



# Info session on EFSA's draft guidance on protocol development

On-line, 28 March 2023, 14.00-17.30 (CEST)

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## Agenda

Chair: Þórhallur Ingi Halldórsson, University of Iceland (IS)		
14:00-14:10	<b>Welcome and introduction to the event</b>	Claudia Roncancio Peña (EFSA)
14:10-14:30	<b>Agenda and speakers</b>  <b>Practical information on Q&amp;A sessions</b>  <b>EFSA's guidance on protocol development: background and terms of reference, scope, degree of obligation and applicability</b> <b>Process for developing the guidance</b> Sections 1 and 2 of draft guidance	Þórhallur Ingi Halldórsson (University of Iceland)
14:30-14:45	<b>The scientific assessment process at EFSA</b> <b>Dynamic approach to protocol development at EFSA</b> <b>Steps in protocol development</b> Sections 3, 4 and 5 of draft guidance	Elisa Aiassa (EFSA)
14:45-14:55	<b>Step 1 in protocol development: Problem formulation (introduction)</b>  Section 6 of draft guidance	Laura Martino (EFSA)
14:55-15:20	<b>First round of Q&amp;A</b>	Chair Chat moderators: Davide Arcella and Špela Supej (EFSA) Presenters
15:20-15:30	<b>Coffee/Tea break</b>	
15:30-15:40	<b>Step 1 in protocol development: Problem formulation (the new APRIO paradigm - Agent, Pathway, Receptor, Intervention, Output)</b> Section 6 of draft guidance	Laura Martino (EFSA)
15:40-16:20	<b>Examples of APRIO in four hypothetical assessments</b> a. High-pressure processing of food	a. Konstantinos Panagiotis



	<ul style="list-style-type: none"> <li>b. Aflatoxin B1 in food</li> <li>c. Pathway-to-harm Avian influenza</li> <li>d. Noncancer hazard assessment of formaldehyde in air</li> </ul> <p>Appendix A of draft guidance</p>	<p>Koutsoumanis (Aristotle University of Thessaloniki) and Winy Messens (EFSA)</p> <ul style="list-style-type: none"> <li>b. Susanne Hougaard Bennekou (Danish Patient Safety Authority) and Luisa Ramos Bordajandi (EFSA)</li> <li>c. Andrea Gervelmeyer (EFSA)</li> <li>d. Andrew Kraft (US-EPA)</li> </ul>
16:20-16:45	<b>Second round of Q&amp;A</b>	<p>Chair</p> <p>Chat moderators: Davide Arcella and Špela Supej (EFSA)</p> <p>Presenters</p>
16:45-17:00	<p><b>Step 2 in protocol development: Method specification</b></p> <ul style="list-style-type: none"> <li>• Approaches to answering individual (sub-)questions</li> <li>• Synthesising and integrating evidence</li> <li>• Uncertainty analysis</li> </ul> <p>Sections 7, 8 and 9 of draft guidance</p>	Fulvio Barizzzone (EFSA)
17:00-17:10	<p><b>Conclusions and recommendations</b></p> <p><b>Recommendations for future developments</b></p> <p>Sections 13 and 14 of draft guidance</p>	Þórhallur Ingi Halldórsson (University of Iceland)
17:10-17:25	<b>Final round of Q&amp;A</b>	<p>Chair</p> <p>Chat moderators: Davide Arcella and Špela Supej (EFSA)</p> <p>Presenters</p>
17:25-17:30	<b>Next steps, concluding remarks</b>	Þórhallur Ingi Halldórsson (University of Iceland) and Elisa Aiassa (EFSA)