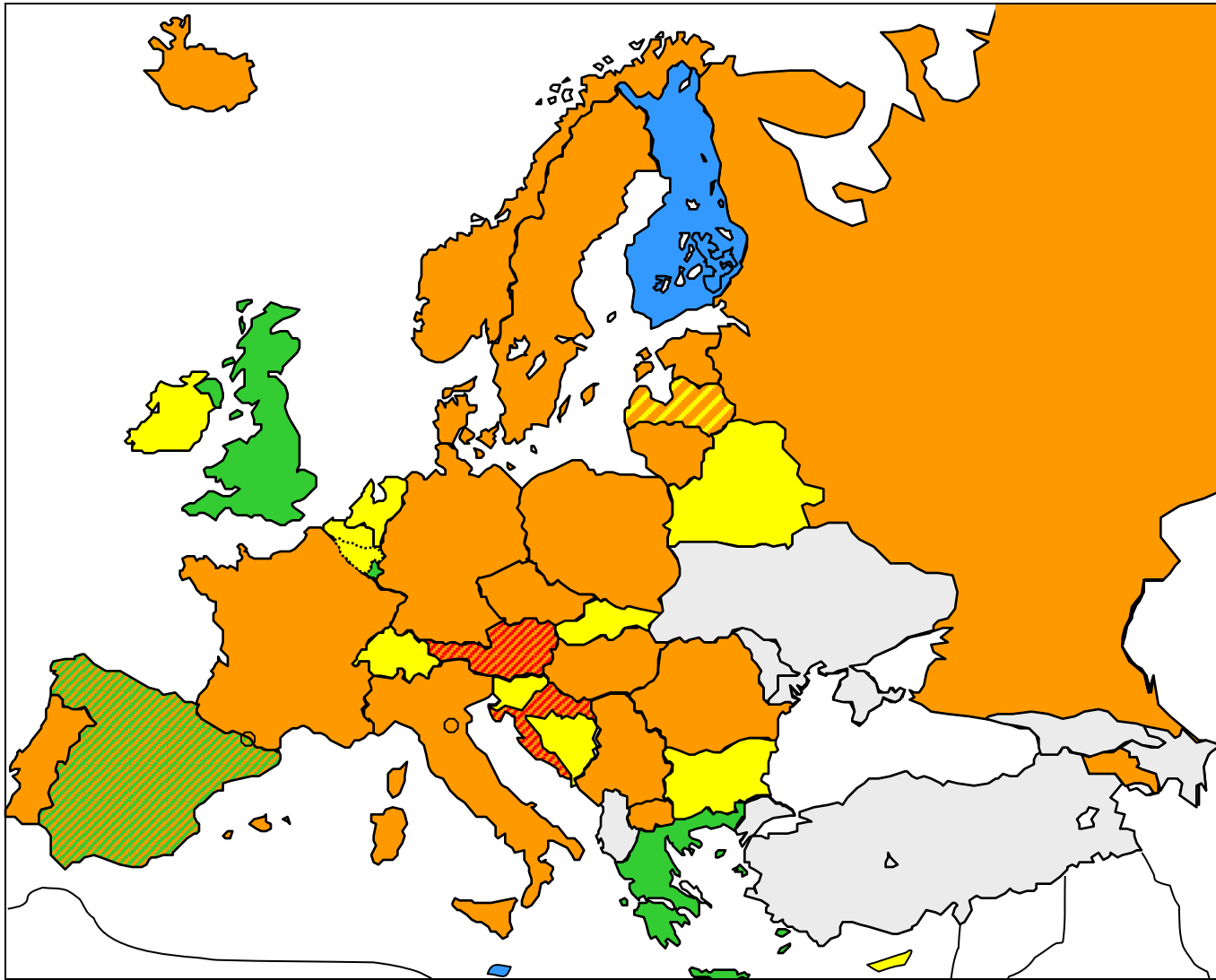
no data

Informed consent for participation

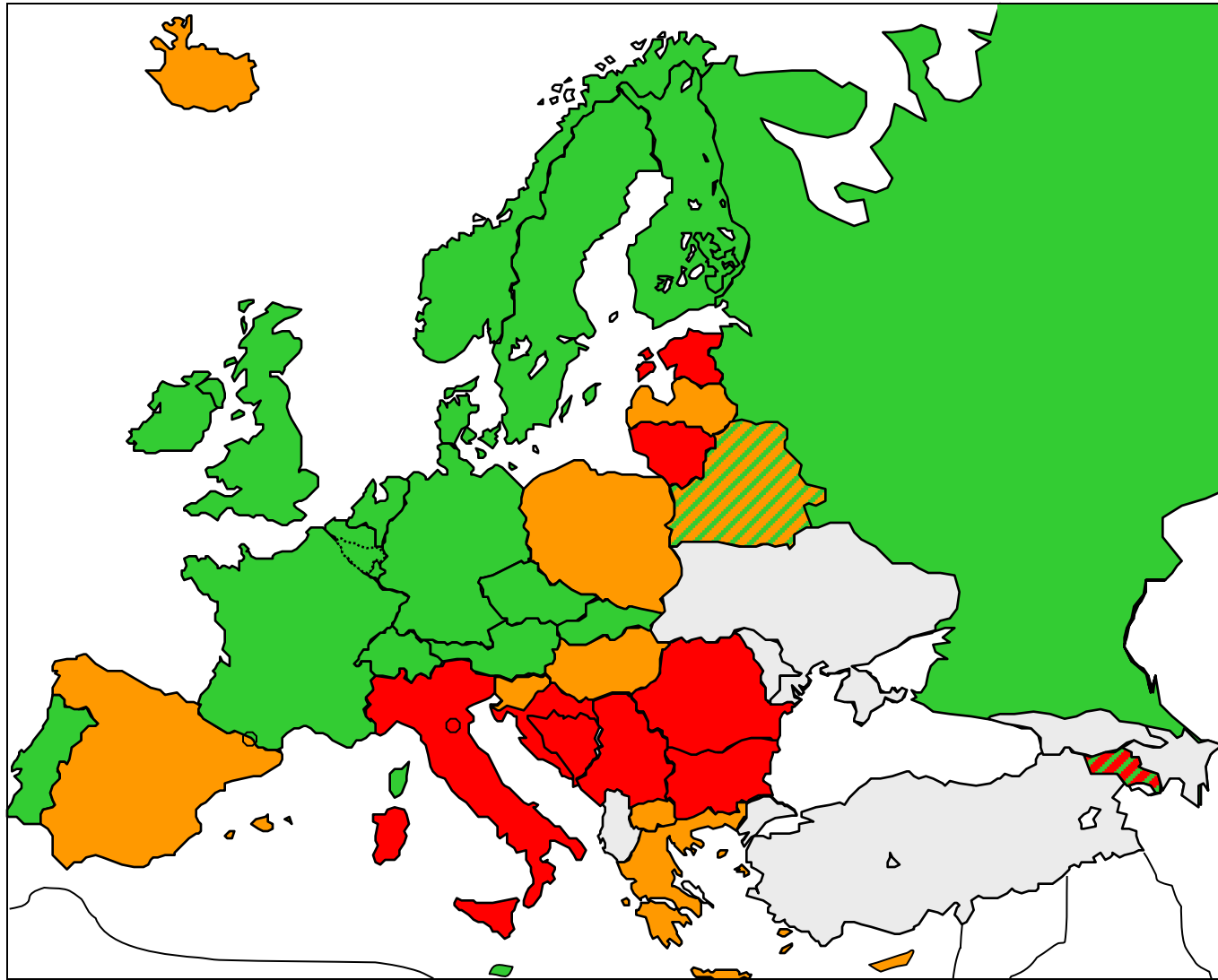


Part 2 Blood sampling and transport

Age at blood sampling

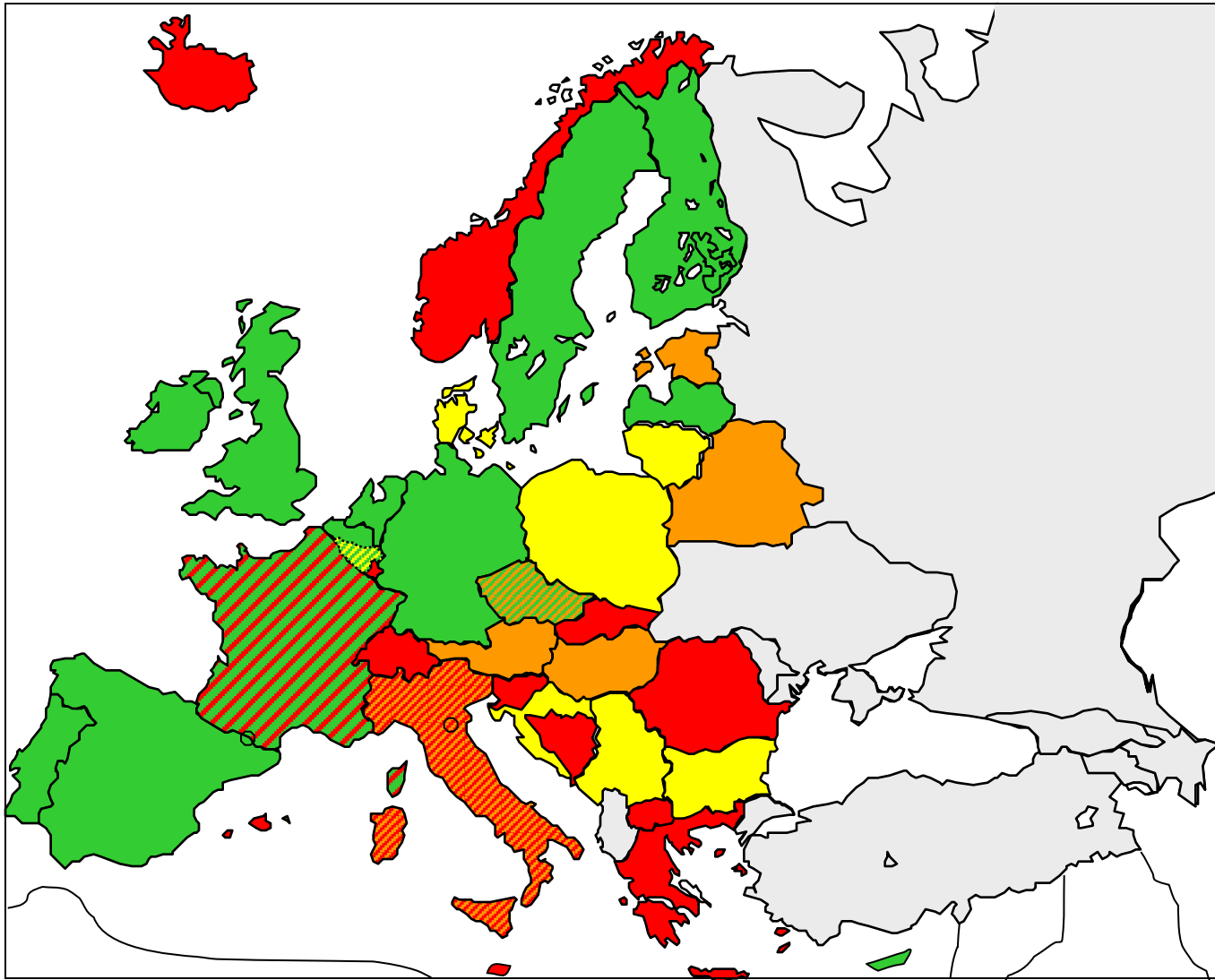


Interval sampling- analysis



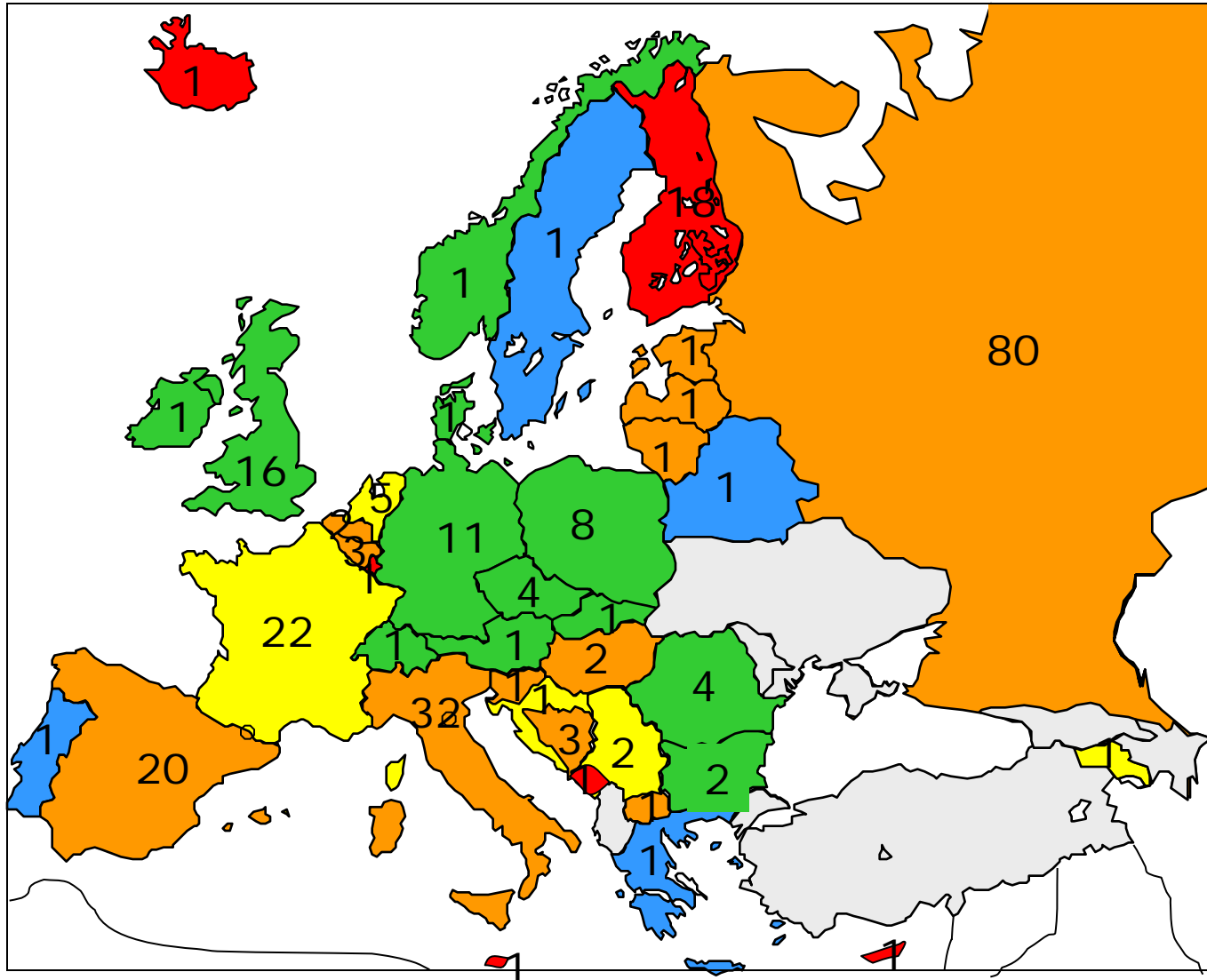
Part 3 Laboratory procedures, quality etc.

Accreditation / Certification



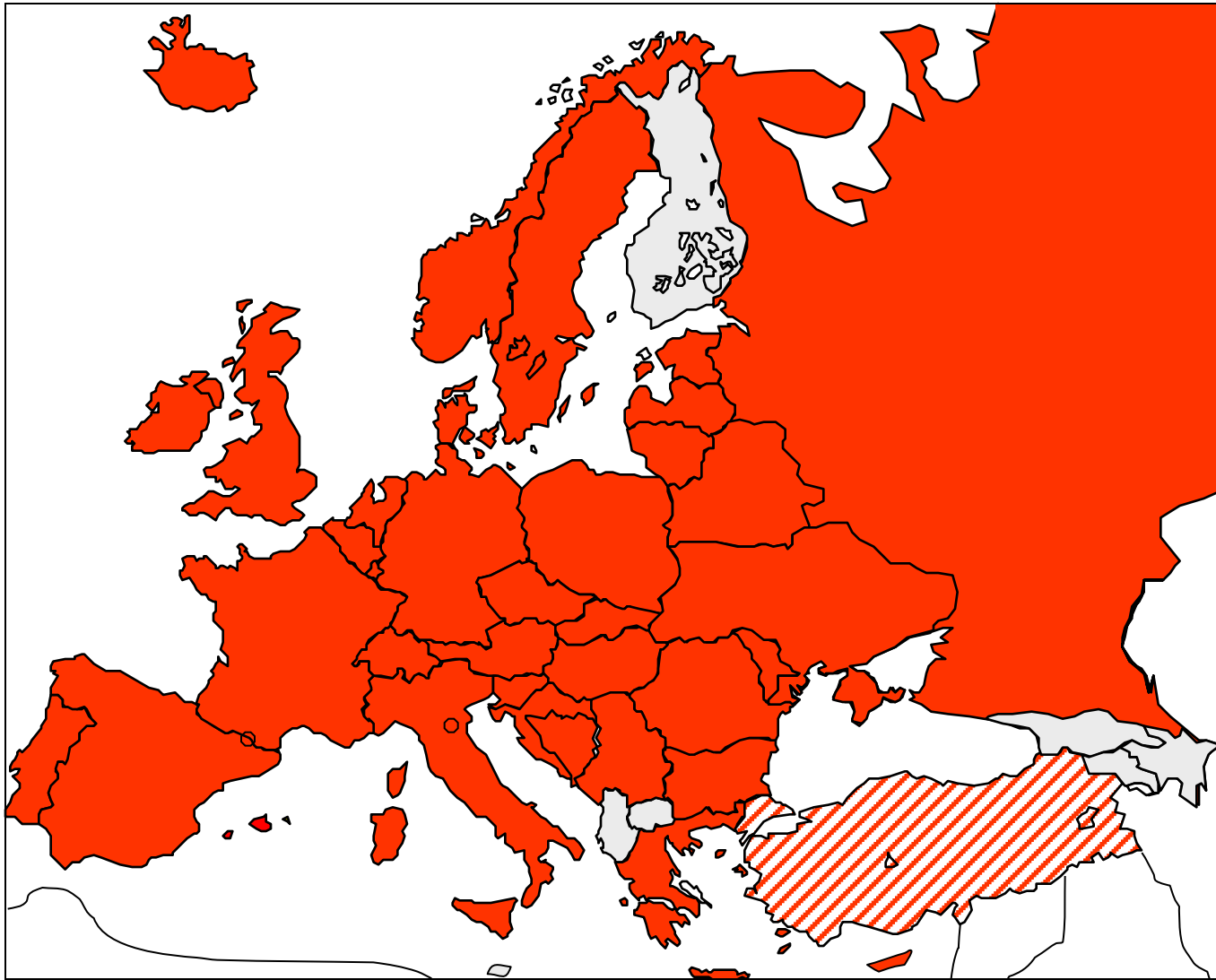
Average number of specimens per lab

In CZ, BG
separate
PKU and
CH-labs



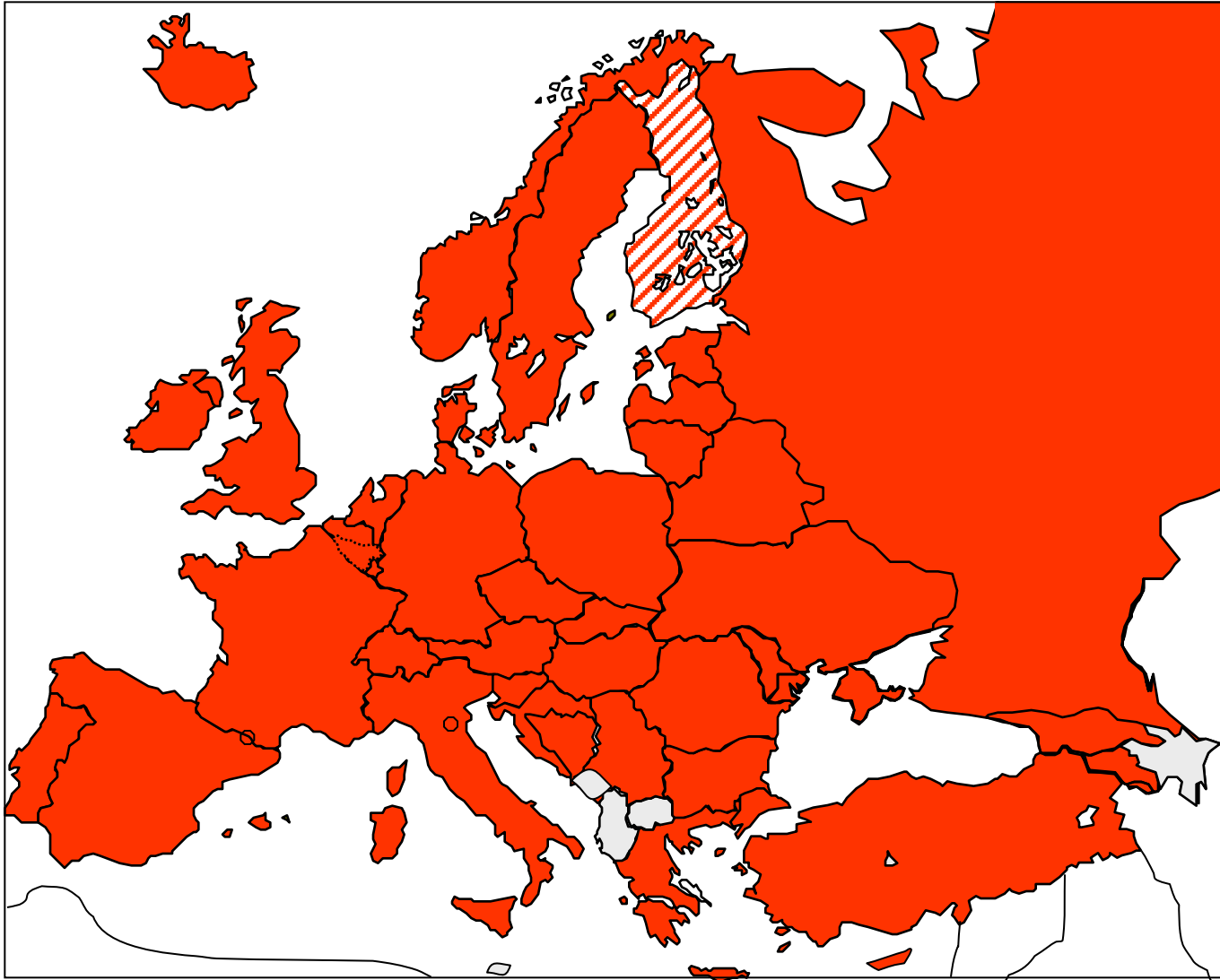
Part 4 Screening panels

Phenylketonuria



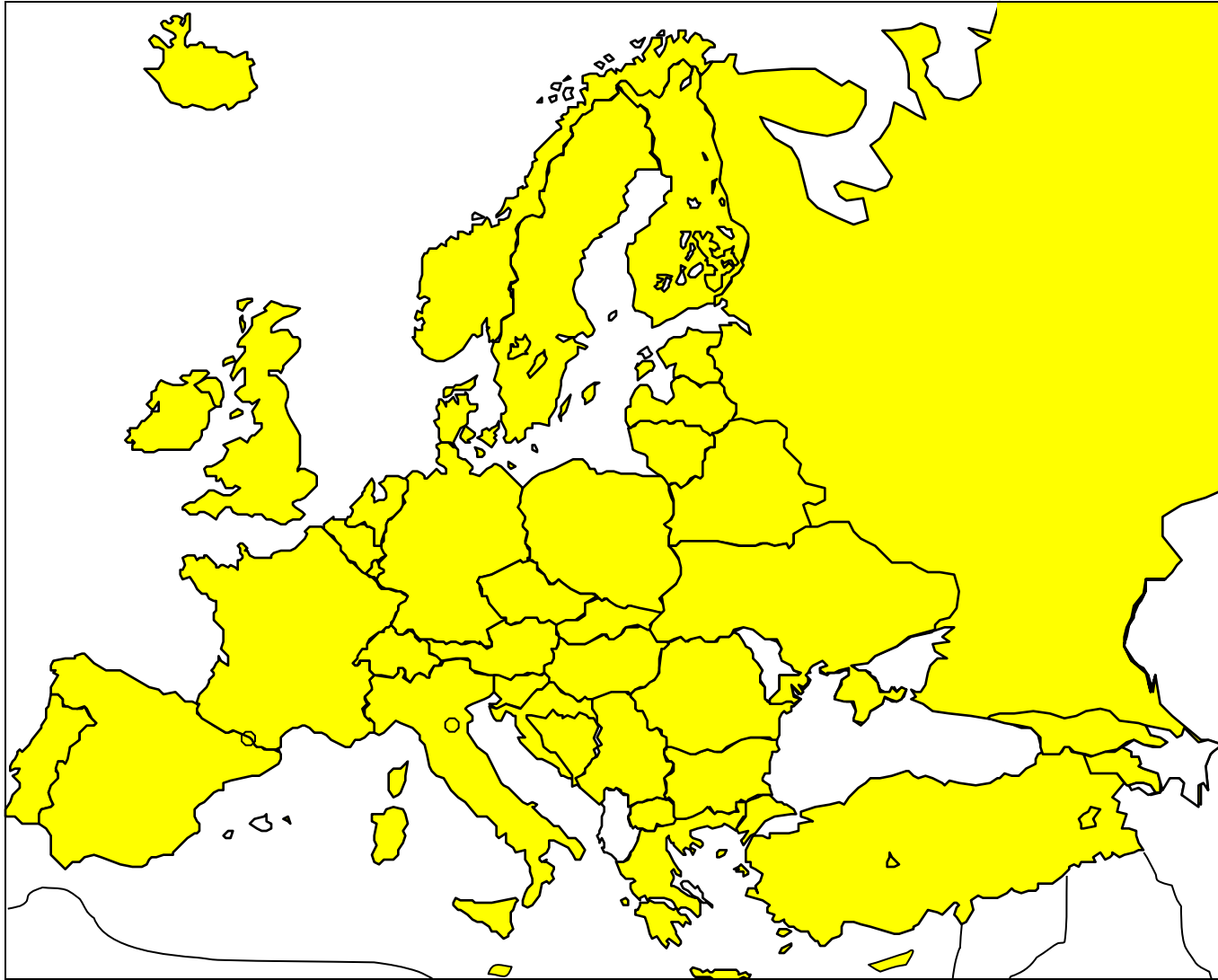
Not in Malta, Montenegro, Macedonia; partly in Finland

Phenylketonuria



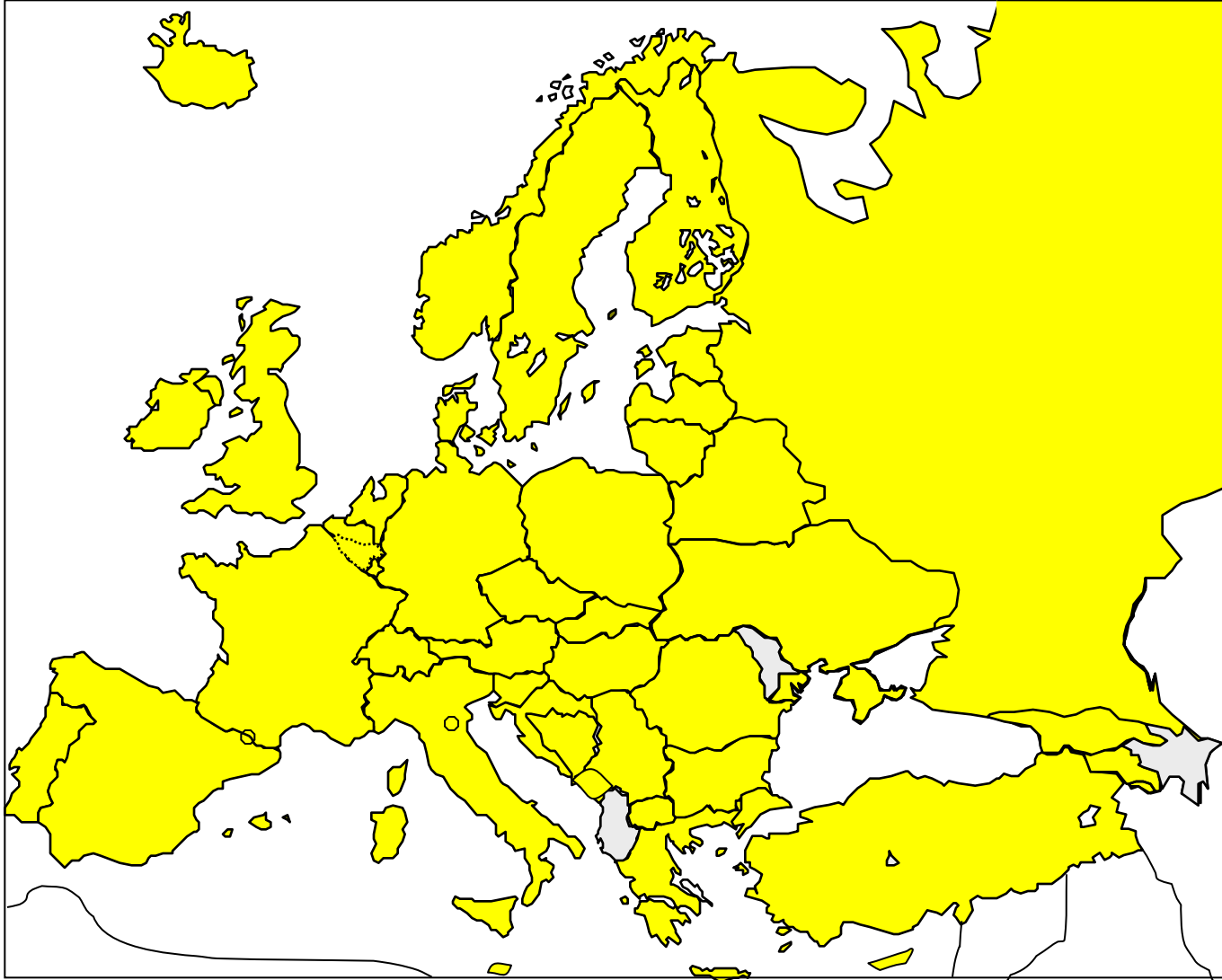
Not in Azerbaijan, Malta, Montenegro, Macedonia; partly in Finland

Congenital Hypothyroidism



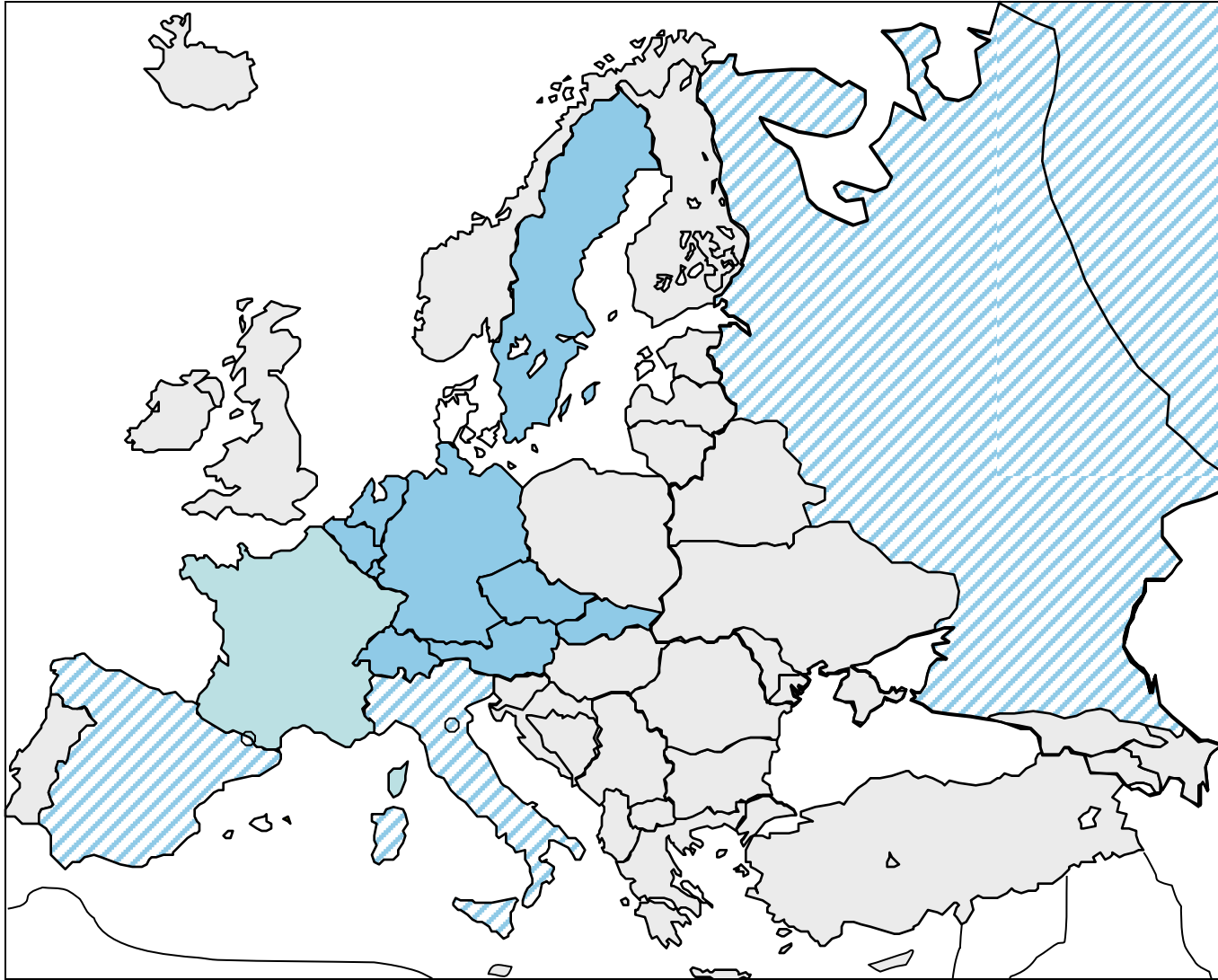
Not in Moldova, Azerbaijan

Congenital Hypothyroidism



Not in Moldova, Azerbaijan

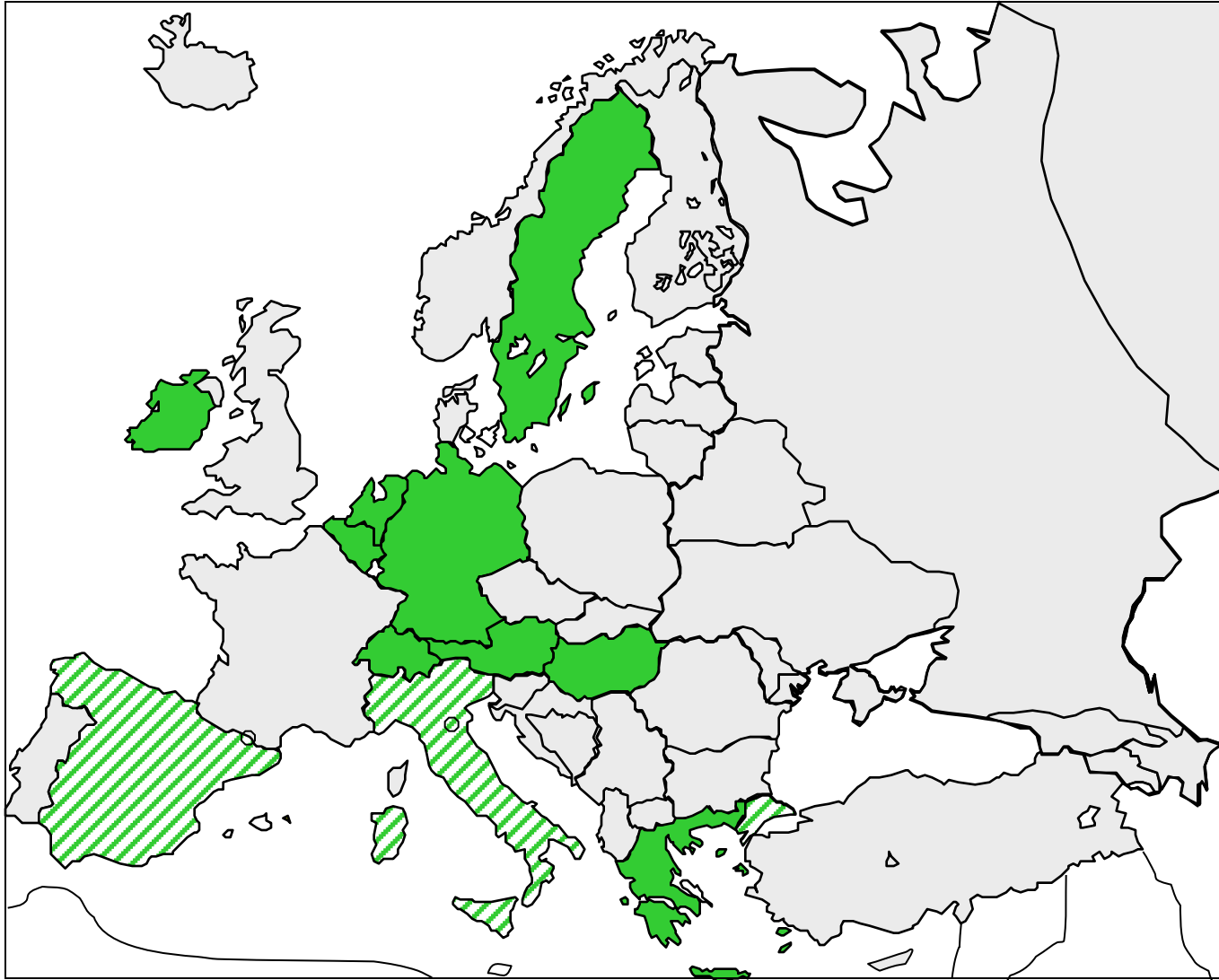
Congenital Adrenal Hyperplasia



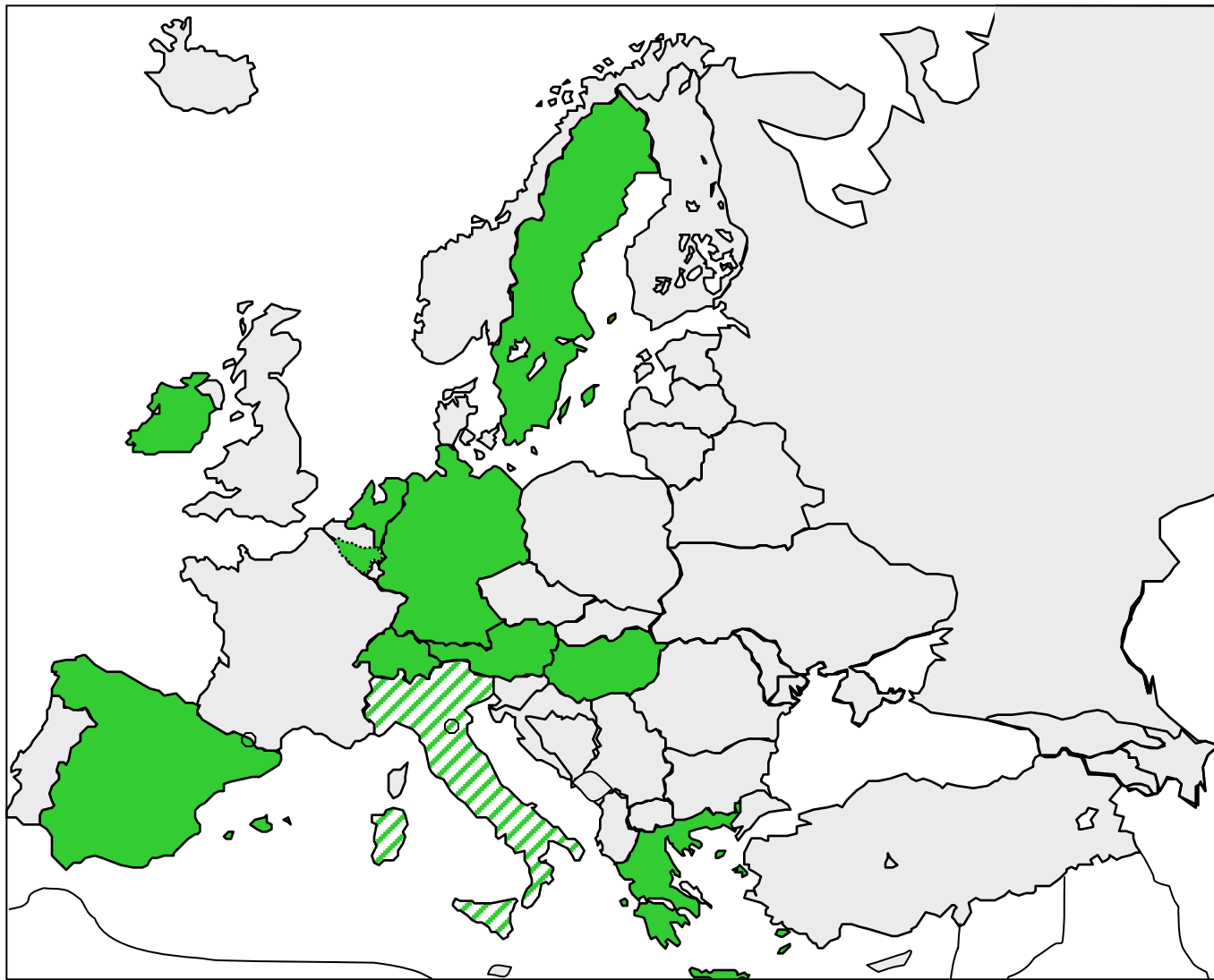
Congenital Adrenal Hyperplasia



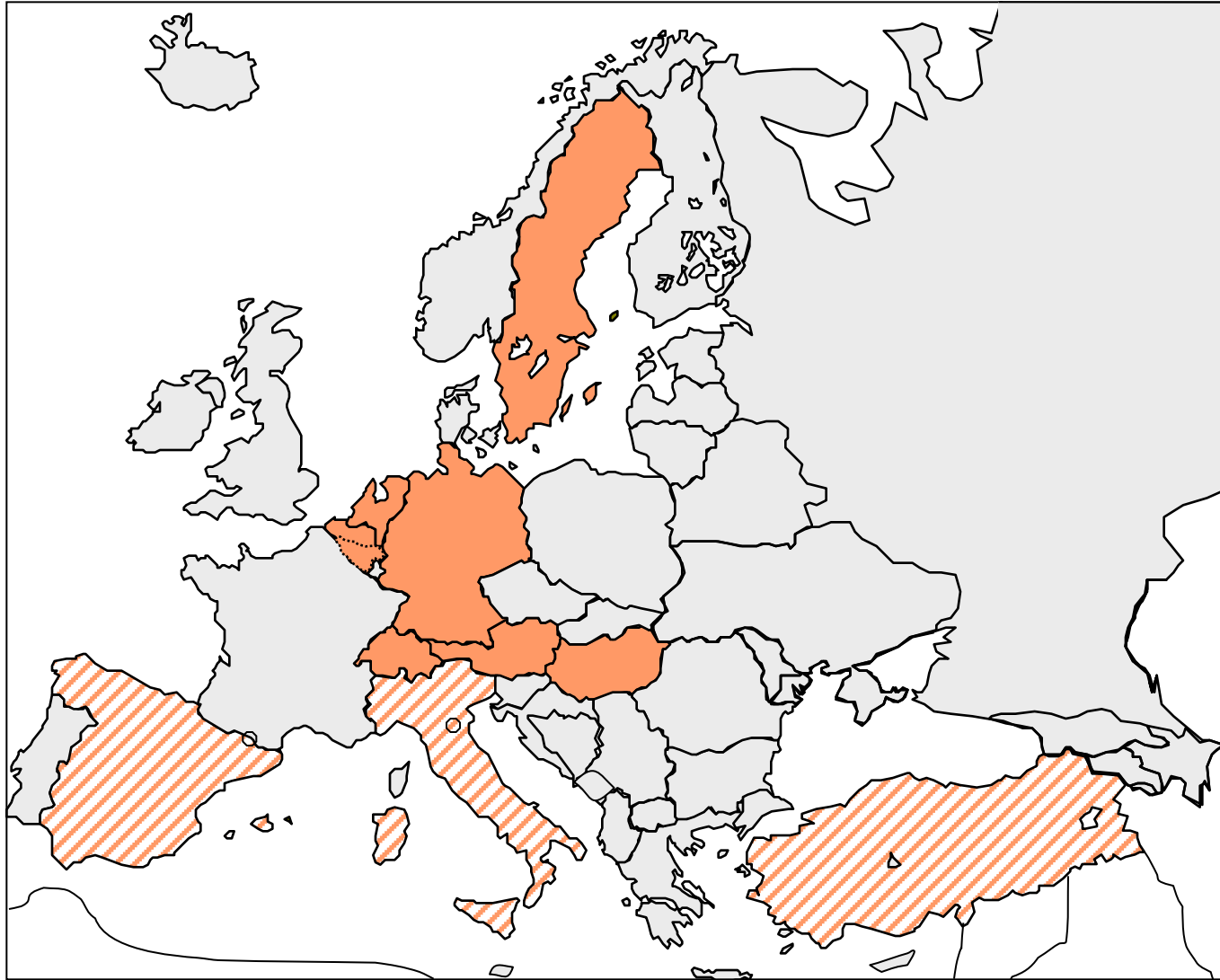
Galactosemia



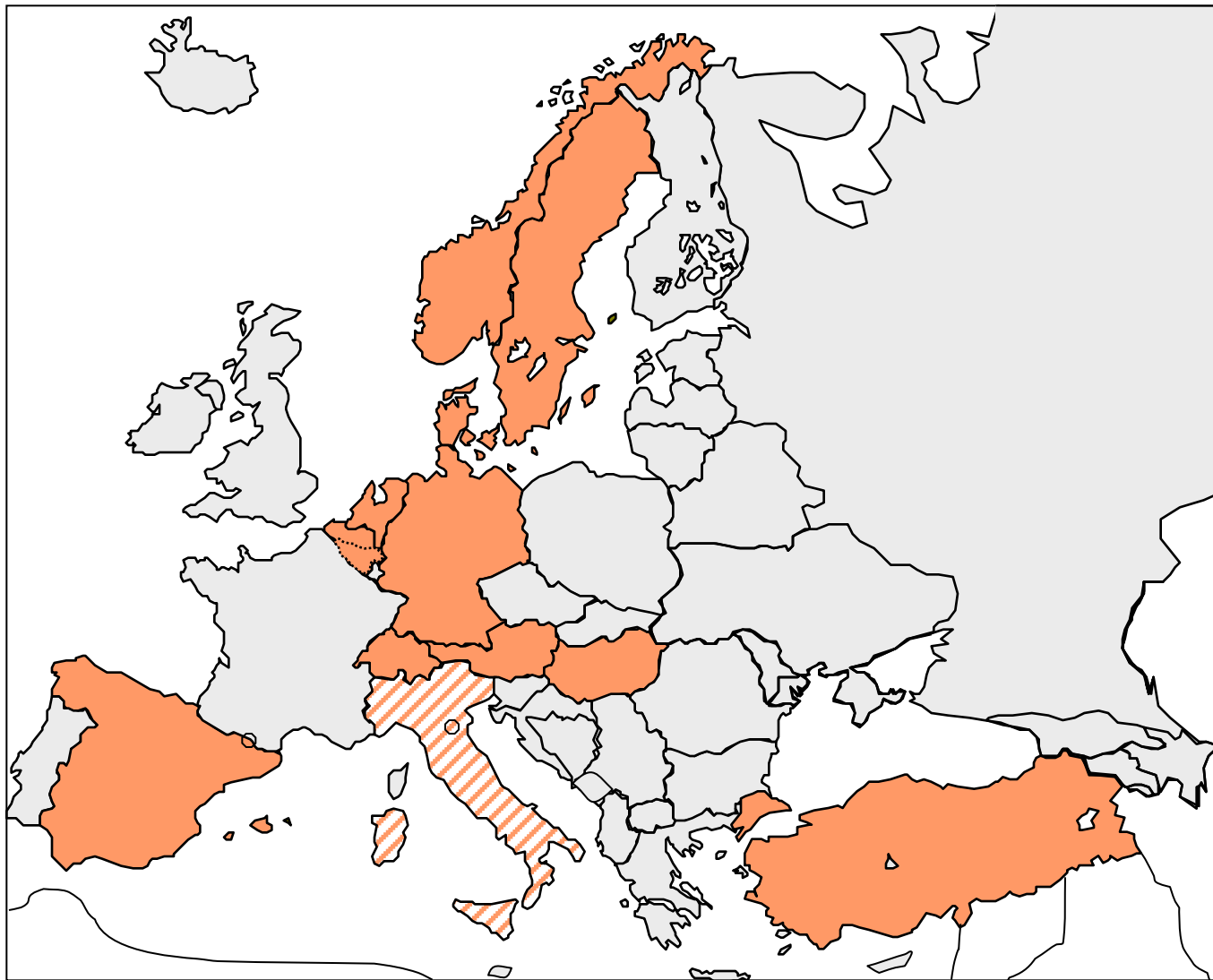
Galactosemia



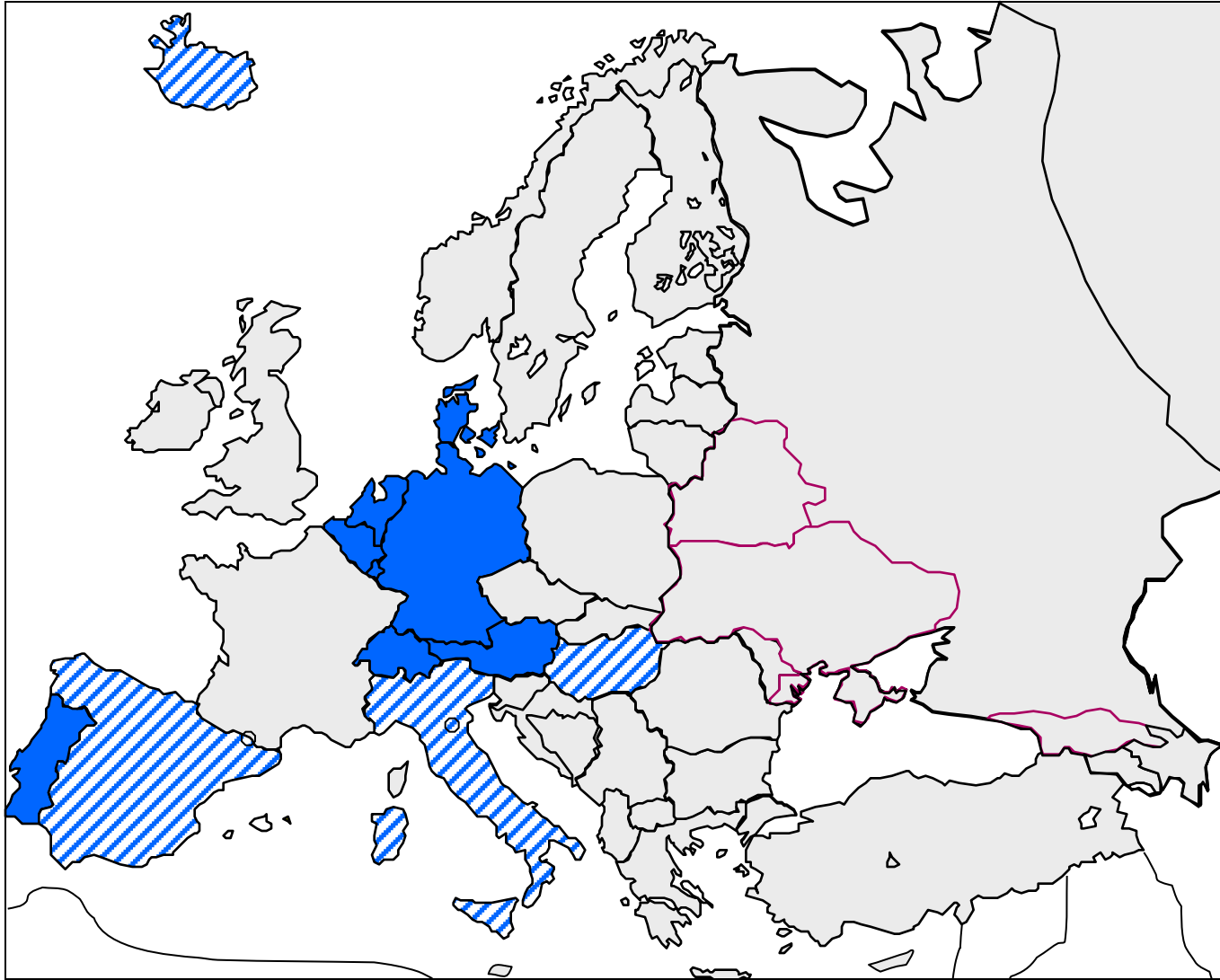
Biotinidase deficiency



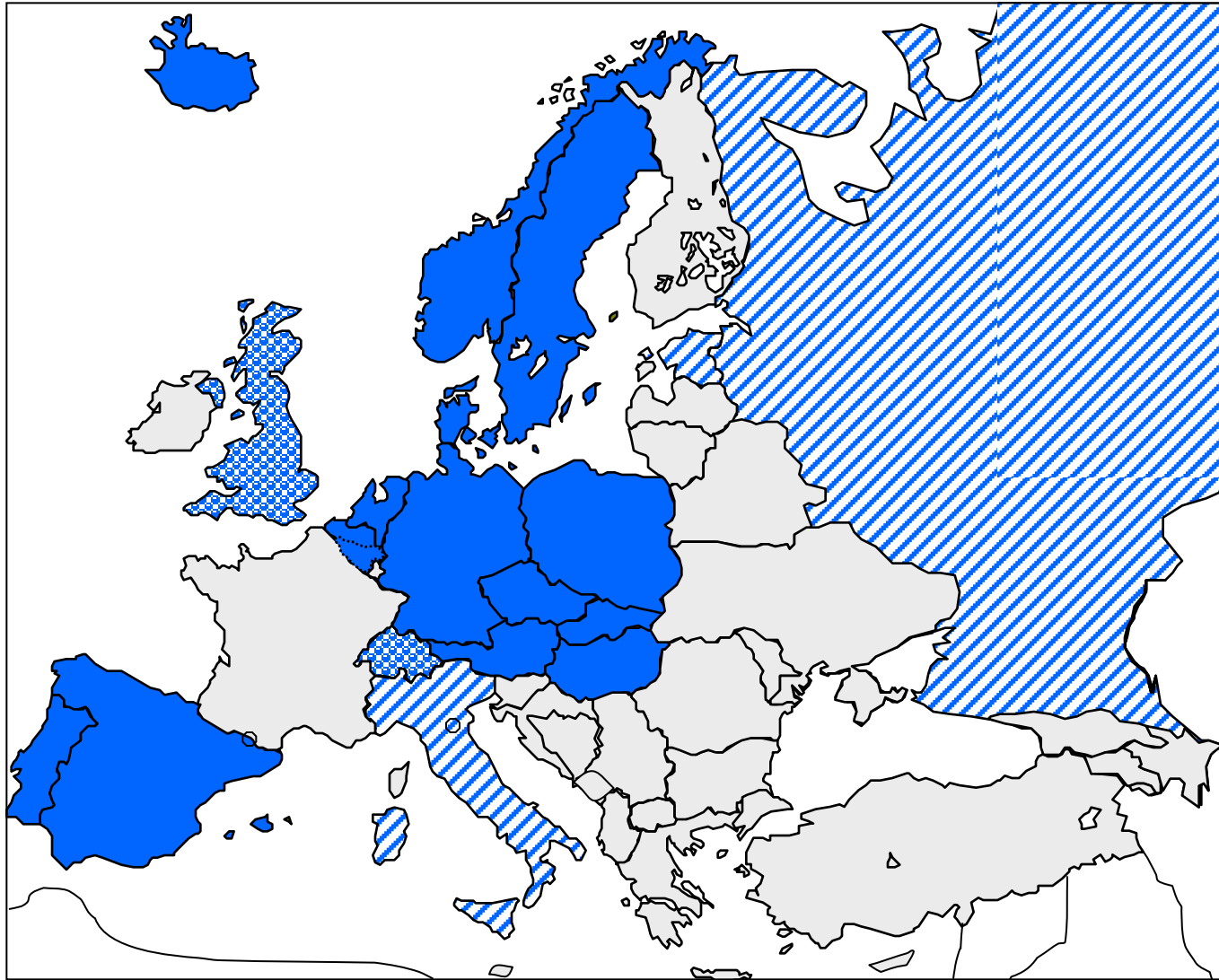
Biotinidase deficiency



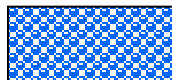
MS / MS



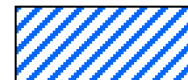
MS / MS



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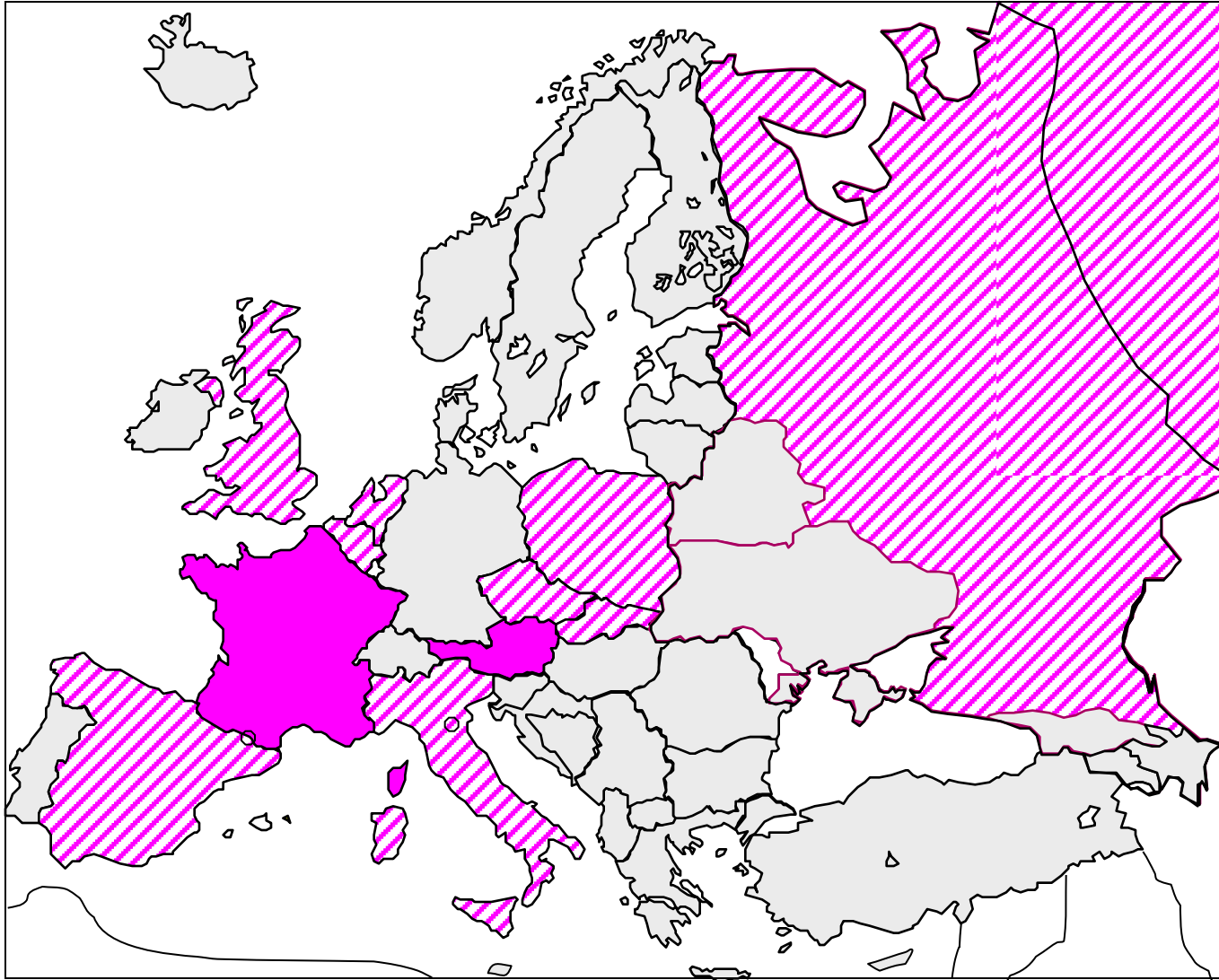


1-5

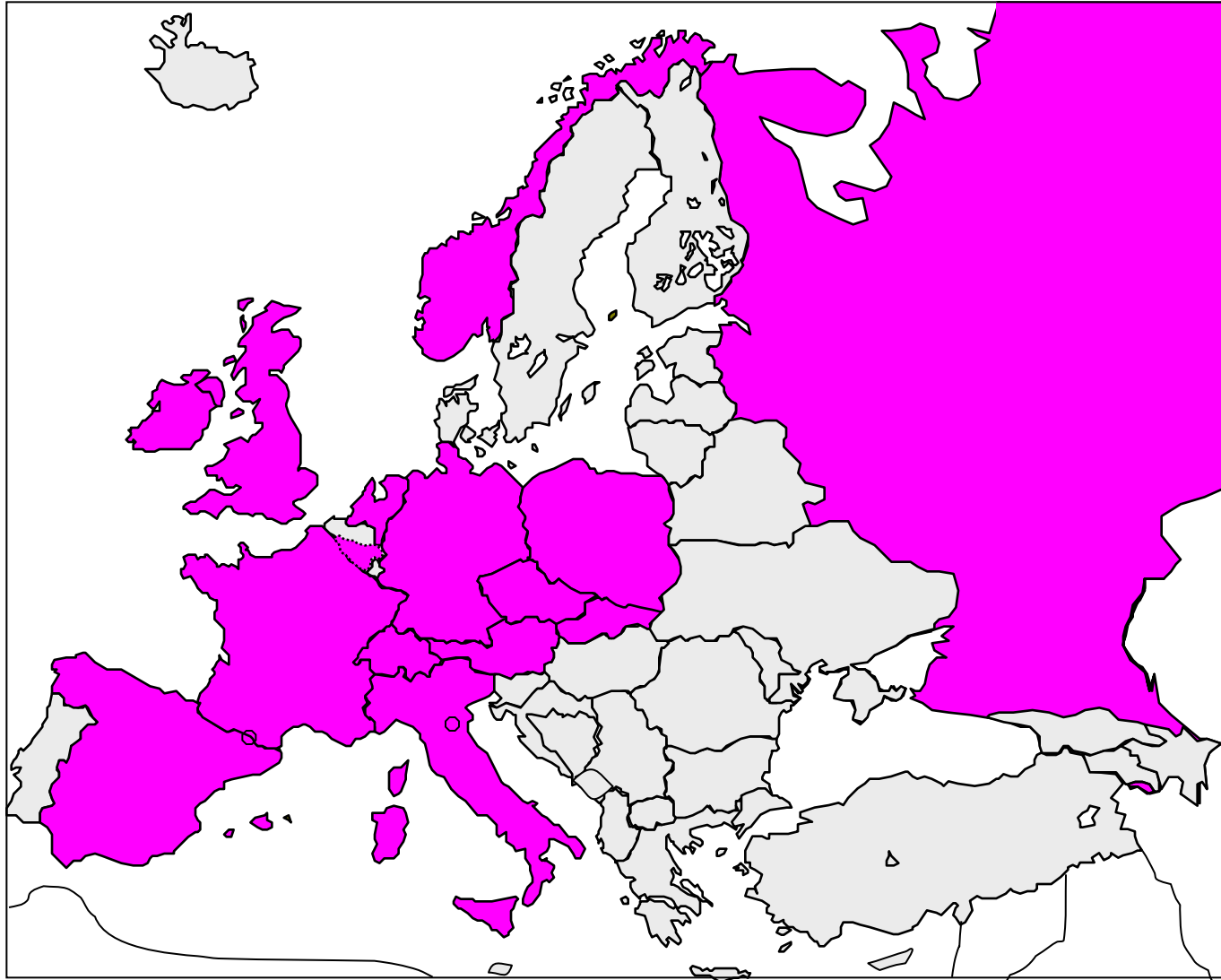


pilot/partly

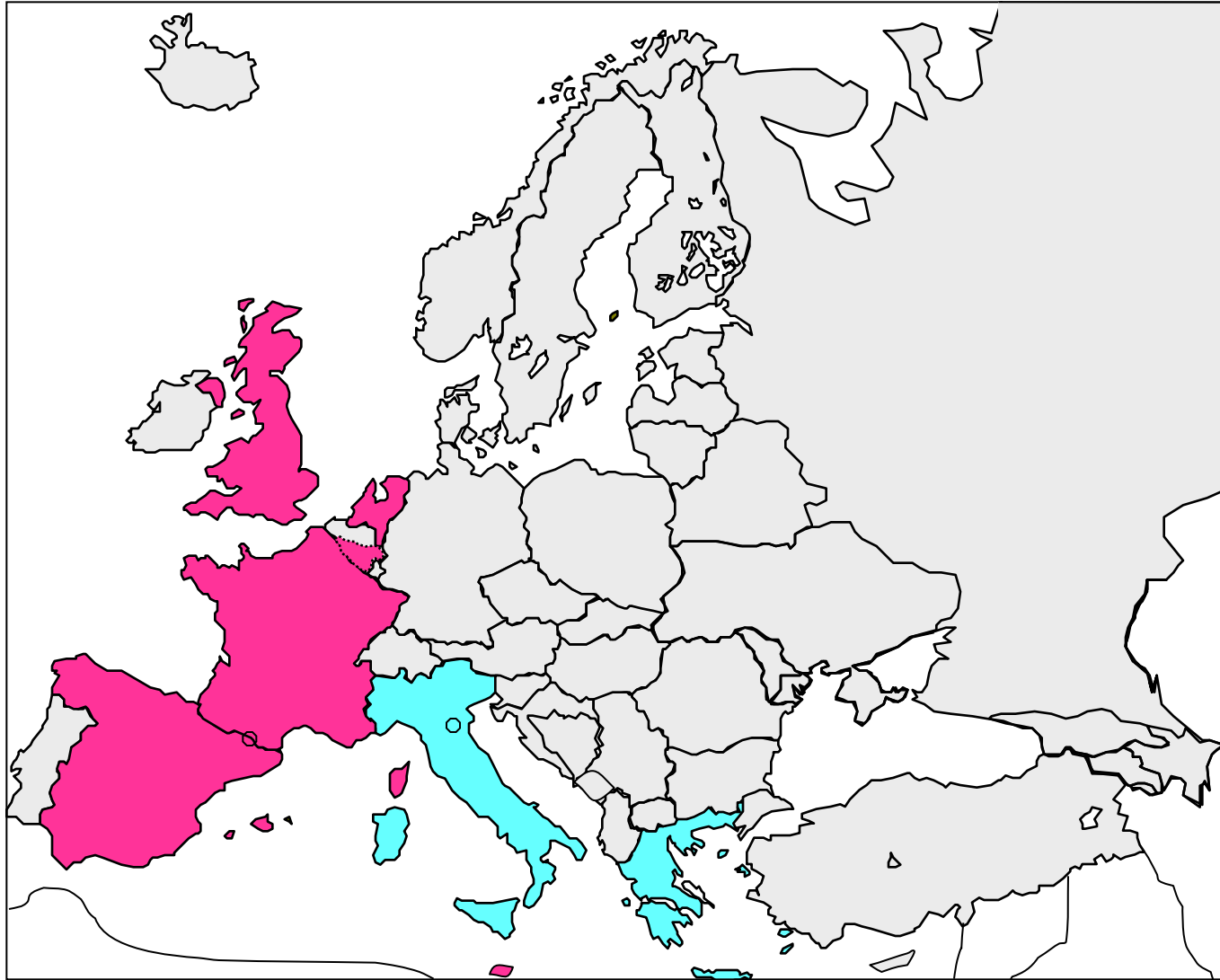
Cystic Fibrosis



Cystic Fibrosis



Other conditions

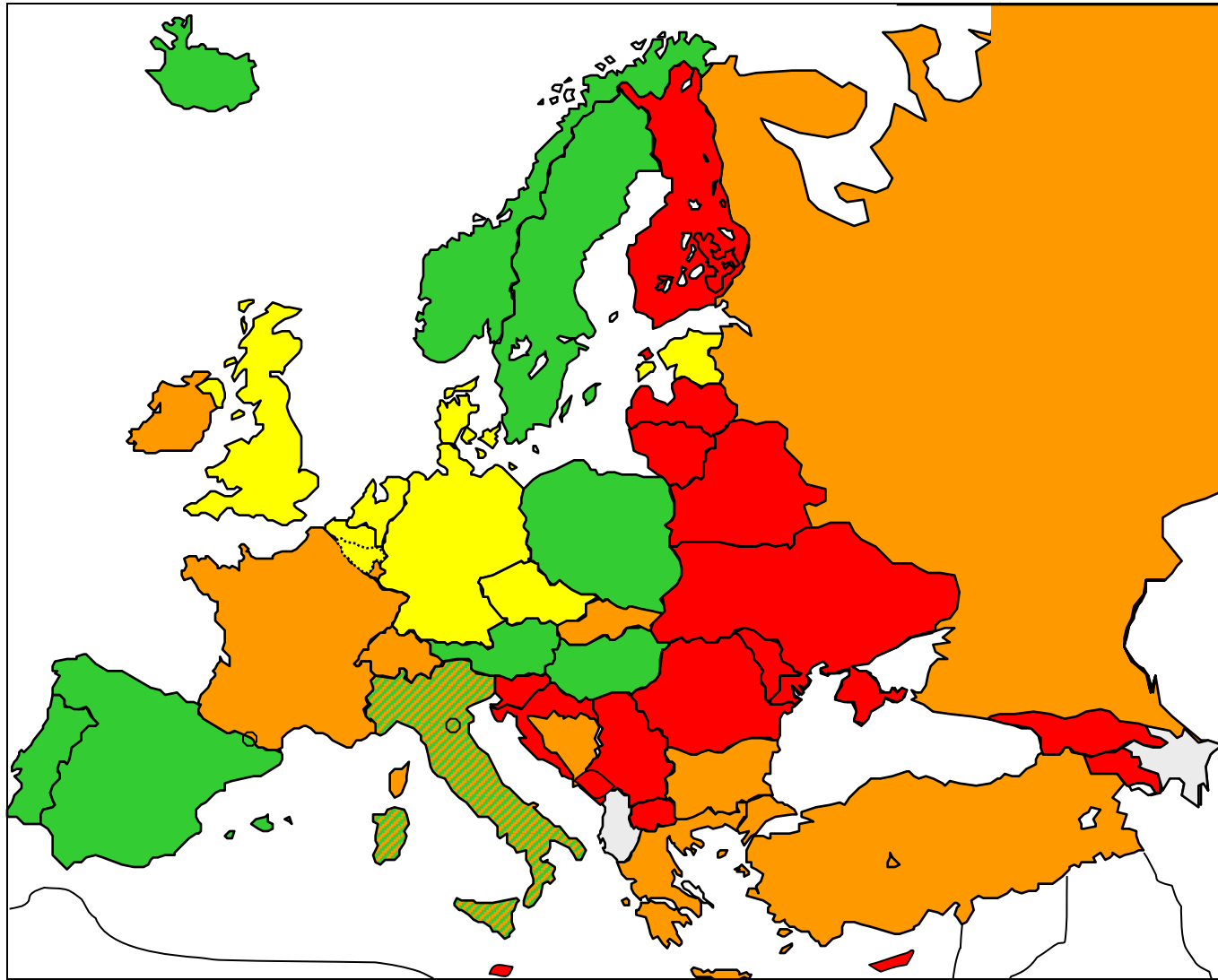


SCD



G6PD

Number of conditions per country

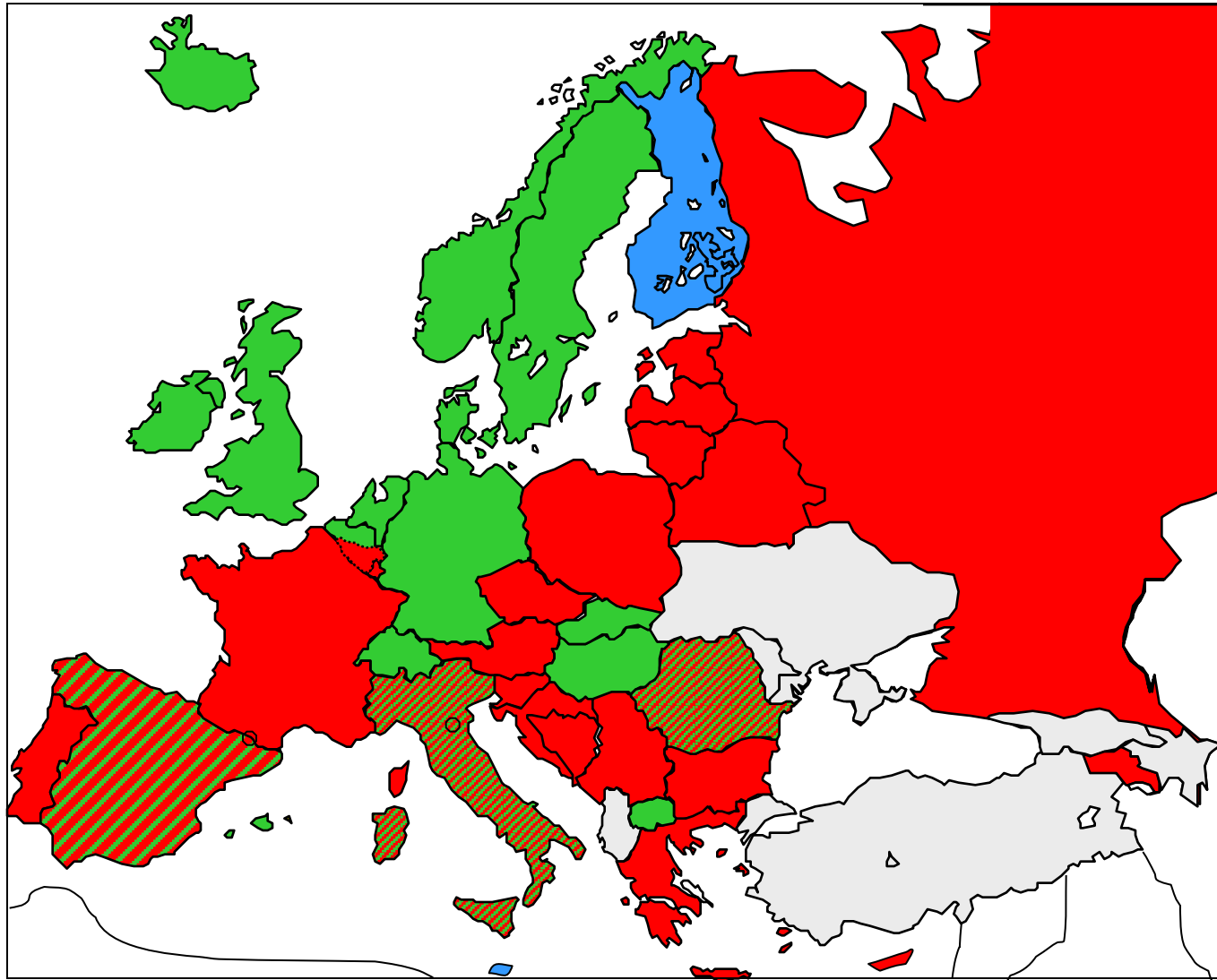


Number of conditions, status quo

- No NBS: Albania
- Number of conditions screened is not related to BNP
- Sometimes there is money for bullet trains but not for ms/ms apparatus

Part 5 Blood spot storage

Information on blood spot storage



yes

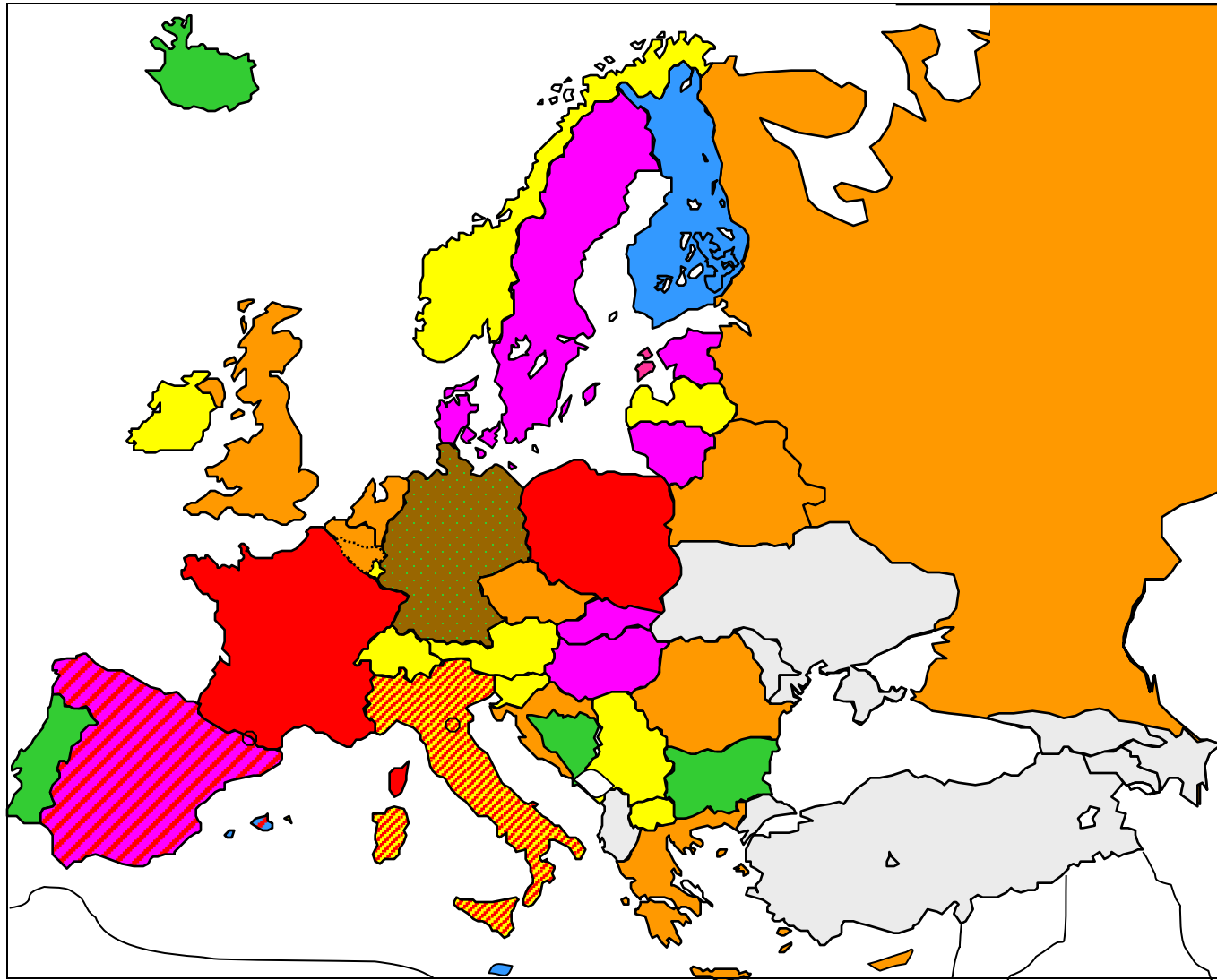


no



not applic.

Length of storage



not appl



International Society for
Neuroimaging

What has been done with the results?

- Report and Expert Opinion Document (= recommendations) have been submitted to the EU in 2012
- EU has asked EUCERD (EU Committee of Experts on Rare Diseases) for advice

EUCERD's conclusions on the recommendations in the EOD

The topics identified respect the *principle of subsidiarity*.

They include actions to improve the quality and the efficiency of the screening process, while *respecting the values of the Member States*.

They are presented *in no particular order* and do not represent a *prioritisation* of areas for action.

These points are submitted to the European Member States, to the European Commission and to any third party involved for further consideration.

http://www.eucerd.eu/wp-content/uploads/2013/07/EUCERD_NBS_Opinion_Adopted.pdf

EUCERD's conclusions on the recommendations in the EOD

In short: EU is not going to take any further initiative to achieve harmonisation

EUCERD's mandate expired in 2014

- New Committee of Experts formed:

EU Commission Expert group on Rare Diseases

- WE PROBABLY HAVE TO DO HARMONIZATION OURSELVES !!

In addition

- European populations are not concerned with what happens elsewhere
- They do not know about NBS panels in neighbouring countries, sometimes not even in neighbouring provinces
- Advocacy groups exist but have little influence
- Thus, horse carriages and bullet trains can co-exist easily



Horizon 2020

- A new EU fund (successor of the 7th Frame Work); Horizon 2020 is the biggest EU Research and Innovation programme ever with nearly €80 billion of funding available over 7 years (2014 to 2020)
- 22 fields including Health
- Project applications for funding August 2014, decision January 2015
- At least 3 NBS-related projects

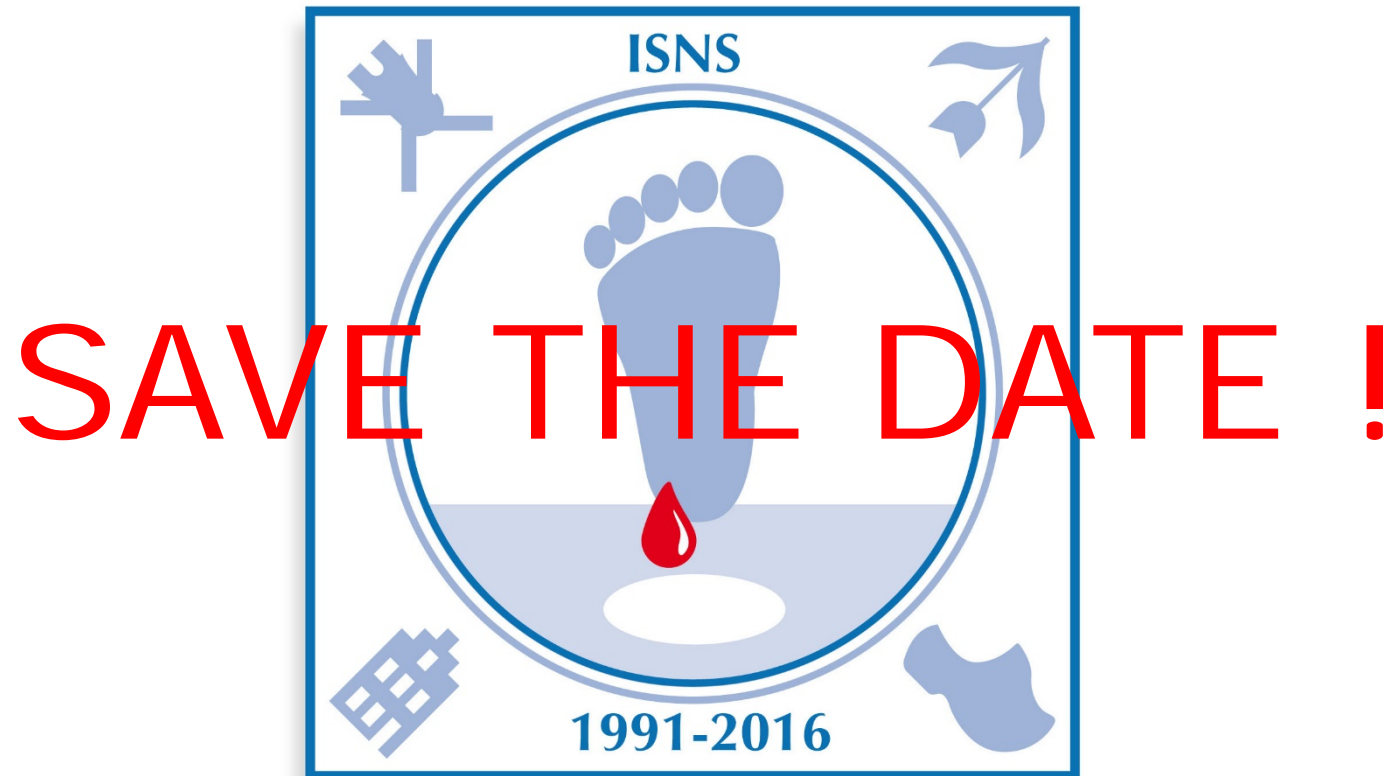
<http://ec.europa.eu/programmes/horizon2020/>

And finally

November 20, 2014 it is the 25th anniversary of the UN Convention of the Rights of the Child !!!

Let's remind the policy makers to spend the money on children's health care! It will be never enough.

ISNS Silver Jubilee: 25 years of sharing knowledge globally



**9th ISNS international symposium
The Hague, The Netherlands
September 11-14, 2016**

See you at ISNS 2016 !!

