UPDATE ON THE NEW EU REGULATIONS ON VETERINARY MEDICINAL PRODUCTS & MEDICATED FEED

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REGULATIONS (EU)2019/6 ON VETERINARY MEDICINAL PRODUCTS & (EU) 2019/4 ON MEDICATED FEED

- Publication: 7 January 2019
- Entry into force: 28 January 2019
- Application: 28 January 2022
- Some 27 delegated (DA) and implementing acts (IA) to be prepared to complement the Regulation.

MAIN ACHIEVEMENTS OF THE NEW EU REGULATIONS

- Providing for a modern, innovative and fit for purpose legal framework on VMPs
- Giving incentives to stimulate innovation & increasing the availability of VMPs
- Strengthening the EU action to fight antimicrobial resistance (AMR)
- Ensuring economically-viable production of safe medicated feed throughout the EU
- Fostering innovation in medicated pet food

STRENGTHENING THE EU ACTION TO FIGHT AMR

Concrete Measures applicable to **EU operators**

- ban on preventive use of antibiotics in groups of animals
- ban on preventive use of antimicrobials via medicated feed
- restrictions on metaphylactic use
- possibility to reserve certain antimicrobials for humans only
- reinforced ban on the use of antimicrobials for promoting growth and increasing yield (*in addition to the 2006 EU ban of using antibiotics as growth promoters in feed*)
- compulsory data collection on antimicrobial sales & use
- other measures: prudent/responsible use

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STRENGTHENING THE EU ACTION TO FIGHT AMR

Concrete Measures relevant to Third Country operators exporting to the EU

- possibility to reserve certain antimicrobials for humans only
- ban on the use of antimicrobials for promoting growthand increasing yield
- *detailed rules on how to apply these measures for third countries exporting to the EU will be laid down in delegated acts*
- *those rules shall be compatible with international agreements (including WTO obligations), legally sound, proportionate, non-discriminatory and based on scientific evidence*

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ORGANISATION OF WORK: PREPARING THE IA AND DA

- Working in packages: 4 packages of IA/DA foreseen
- Criteria for prioritising of acts:
  t i m e – t i m e - t i m e
- Min. 3 consultation phases foreseen
  (Expert group for DAs – VMP Stand Comm for IAs):
  - On the mandates for scientific advice
  - On the scientific advice
  - On the draft acts

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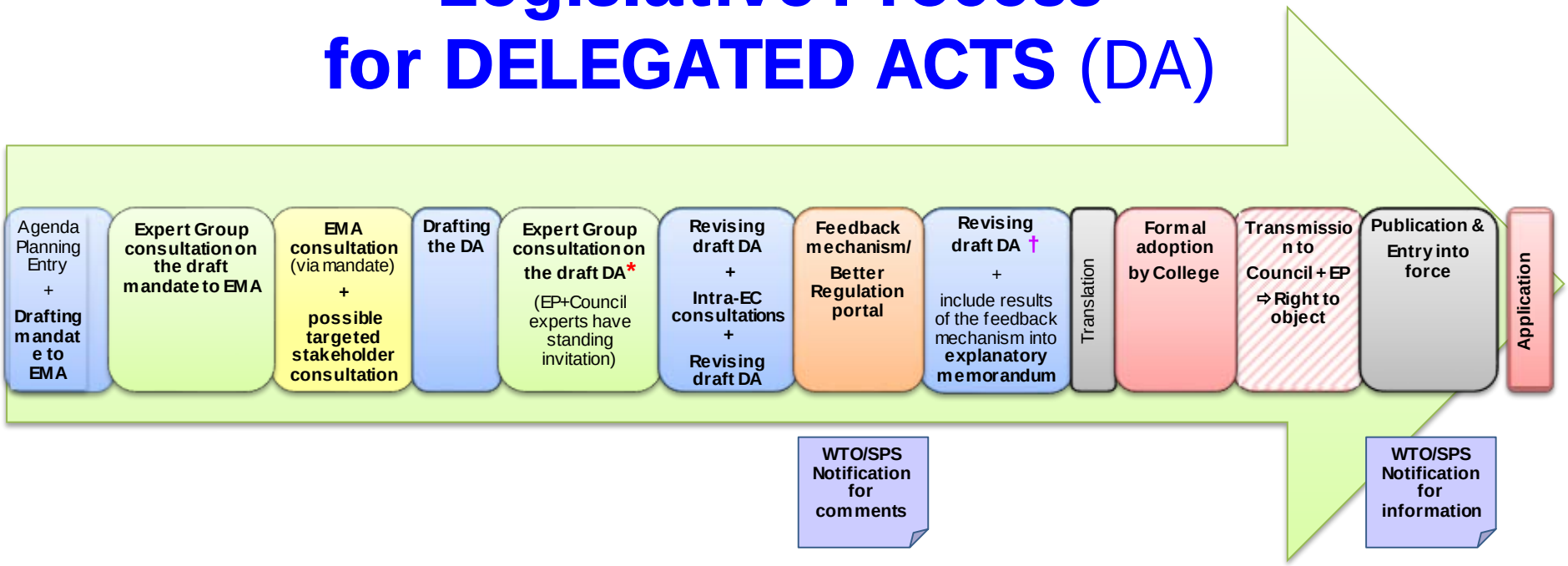
NEW EU REGULATION FOR VMP ON THE WAY TO APPLICATION…

Indicative Implementation of the Legislative Process for DELEGATED ACTS (DA)



* Additional Expert Group consultations may be organised, if deemed appropriate.

† Input from the 'feedback mechanism' and from the WTO/SPS comments will be considered while revising the draft DA.

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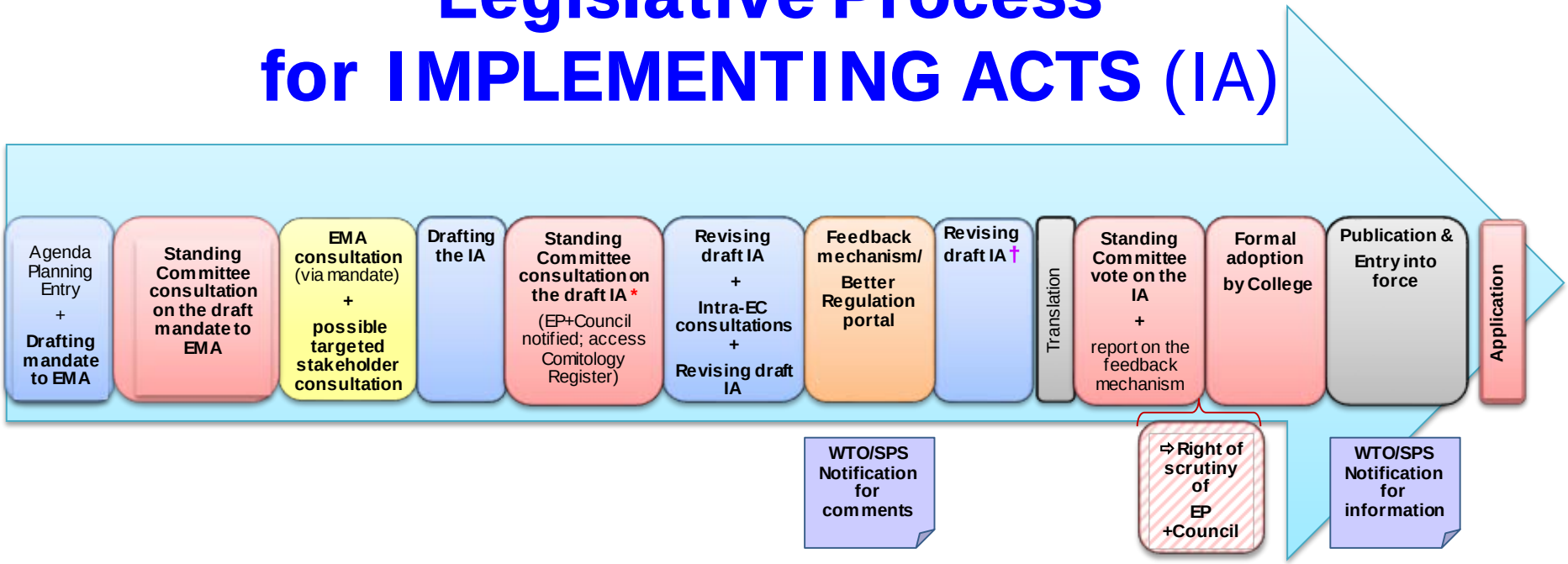

* Additional Standing Committee consultations may be organised, if deemed appropriate.

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FIRST PACKAGE: CONTENT

- Restructuring of Annex II (Art. 146(2), DA)
- Rules and methods of gathering data on antimicrobials (Art.57(3), DA)
- Criteria for antimicrobials reserved for human use (Art.37(4), DA)
- List of variations not requiring assessment (Art.60(1), IA)
- Good pharmacovigilance practice (Art. 77(6), IA)
- Content of pharmacovigilance master file (Art. 77(6), IA)
- Union product database (Art. 55(1), IA)

PRODUCT DATABASE MANDATE

- Work divided into 3 phases
  - **1** & **2**: technical specifications, practical arrangements, contingency arrangements, and possible additional information, required for the drafting of the IA
  - **3**: analysis and design for the IT development that follows
- Two deadlines set:
  - Phases **1 & 2**: end of August 2019
  - Phase **3**: end of December 2019 added

FIRST PACKAGE: STATE-OF-PLAY

- 14 December 2018: meetings of the Standing Committee and the Expert Group
  (*EMA also attended and was consulted on the mandates*)
- Feedback from MS on the mandates was solicited by 11 Jan 2019
- The mandates were then updated as appropriate in light of the MS comments received
- The mandates were sent to EMA in February 2019
- EMA expert working groups are preparing advice

SECOND PACKAGE: CONTENT

- Detailed rules on imports from Third Countries (Art. 118, DA)
- Format for the collection of data on antimicrobials (Art.57(4), IA)
- Good distribution practice (GDP) for veterinary medicinal products (Art.99(6), IA)
- Good distribution practice (GDP) for active substances (Art.95(8), IA)
- Common logo for online sales (Art.104(7), IA)
- List of antimicrobials reserved for human medicine (Art. 37(5), IA)

SECOND PACKAGE: STATE-OF-PLAY

- April-May 2019: drafting of the mandates to EMA and other preparatory work (*depending on the acts*)

- June 2019: meetings of the Standing Committee and the Expert Group

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STAKEHOLDERS INVOLVEMENT

- Possible targeted stakeholder consultation *preliminary to drafting and depending on the acts*

- Feedback mechanism (‘*Better Regulation Agenda*’)

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MEMBER STATES INVOLVEMENT

- Meetings of Standing Committee and Expert Group
- HMA Task Force
- CMDv
- CVMP
- EMA expert groups to work on the COM mandates

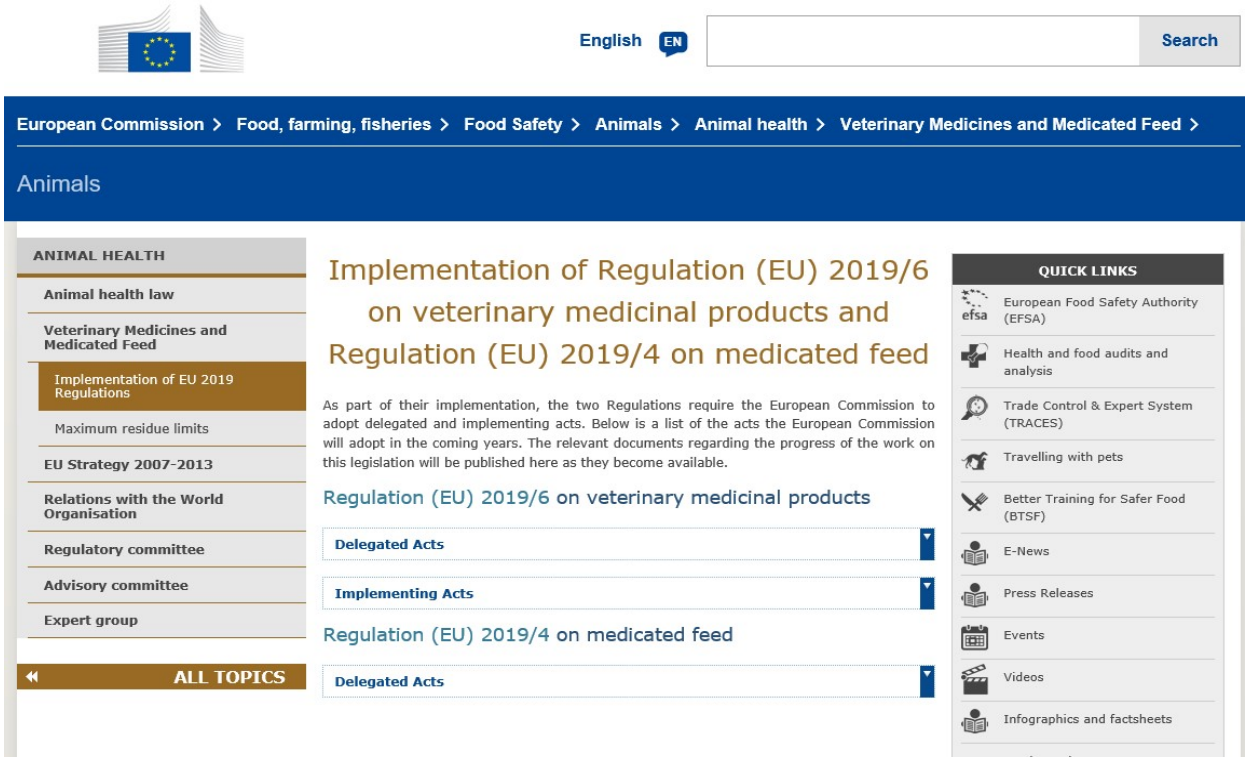
AND

- Public consultation on the draft acts

INFORMATION ONLINE

A dedicated webpage containing the latest updates on implementation has been created by COM

https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en



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Thank you