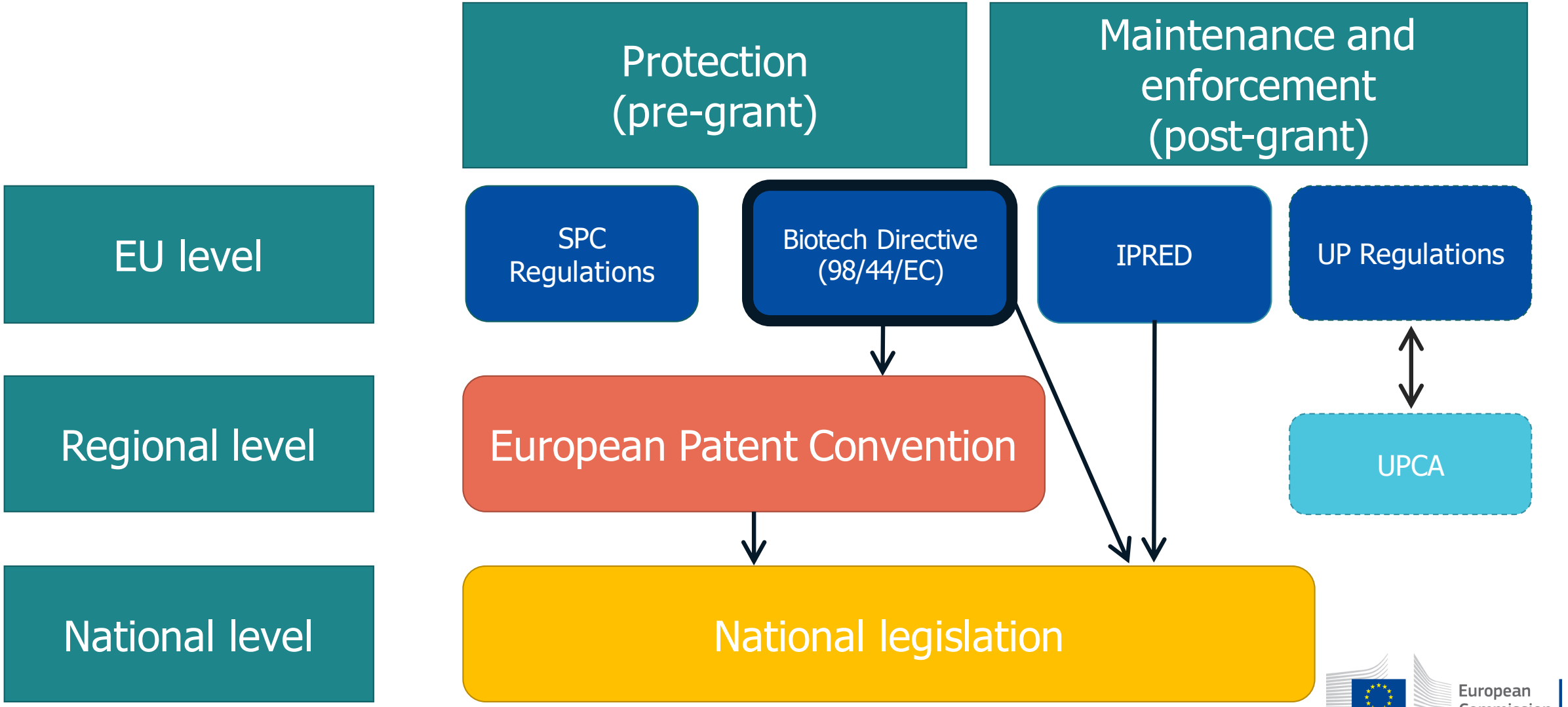
Exceptions to patentability in EU law: Biotech Directive (98/44/EC)

Vytenis Šemeta

DG Internal Market, Industry, Entrepreneurship and SMEs
Unit C4 Intangible Economy

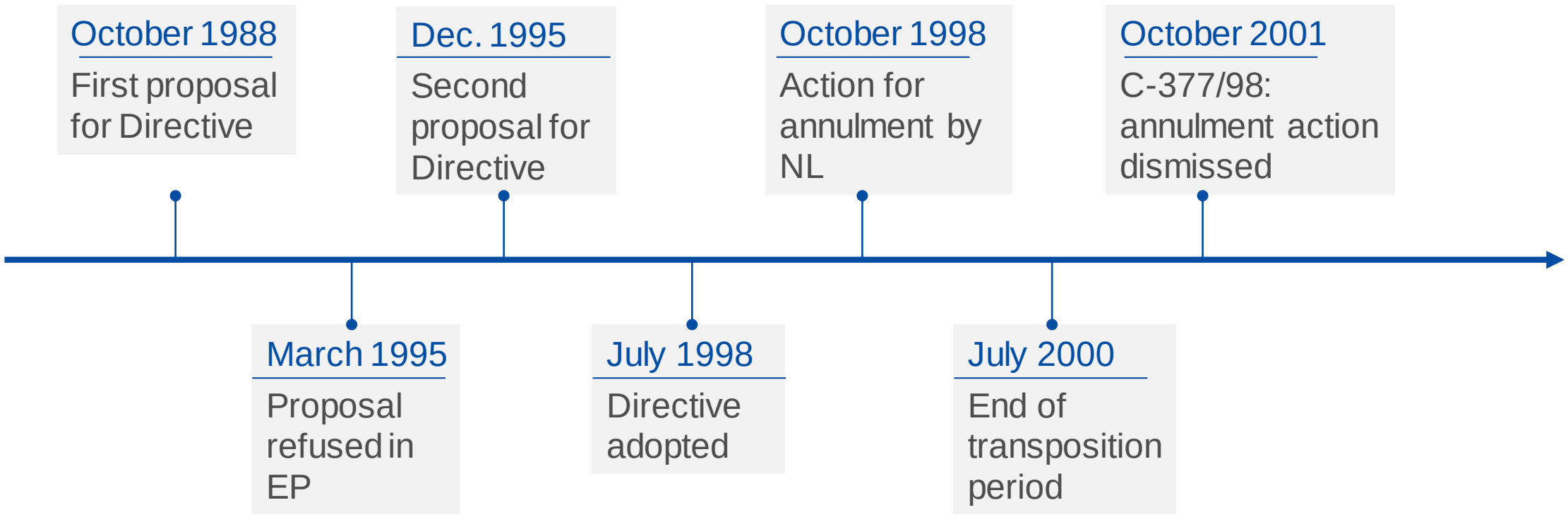
European Commission

Background: Patent law in the EU



European Commission

Biotech Directive: Background



Biotech Directive: Background

- Key objective: Harmonised EU legal framework to protect biotech inventions needed to attract investments and encourage innovation in this field
- Overall picture: 56 Recitals and 18 Articles
  - Patentability of biological material **and exceptions** (Art. 3-6)
  - Scope of protection (Art. 8-11)
  - Non-exclusive compulsory licensing (Art. 12)
  - Deposit of biological material (Art. 13)
  - Final provisions (Art. 14-18)
- Main provisions of the Biotech Directive taken over in the EPC Rules

Exceptions to patentability

Plant and animal varieties (Art. 4(1)a))

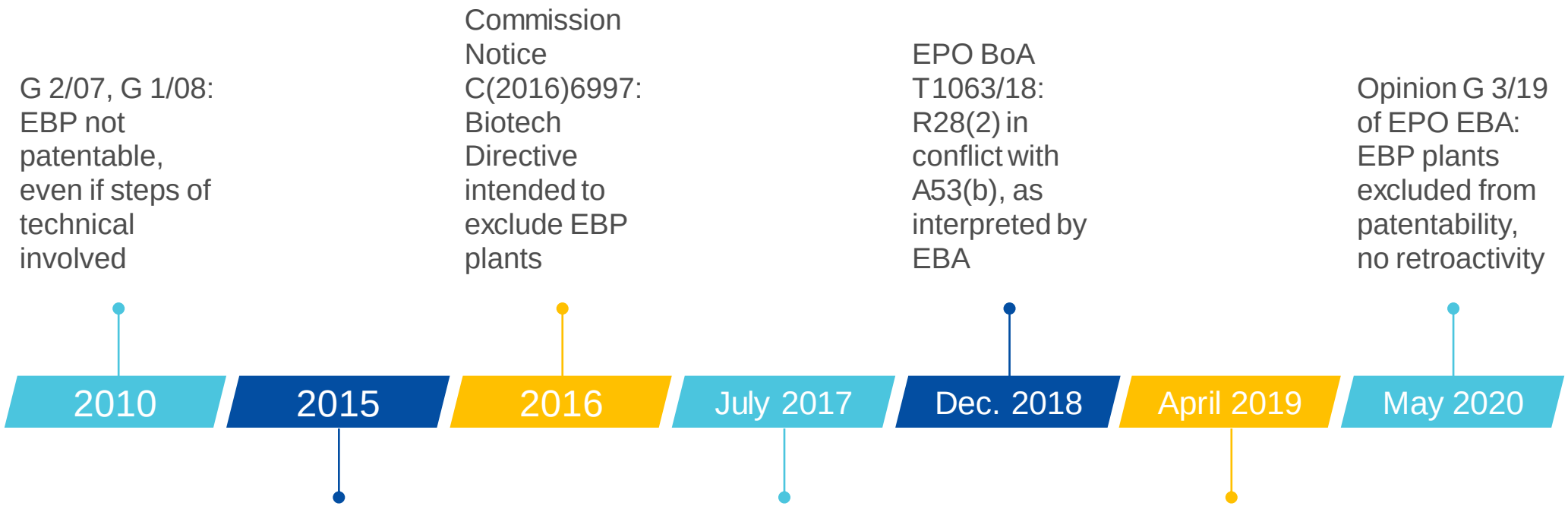
Essentially biological processes (EBP) for the production of plants and animals (Art. 4(1)b))

Human body at the various stages of its formation (Art. 5(1))

Inventions contrary to ordre public or morality (Art.6(1))

EBP exclusion: Link with Article 53(b) EPC

Patentability exception of EBP (and EBP plants)



Biotech Directive: Patentability of EBP plants

- **No explicit exclusion of plants obtained by EBP from patentability (only EBPs)**
- **Commission Notice (C(2016)6997): Directive 98/44/EC must be interpreted in a way that prohibits the patenting of plants obtained by essentially biological processes (EBPs)**
  - Conclusion reached through analysis of the Directive's other provisions, its overall purpose and its legislative history
- **Council and Parliament have publicly supported this interpretation, also many EU MS**
  - This reading of the Directive is reflected in the national patent laws, or practice of most Member States.
- **Notice: Non-binding instrument setting out the Commission's view on the intention of the EU legislators when adopting the Directive**
- **No prejudice to the competence of the CJEU to interpret EU law**

Opinion G 3/19 and consequences for EU law

- **EBA Opinion in the Pepper case (G 3/19)**
  - Patentability exclusion of plant (and plant material) or animal products obtained by EBP under Art. 53(b) EPC confirmed (dynamic interpretation);
  - Validity of Rule 28(2) EPC confirmed; No retroactive effect of product exclusion (< 1.7.2017)
- **Consequences for the Biotech Directive (98/44/EC)**
  - On substance, interpretation in line with Commission Notice of 2016
  - Providing legal certainty and clarity for future patenting of plants (and animals)
  - Limited number of patents may still be granted due to non-retroactivity (~310 applications and ~10 patents, some already proceeding to grant)
- **Discussion with MS experts in autumn 2020**

Discussions post G 3/19

- **Non-retroactivity of plant exclusion**
  - Effects of EBA interpretation upon national courts is a matter of national law/practice
  - Commission Notice remains valid: possible revocation at national level or CJEU reference
  - Outcome of exchanges: Situation to be closely monitored
- **Patentability of plant and animal cells**
  - EPO practice adjusted following G 3/19: cells and cell cultures obtained from plants and animals obtained via EBP excluded from patentability
  - Outcome of discussion: Practice adaptation supported

Discussions post G 3/19

- **Current implementation of patentability exclusion: EPO disclaimer practice**
  - Practice set out in the EPO Guidelines for examination: If a technical feature is obtainable both by technical process or EBP, excluded subject-matter is to be disclaimed
  - Scope of protection of plant patents ultimately a matter for national jurisdictions
  - Art. 8-9 Biotech Directive do not expressly address matters concerning the scope of protection of patents on biological material, which could be obtained both via technical or essentially biological processes
  - Outcome of discussions: disclaimer practice generally sufficient (though not established in law), burden of proof in court proceedings could be an issue

Discussions post G 3/19

- **Possible need for a further clarification on the patentability of random mutagenesis**
  - **Current EPO practice based on G 2/07 and G 1/08:** random mutagenesis techniques are patentable technical processes (thus also the resulting plants and offsprings)
  - **Biotech Directive:** technical processes trigger patentability of biological material (e.g. inserting gene into a genome)
  - **Different views of some stakeholders:** random mutagenesis should be considered as an EBP under G 2/07 and G 1/08;
  - Outcome of discussions: need for further evidence-based exchanges among the interested circles. Possible clarification, but basis needed

Political developments since G 3/19

- **Council Conclusions of 10.11.2020 (2020/C 379 I/01)**
  - Conclusion in opinion G 3/19 welcomed
  - Welcoming discussions between the Commission and the MS on the patentability of EBPs and the products obtained by such processes, with the intention of achieving a deepened understanding of the Biotech Directive and the corresponding provisions of the EPC
- **Commission‘s IP Action Plan of 25.11.2020 (COM(2020) 760 final)**
  - Emphasis on the need to maintain a balanced framework preserving incentives for innovation, whilst ensuring that biotech patents are granted only where justified
  - Biotech Directive offers a balanced framework, the Commission will continue to monitor closely the application of this legislation

Concluding remarks

- Commission‘s Notice of 2016 played an important role in shaping the EBP plant patenting rules both in the EU and, indirectly, under the EPC
- G 3/19 confirming the exclusion of EBP plants provides legal certainty and clarity for the future cases
- Effects of non-retroactivity of G 3/19 to be closely monitored
- Issue of random mutagenesis to be further explored with the EU MS
  - Any clarifying statements would need a basis under the Biotech Directive
- Discussions with MS experts: re-opening the Biotech Directive not wished

Questions?

Thank you for the attention!

European Commission