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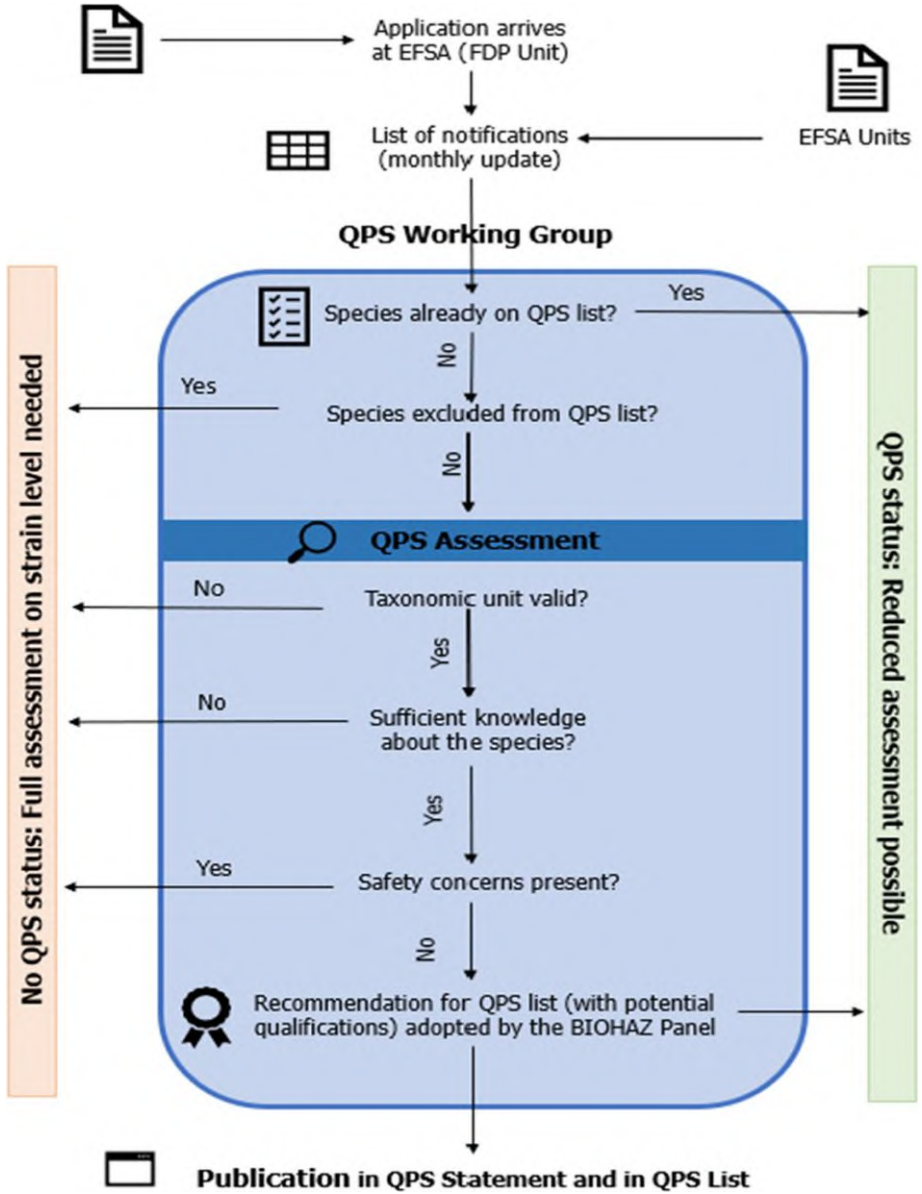
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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Biotech Act)
Subject:	Working Party on Pharmaceuticals and Medical Devices - Commission presentation

Delegations will find enclosed the presentation of the Commission on the proposed Biotech Act - Directive (GMM) given at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 5-6 March 2026.



- → Generic safety pre-assessment of a defined taxonomic unit (usually species) aiming to exclude certain risks
- → Conducted by EFSA BIOHAZ Panel with support from EFSA staff
- → Assessment based on literature and history of exposure
- → Knowledge must be sufficient to provide assurance that the potential to produce adverse effects in humans, animals or the environment is understood and can be excluded
- → Assessment question:

  "*Is there evidence of any safety concerns, including virulence features and toxin production, for humans, animals, plants and/or the environment associated with the microbial species?*"

Overview of the workflow from application of a regulated product to a potential inclusion in the QPS list of a microorganism
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