



Revision of the Act on Human Genetic Testing

Interim Results

Molecular Diagnostics Symposium, 4 March 2016



Good morning!



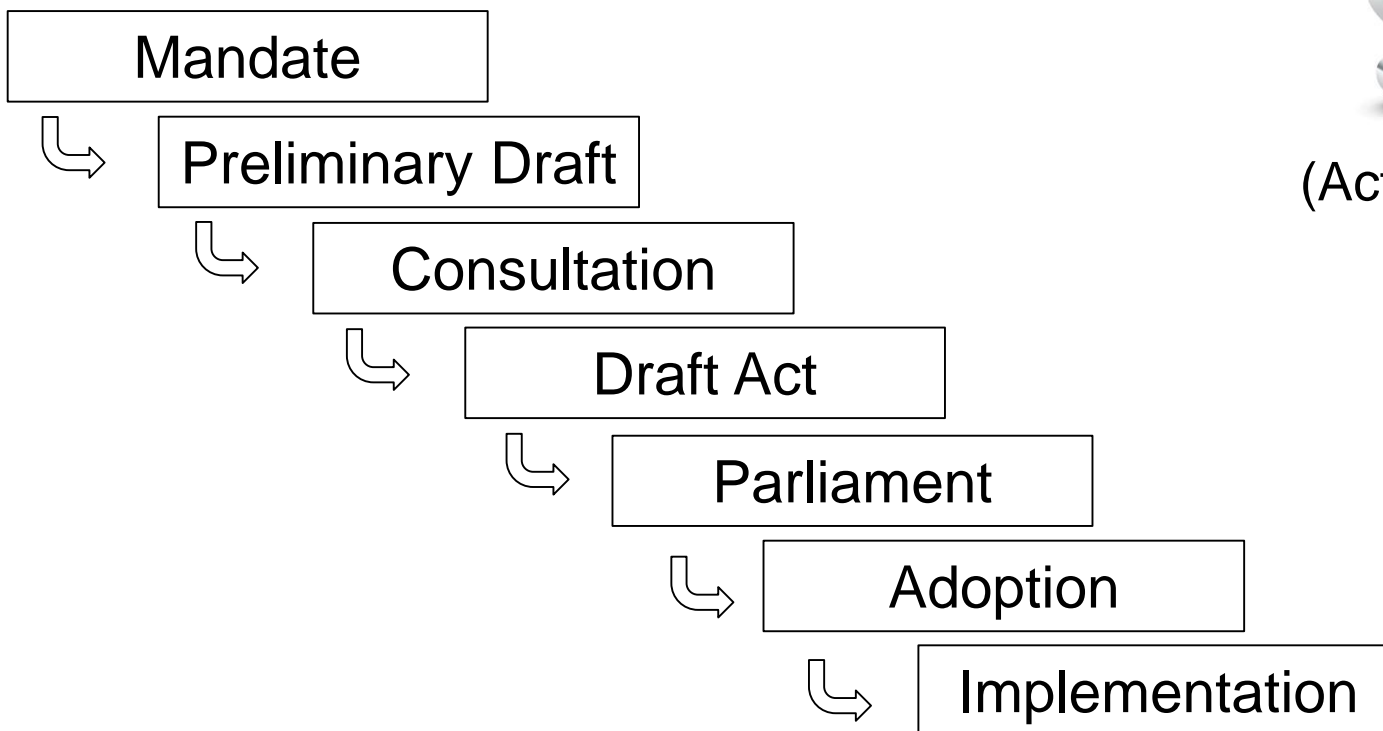
- Legislative procedure
- Current Act of Human Genetic Testing
- Why we need a revision
- Main topics of revision project
- Results of public consultation and evaluation
- Further steps



Legislative procedure



(Act = law)

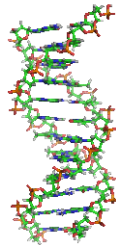




Current Act on Human Genetic Testing

- Elaboration during the 1990ies
- Transfer to Parliament in September 2002
- Adoption by the Parliament in October 2004

- Implementation of Act and its Ordinances in April 2007



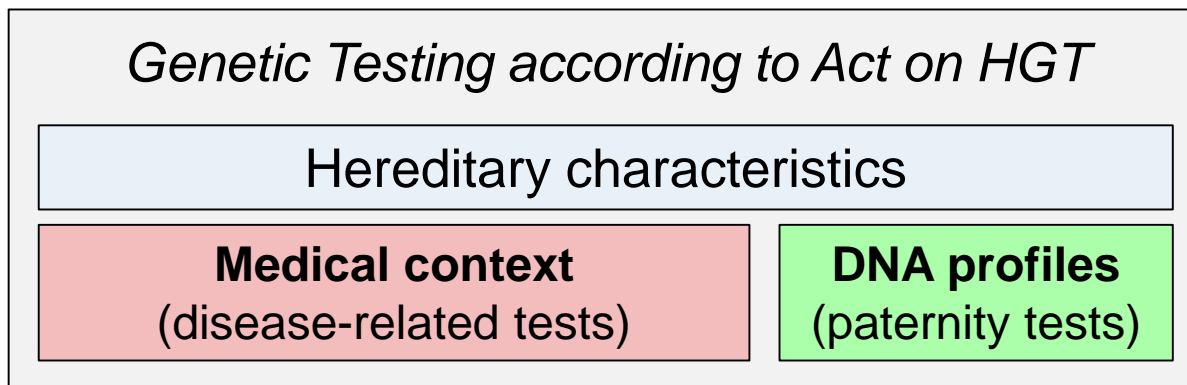


Purpose of the Act

- To protect human dignity and personality
- To prevent misuse
- To ensure quality of genetic tests and interpretation of results

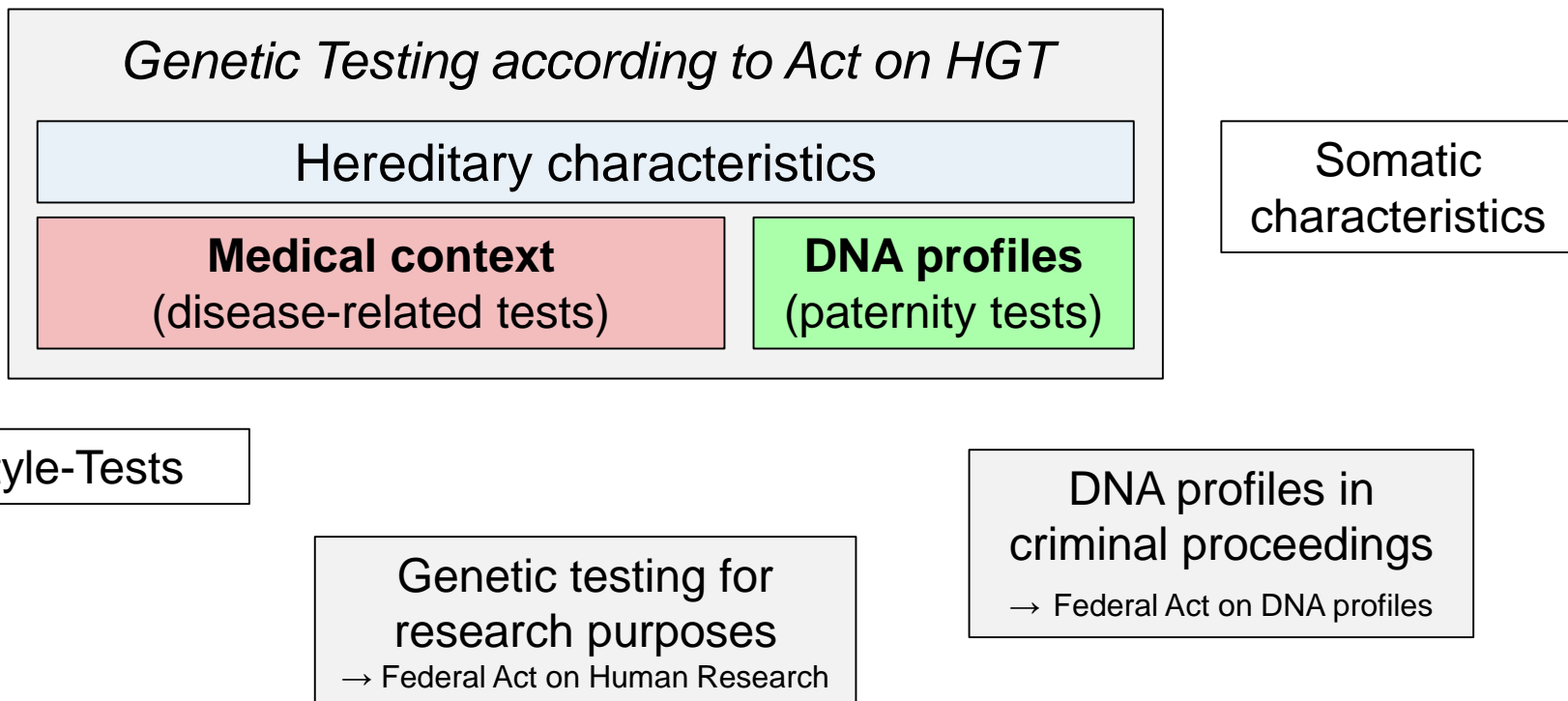


Scope of the Act





Exemptions





Why do we need a revision?

- Considerable progress in the field of genomic science and technology
 - New « lifestyle-tests »
 - Direct-to-consumer genetic testing (DTC)

Born to Run? Little Ones Get Test for Sports Gene

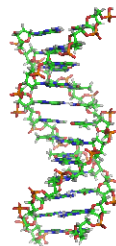


The New York Times November 2008



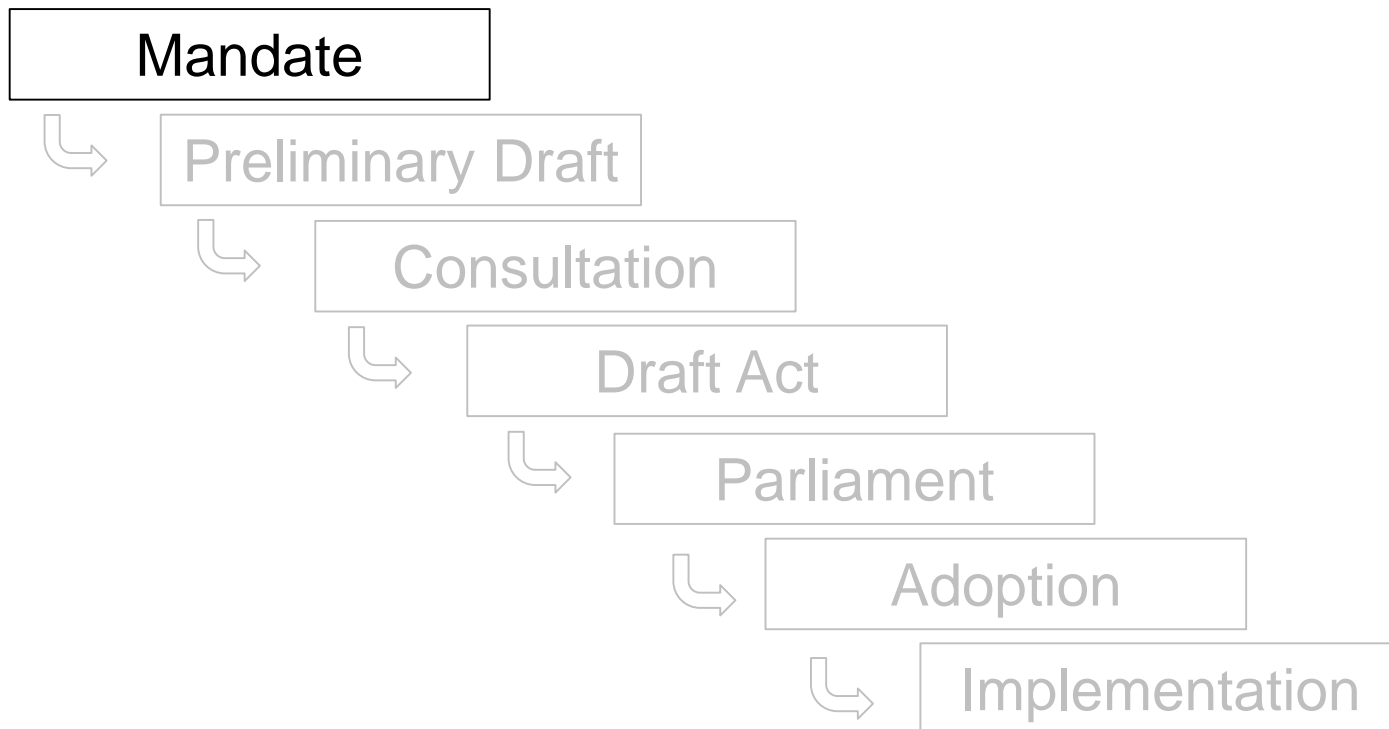
Mandate of Parliament

- Autumn 2012: Parliament assigned the Federal Council
 - to examine current legislation and to specify legislative gaps
 - to propose necessary modifications of the act on human genetic testing





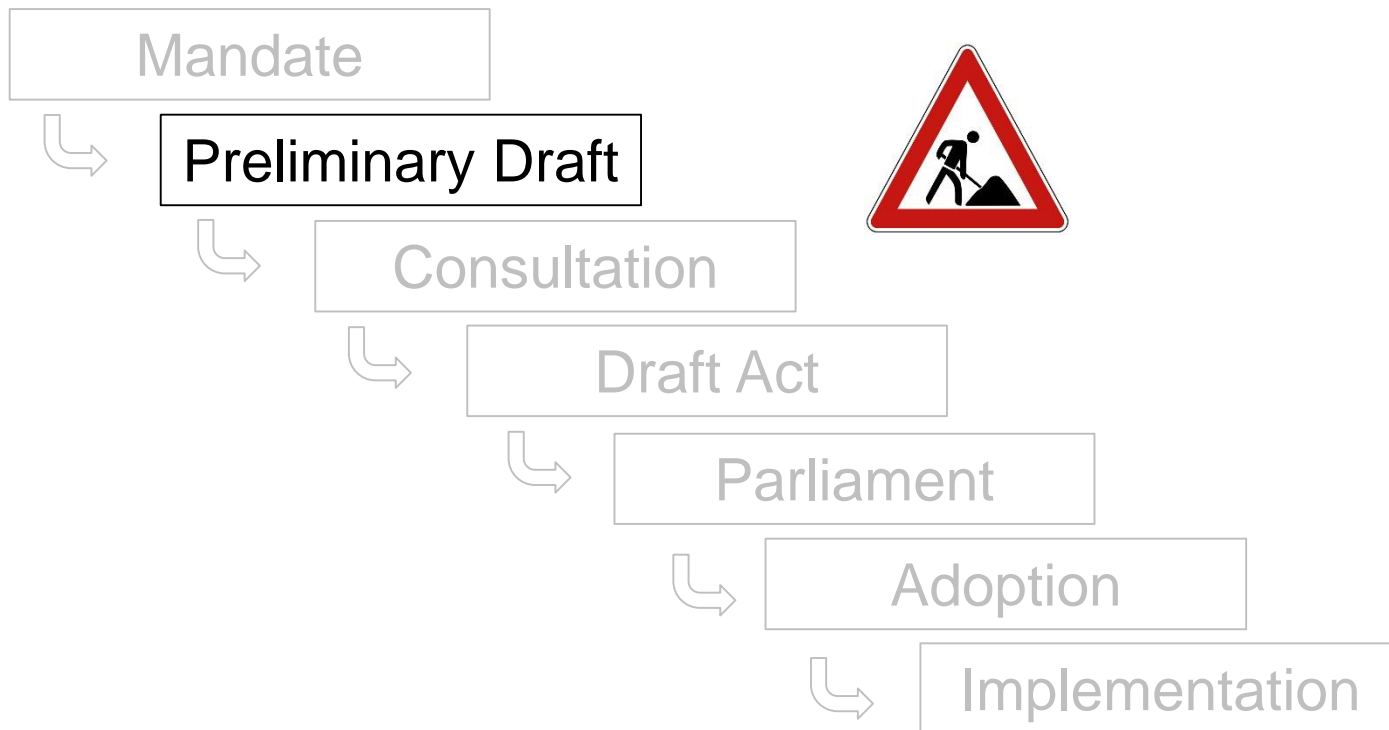
Revision process



2012



Revision process





Main topics of preliminary draft

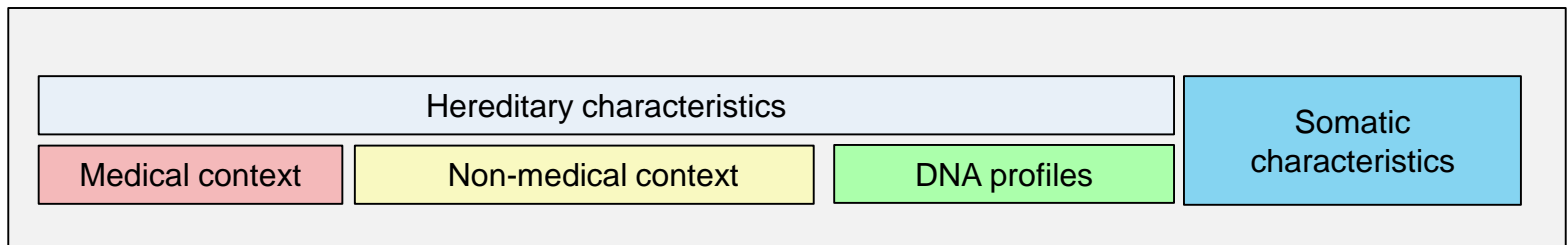
- Expansion of scope
- Adjustment of regulation concerning prenatal testing
- Regulation of incidental findings



Expansion of scope

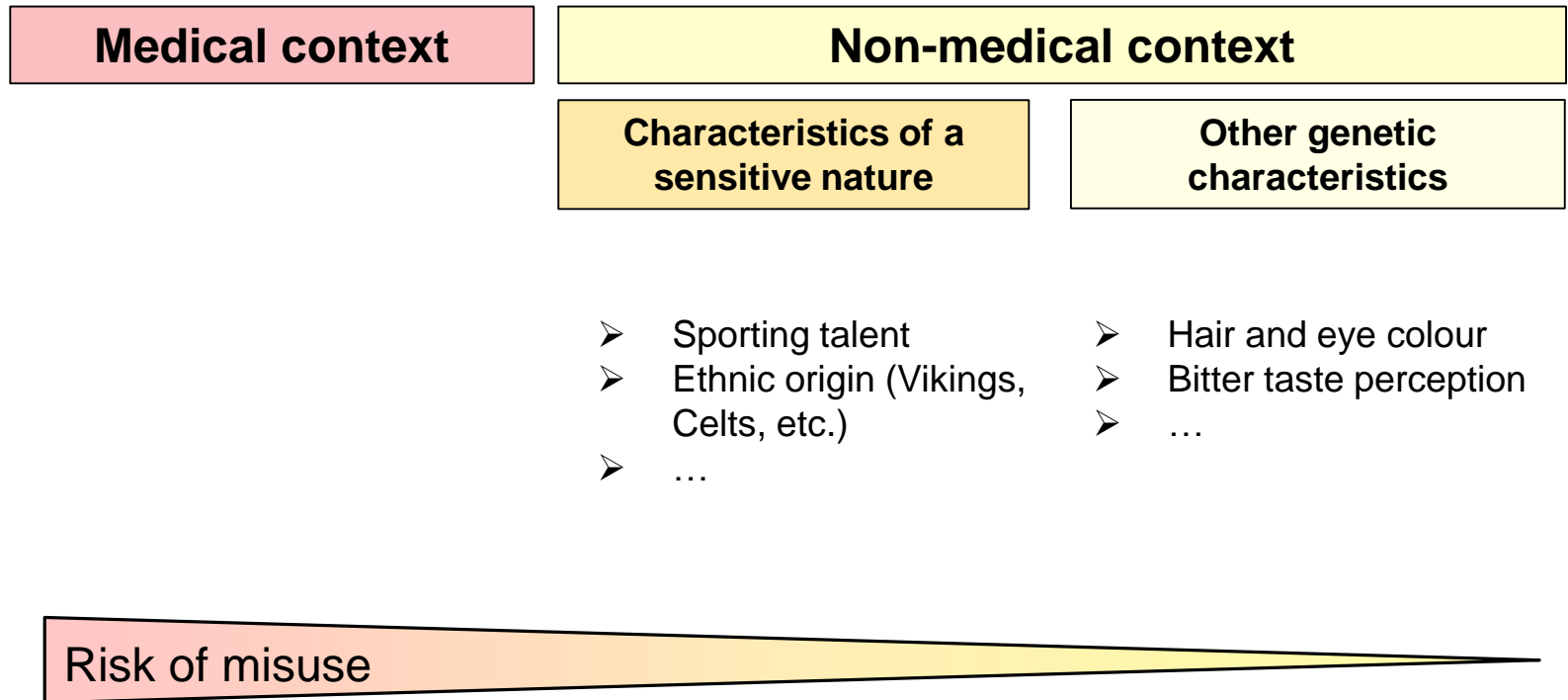
New regulation on genetic testing concerning

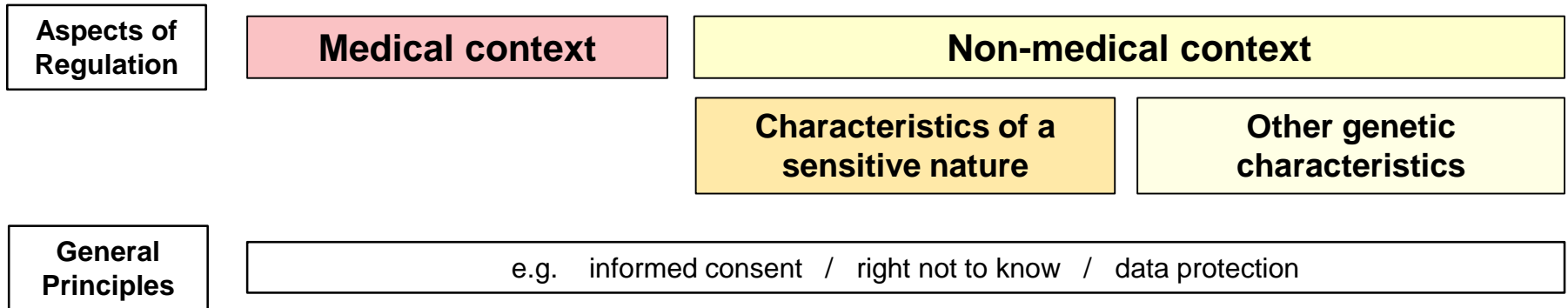
- non-medical characteristics
- somatic characteristics

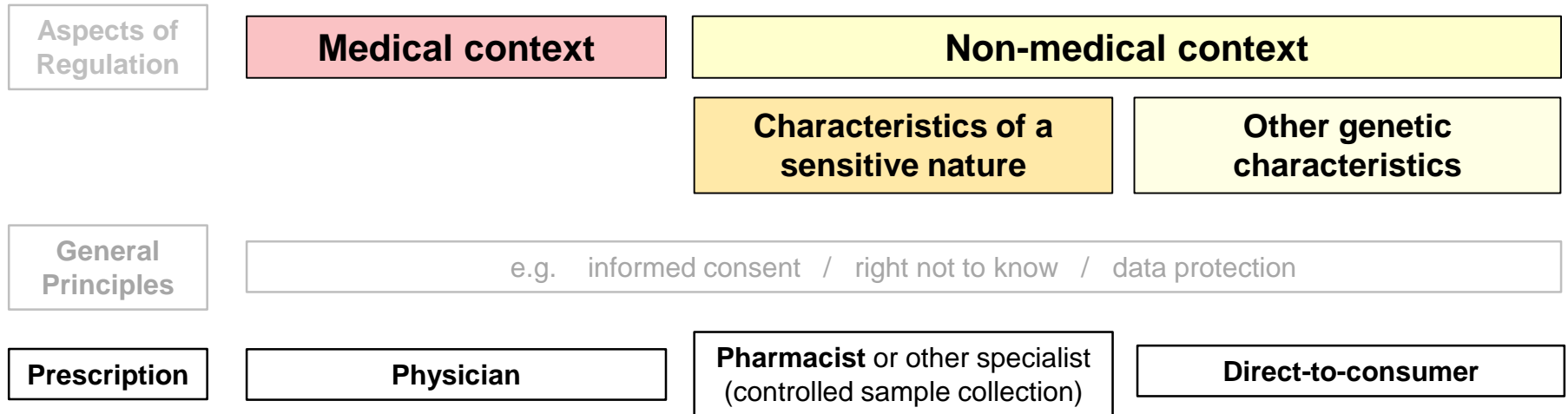




Expansion to non-medical characteristics









Aspects of Regulation	Medical context	Non-medical context	
		Characteristics of a sensitive nature	Other genetic characteristics
General Principles	e.g. informed consent / right not to know / data protection		
Prescription	Physician	Pharmacist or other specialist (controlled sample collection)	Direct-to-consumer
Patients / Customers	Adults, children, embryo/foetus	Adults	Adults



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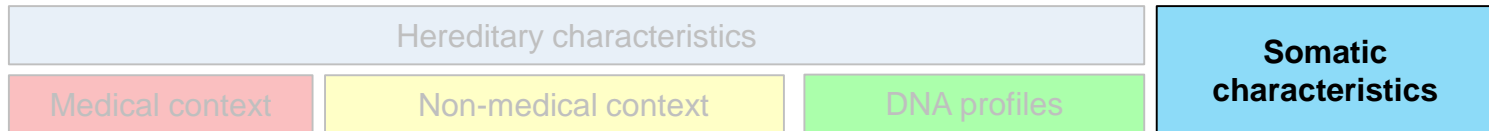
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Risk of misuse	Controlled conditions		Uncontrolled conditions



Expansion to somatic characteristics



- Tumor diagnostics
- General Principles (e.g. informed consent, right not to know, data protection)
- Incidental findings
- Laboratories not authorised



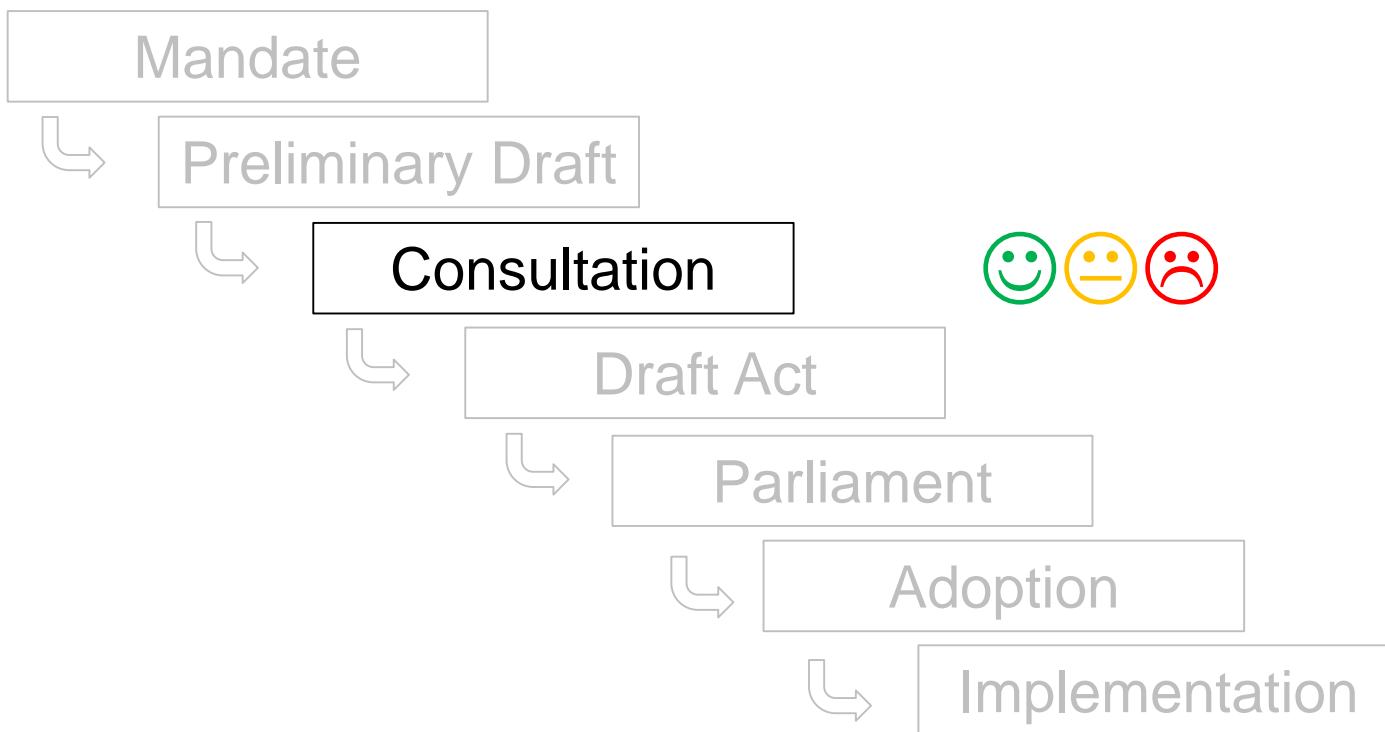
Adaptation of prenatal diagnostics (PND) regulation



- **Health:** determination of characteristics which do directly and *considerably* impair the health of the embryo or the fetus
- **Sex determination:**
 - It is still not allowed to determine the sex of the embryo or foetus for a purpose other than the diagnosis of a disease.
 - If detected incidentally it must not be communicated within the first twelve weeks of pregnancy.



Revision process



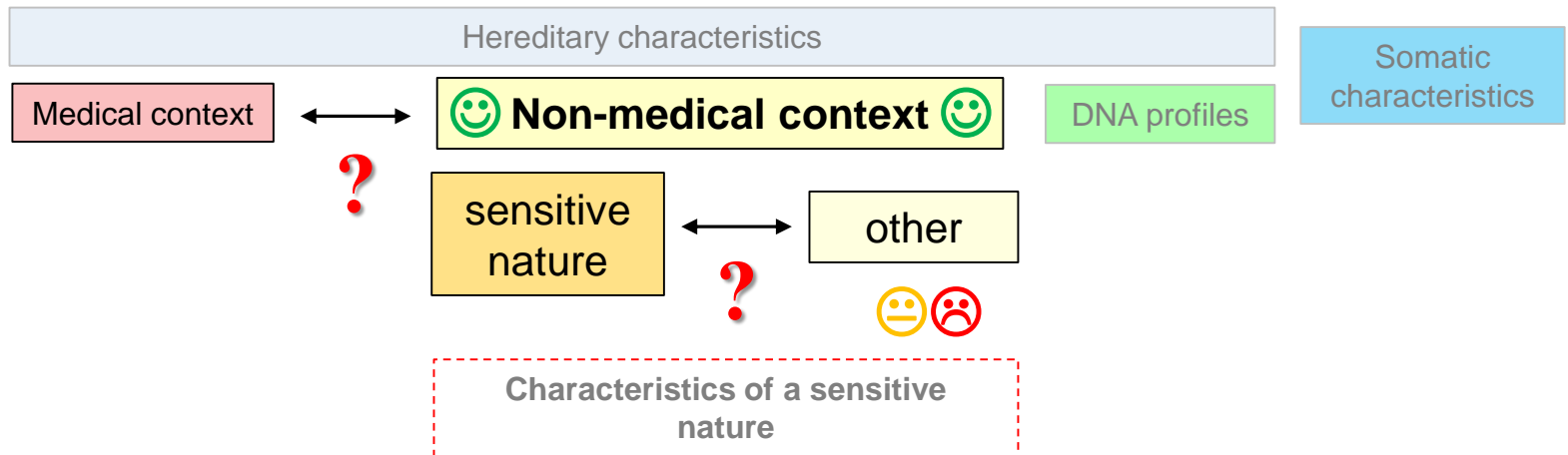


Results of consultation and their evaluation

- 102 opinion statements of cantons, political parties and other interested parties
- Generally positive response: 70% 😊
- But... 😐😞



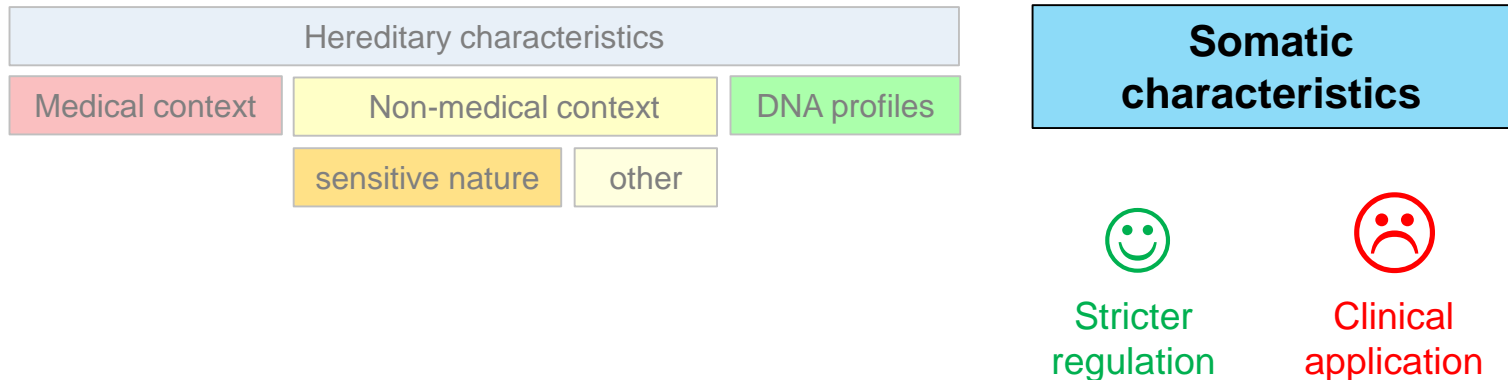
Expansion of scope to non-medical context: well accepted



➔ Federal Council decided to maintain the proposed categories but to verify if differentiation can be optimised



Expansion of scope to somatic characteristics: controversial feedback



➔ Federal council decided to maintain a regulation for somatic mutation analysis but to check how clinical practice can be better taken into consideration



Feedback to adjusted PND regulation

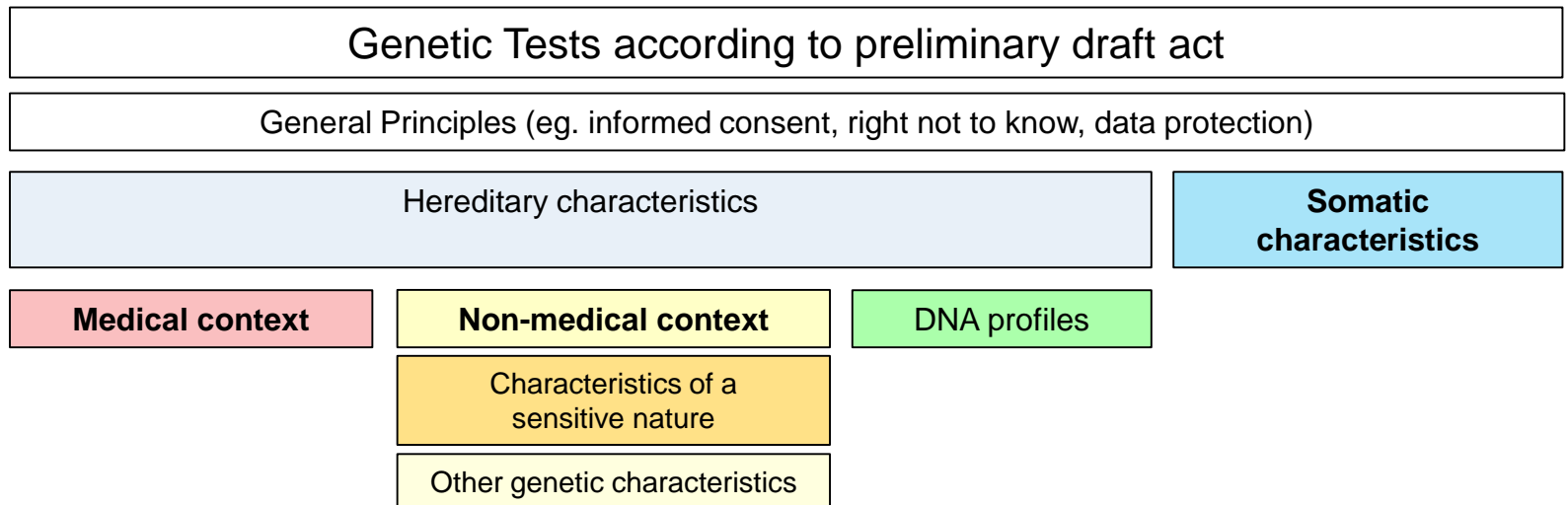
- *Direct and considerable impairment of health ?*
 - Interpretation problems
 - Clearer definition

- Why should sex not be communicated?
 - Impairment of self-determination of pregnant woman
 - Internet-Test

- ➔ Federal council decided to maintain regulation but to revise formulation concerning health-related aspects



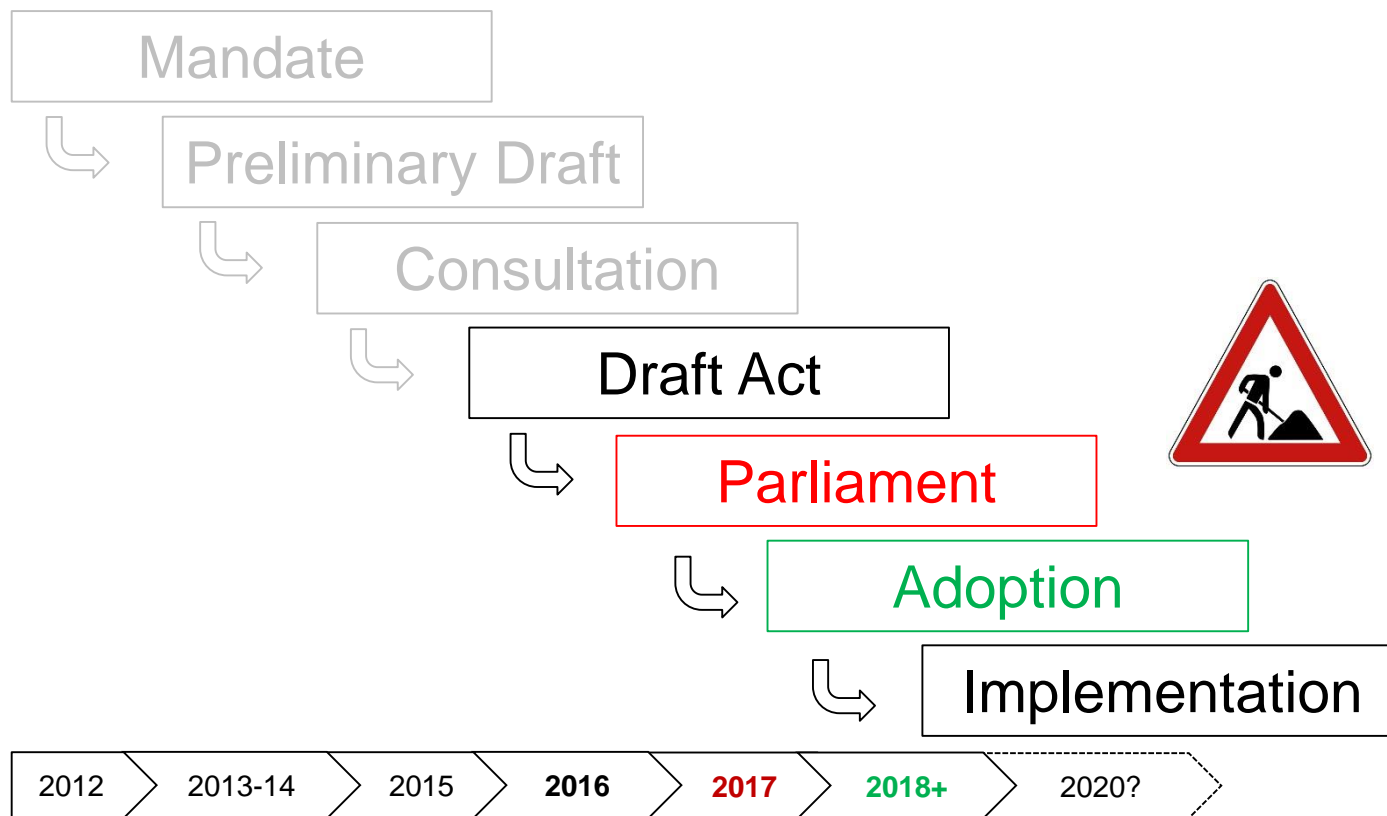
Preliminary draft → draft act



- ➔ Strategy of preliminary draft will generally be maintained
- ➔ Several adaptations



Further steps





Thank you for your attention!

Questions?

Further information:

- www.bag.admin.ch/de/gumg
- genetictesting@bag.admin.ch

