

Dialogue on the future of public commenting

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Agenda

- ▶ Walk through comment process flow chart
 - Transformational comment changes
 - Continuous improvement
 - ATP
 - PILIP
 - Comment transparency
 - Industry proposal
- ▶ Moving forward together
 - Breakouts
 - Throughout this presentation, ‘Stakeholders’ refers to those who submit comments to the USP-NF



Current Public Comments Process

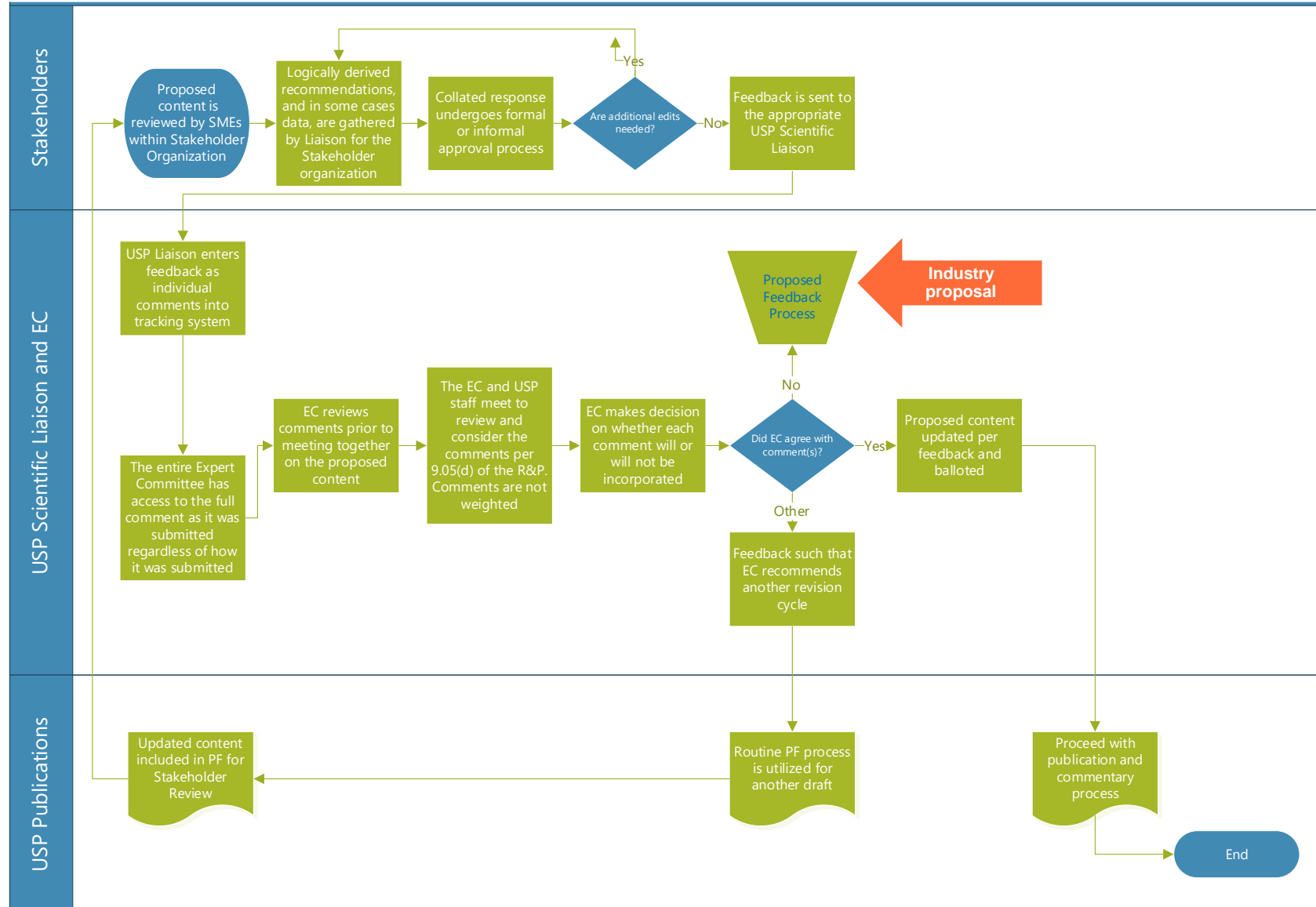
(Includes Industry Proposal)

Roles include:

Stakeholders,

USP Scientific Liaison/Expert Committee (EC), and

Publications Staff



Stakeholder Comment Process



- ▶ Proposed content in the PF and other posted USP-NF sources are reviewed by Subject matter experts (SME) within Stakeholder organizations
- ▶ SME generate scientifically-relevant recommendations, data, and preferences that are based upon experience and expertise
- ▶ Such recommendations go through informal or formal approval processes before being sent to the appropriate USP Scientific Liaison

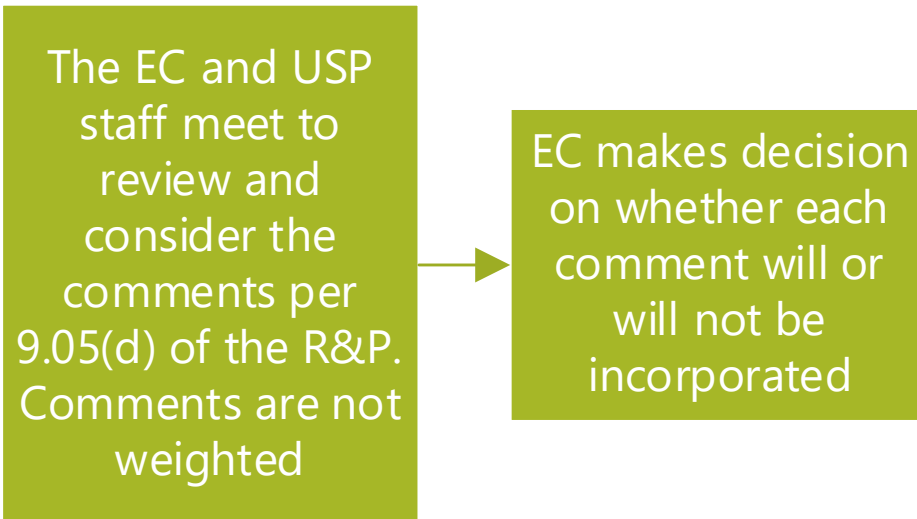
USP Collection of Comments

USP Liaison enters feedback as individual comments into tracking system

The entire Expert Committee has access to the full comment as it was submitted regardless of how it was submitted

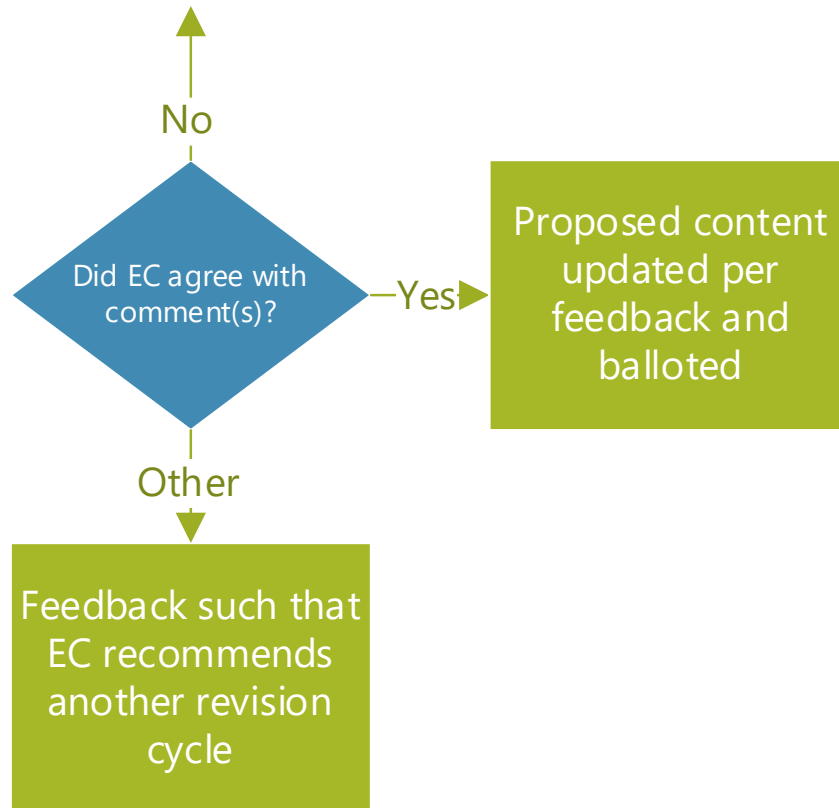
EC reviews comments prior to meeting together on the proposed content

- ▶ Intake of the comments by USP in current state
 - Access to full comments
 - Processes that give experts ample review time
- ▶ Transformational changes coming to future state through ATP and PILIP
 - Comment form
 - Automation
 - Enhanced communication
 - Comment tracking



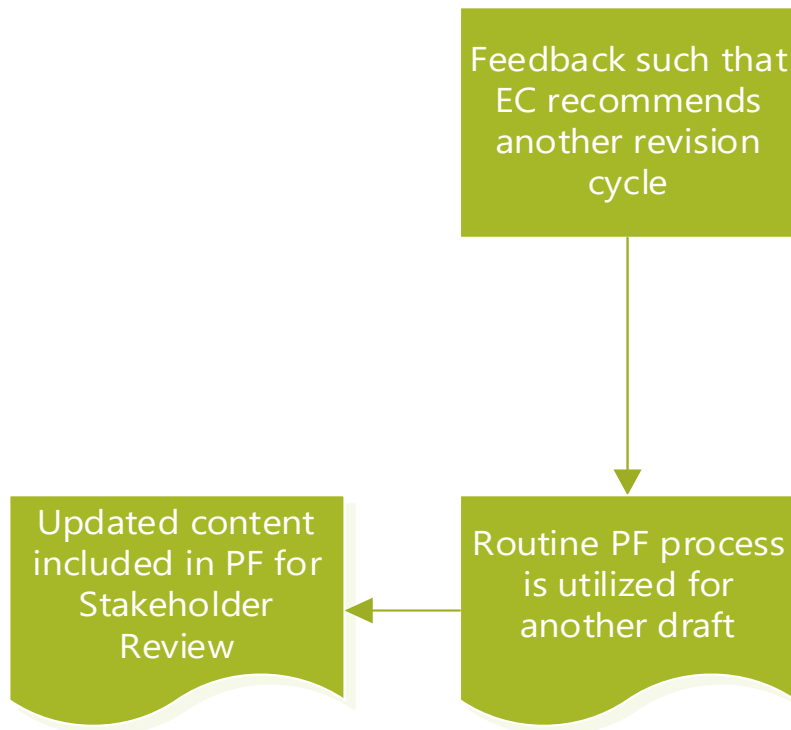
- ▶ ATP and PILIP impacts dialogue at this point and prior to this point
 - Future state can change the comment dialogue between USP and commenters
 - Robust system enhancements for communication through standards development
- ▶ Transparency of comments
 - Moving towards public posting of comments
 - Working with stakeholders on the journey
- ▶ Rules and Procedures of the Council of Experts
 - 9.05 (d) USP staff and the EC review all comments

USP EC Evaluation of Comments



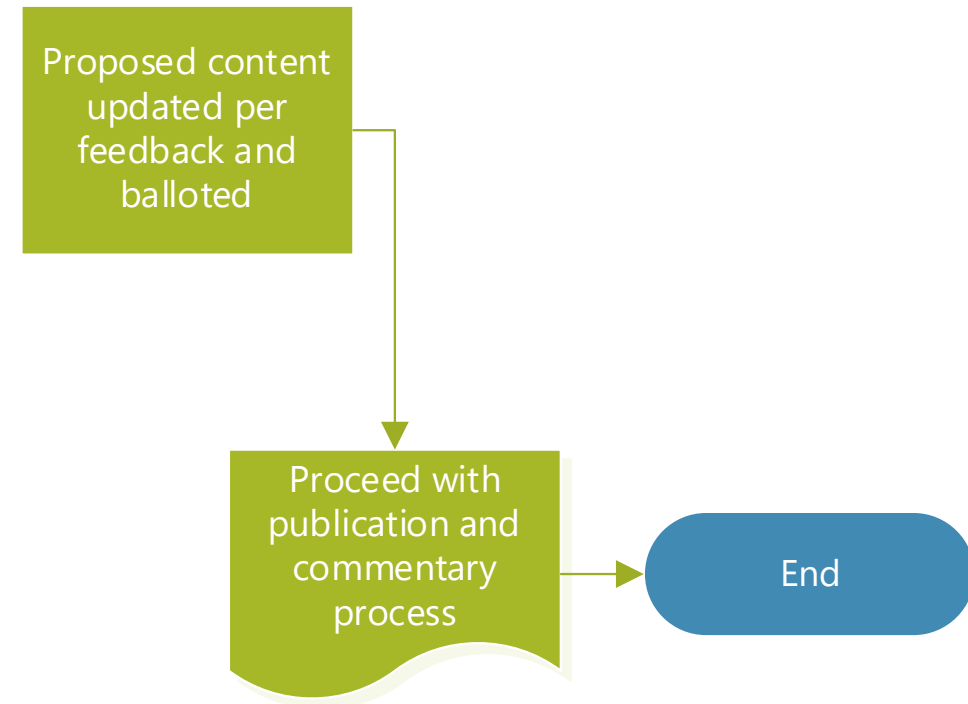
- ▶ EC decides how to reconcile each comment and how to respond
 - Stakeholders will see responses in commentary
 - Any changes that create a new compendial requirement must be re-proposed in a future PF (R&P 9.05(d))
- ▶ After the EC addresses the comments, the proposed content is incorporated and balloted

Additional PF Cycle

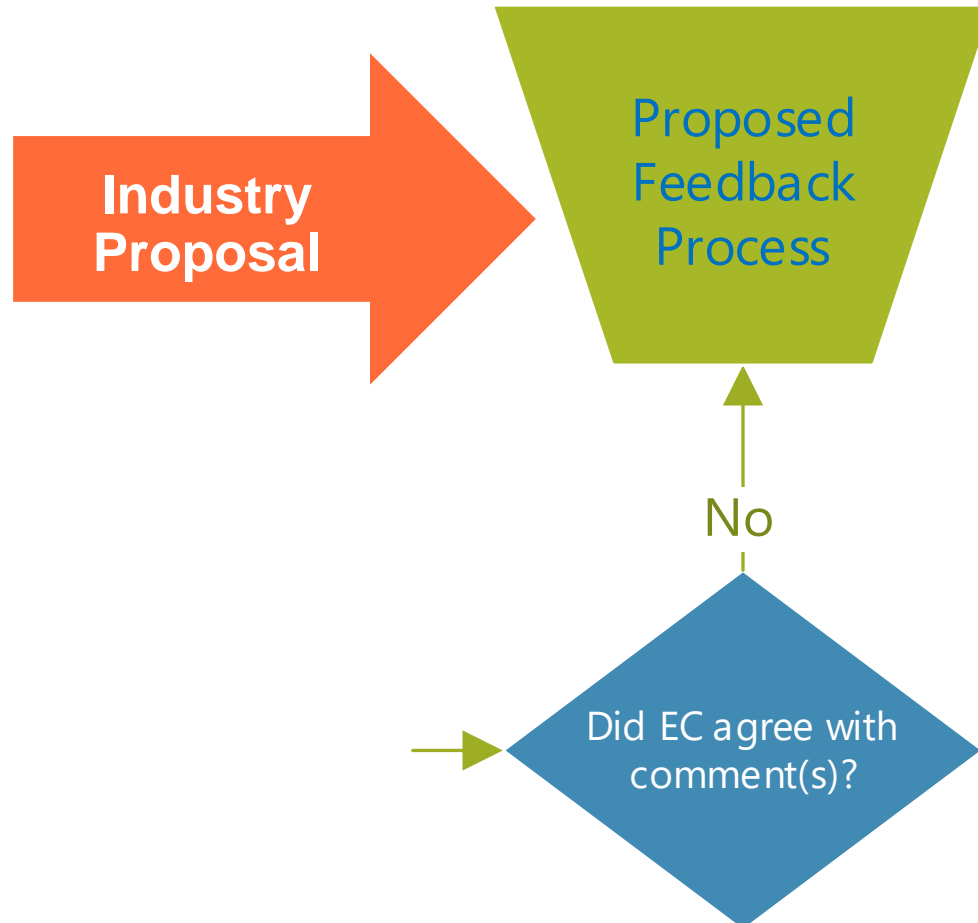


- ▶ If the EC determines that proposed content should go through another PF, the EC drafts a new proposal and submits to a future PF volume

Publication after Ballot



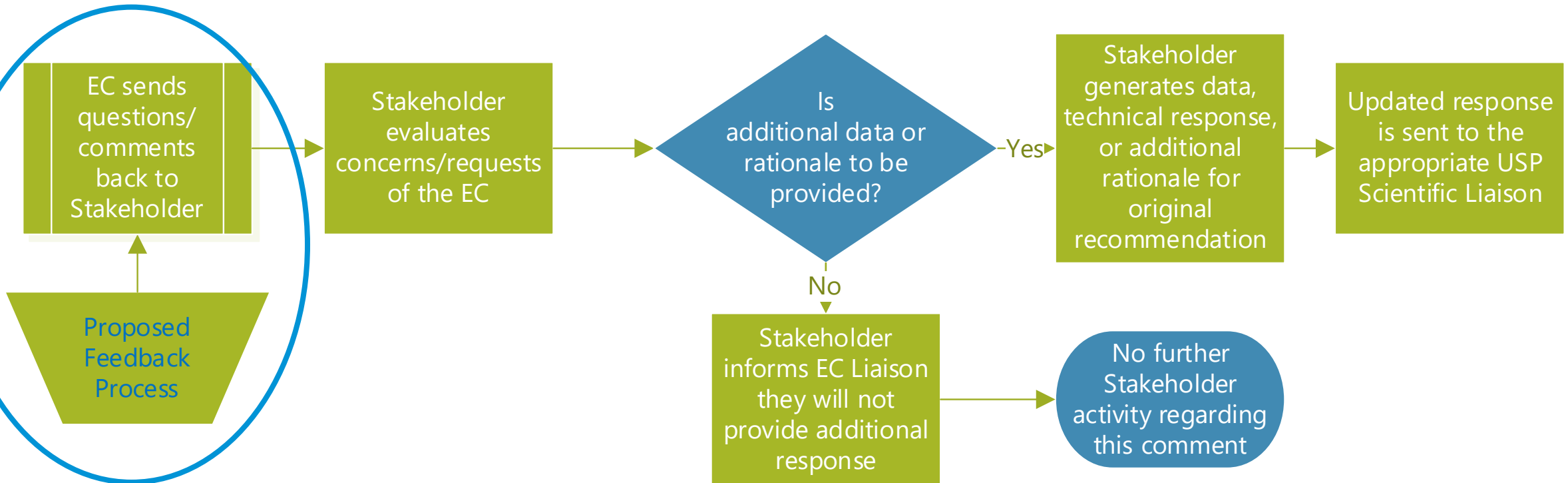
- ▶ If the EC decides to move ahead with or without changes based on comments, the proposal goes to ballot. Once approved it is published along with Commentary.



- ▶ The next slides propose a feedback process based on historical Stakeholder recommendations for increased dialogue after comments are submitted, but before the USP Commentary is published (final ballot).
- ▶ View this **proposed future process** with the understanding that:
 - Concepts are presented for a process that is not static and may need to be altered
 - Timelines are not included, as they could be adjusted as appropriate
 - Whatever the future process(es), flexibility will always be necessary

Stakeholder Option to Supply Clarification/Data (Industry Proposal)

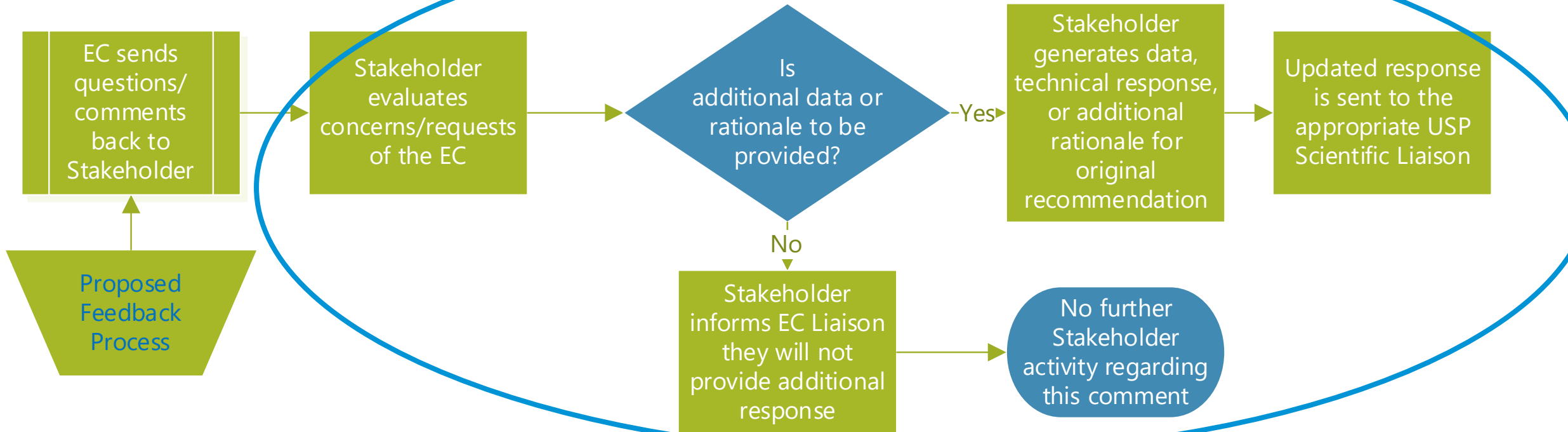
Proposed process begins with feedback/questions from the EC ...



- ▶ The EC sends to the Stakeholder organization their questions (e.g., requesting clarification, rationale) or comments (e.g., rationale why recommendations may not be adopted)
- ▶ The EC communication may be sent prior to the full quorum (e.g., to request data or clarification to support full discussion of recommendations)

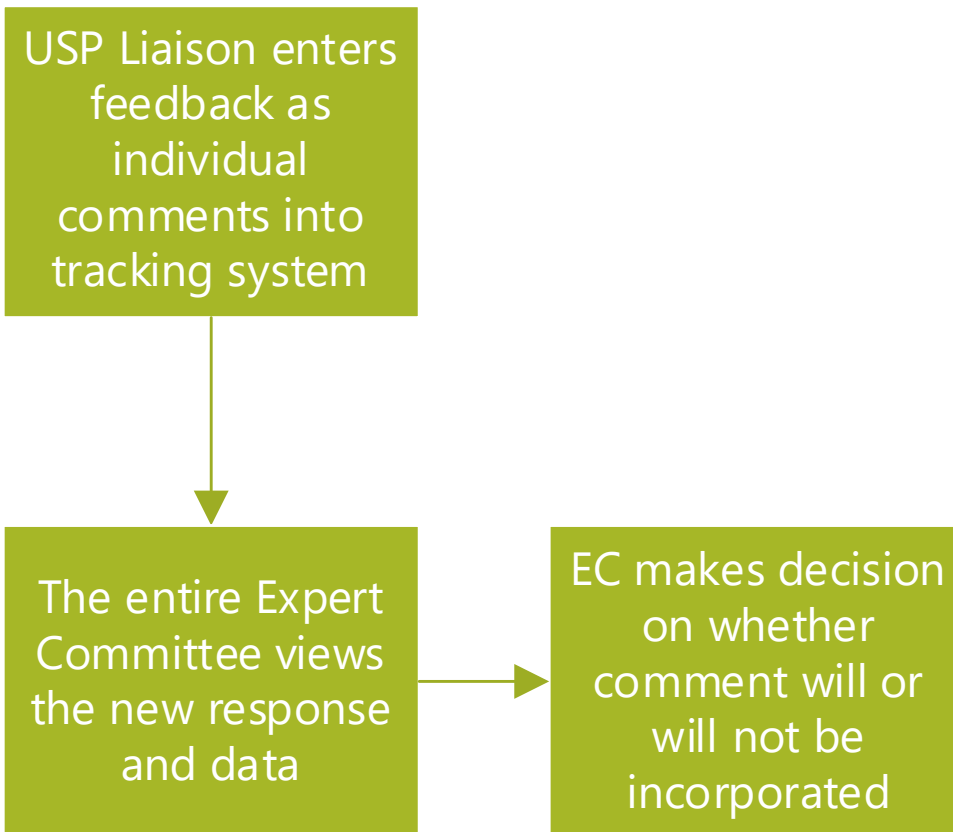
Stakeholder Option to Supply Clarification/Data (Industry Proposal)

Proposed Process, Continued ...



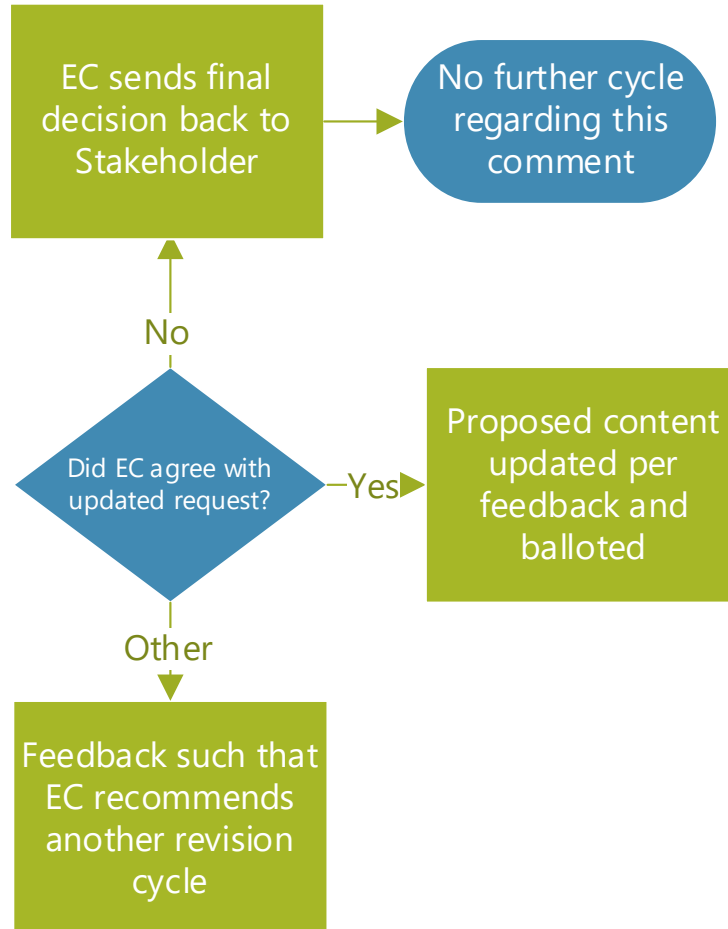
- ▶ Stakeholders would evaluate the EC communication to determine whether the SME recommendation will be supported with additional data or rationale
 - If yes, such supporting responses may be provided to the USP.
 - If no, then the Stakeholder organization accepts the EC decision and there is no further activity.

If the Stakeholder provides supporting rationale or data ...



- ▶ Similar to the collection of original comments, the EC would be provided the new response and data in their entirety.
- ▶ After considering the supporting rationale/ data, and obtaining further clarification as needed, the EC decides whether or not to adopt the recommendation.

Outcomes of the EC decision ...

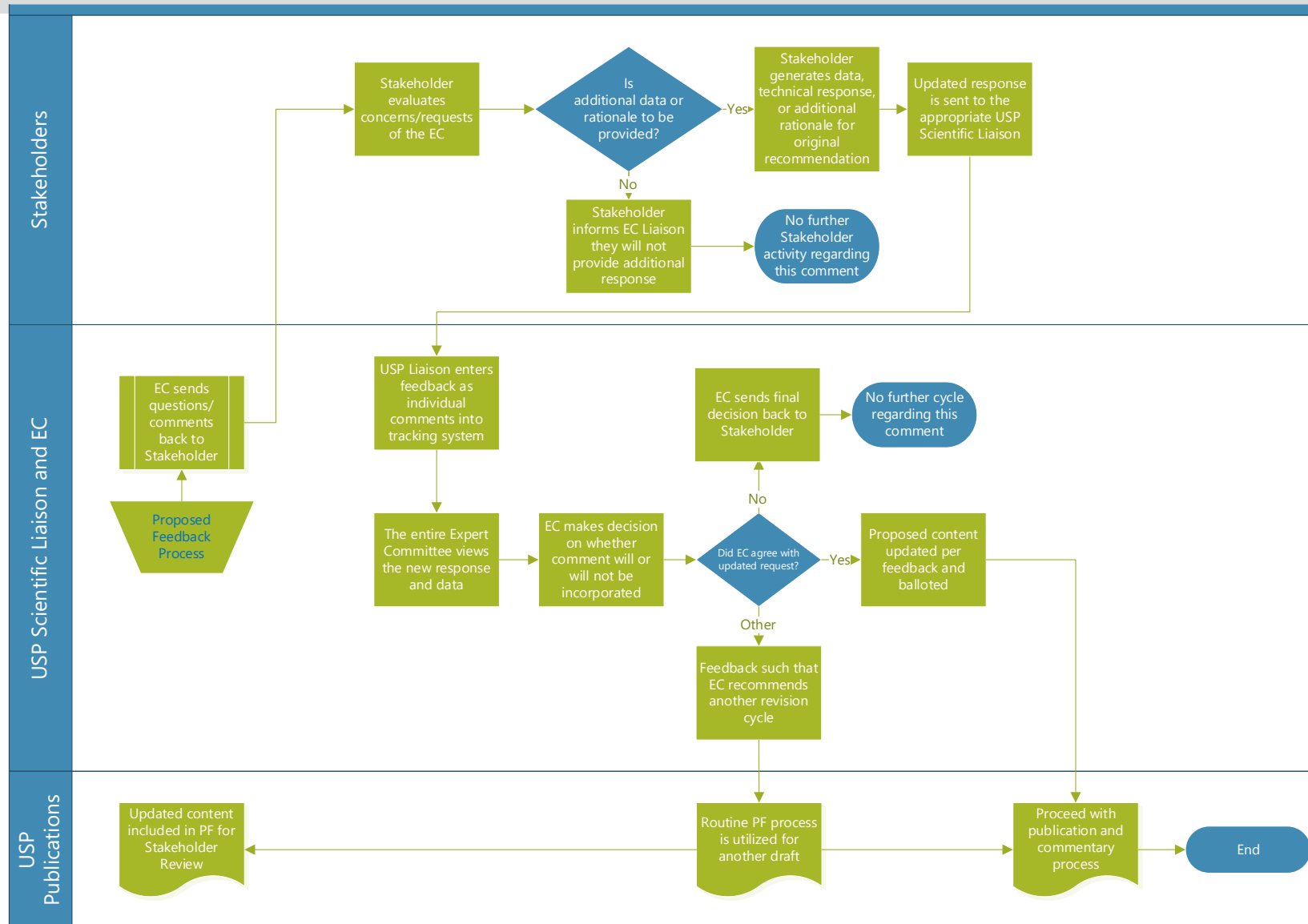


▶ If the Stakeholder recommendation:

- **Will be adopted**, it is incorporated into the USP-NF publication.
- Is such that **another revision cycle is warranted**, the process is repeated.
- **Is not adopted**, the EC provides the decision, with rationale, back to the Stakeholder. No further exchange regarding the proposed content occurs prior to publication.

Proposed Feedback Process (Industry Proposal)

This conceptual process could follow the flow shown at the right in the future, or perhaps it will look significantly different ...



Thank You

