U.S. Food and Drug Administration
Protecting and Promoting Public Health
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FDA/PQRI Conference on Advancing Product Quality

Product Development and Manufacturing Science

Palatability and Swallowability-
Benefit of Transdisciplinary Learnings

North Bethesda, Maryland

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A Learning Opportunity for Assessing Mouthfeel of Oral Drug Products?

Tribology?

- http://www.apfoodonline.com/index.php/iaf/item/445-promising-mouthfeel-with-tribology

Expectations

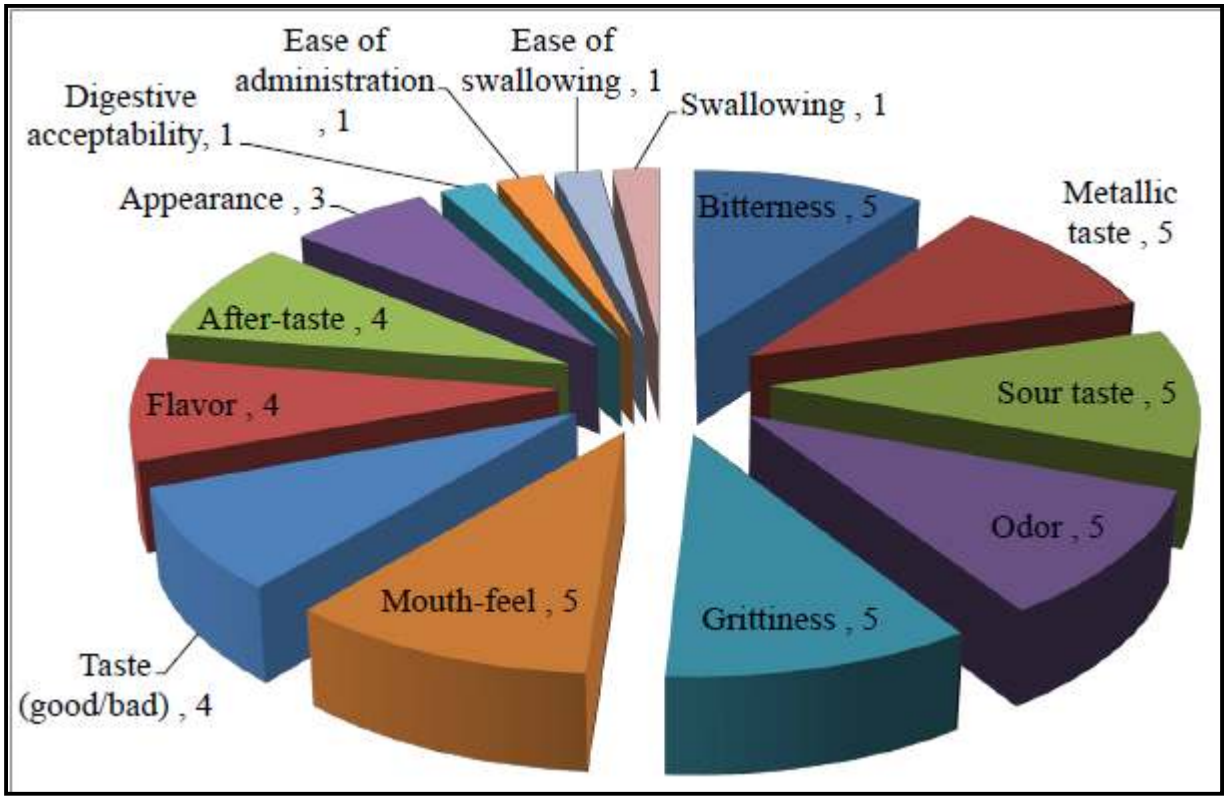
- Start a dialog to explore and advance methods for mouthfeel assessments (such as tribology-- as an approach for leveraging expertise/knowledge from food science)
- Review and explore opportunities for advancing in vitro methods and technologies used in taste-masking assessments (such as the e-tongue)

Our Program

- Introduction (Arzu Selen, Ph.D.)
- The role of tribology in oral processing (Stefan K. Baier, Ph.D.)
- In-Vitro Taste Sensors: Methods, Uses and Opportunities (Julie K. Lorenz, Ph.D.)
- Panel Discussion
- Wrap up (Rob Ju, Ph.D.)

Challenges and Opportunities?

From a 2013 survey on current practices in palatability and swallowability assessments— breakdown of positive responses (n=5) to organoleptic assessments– showing the type of assessments.



(total responses, n=10)

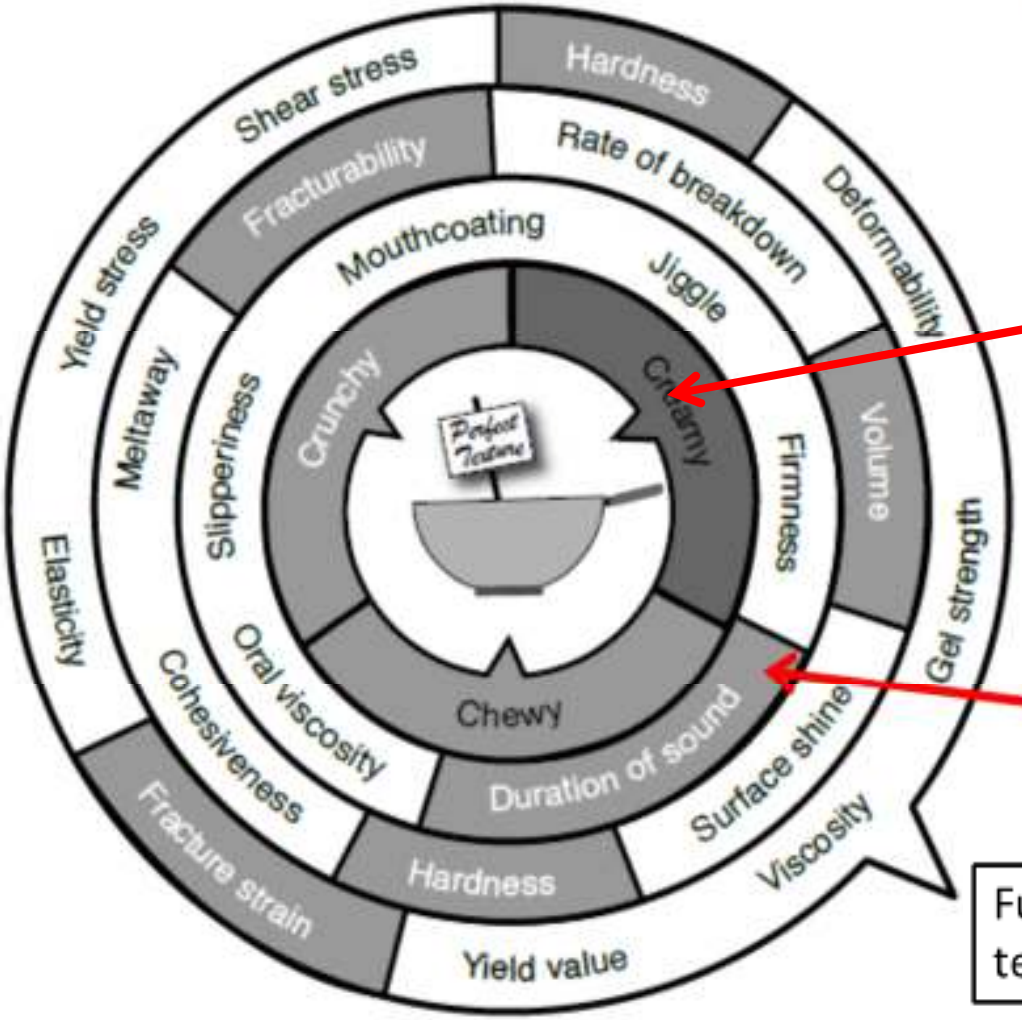
C.A. Thompson, D.P. Lombardi, P. Sjostedt, and L.A. Squires. 2013. Industry Survey on Current Practices in the Assessment of Palatability and Swallowability in the Development of Pediatric Oral Dosage Forms Therapeutic Innovation & Regulatory Science 47(5) 542-549

Leveraging Opportunities for Oral Drug Products

Considerations for Drug Product Quality Attributes:

- Patient related
- Drug product related
- Patient-drug product interface

Sharing Terminology?



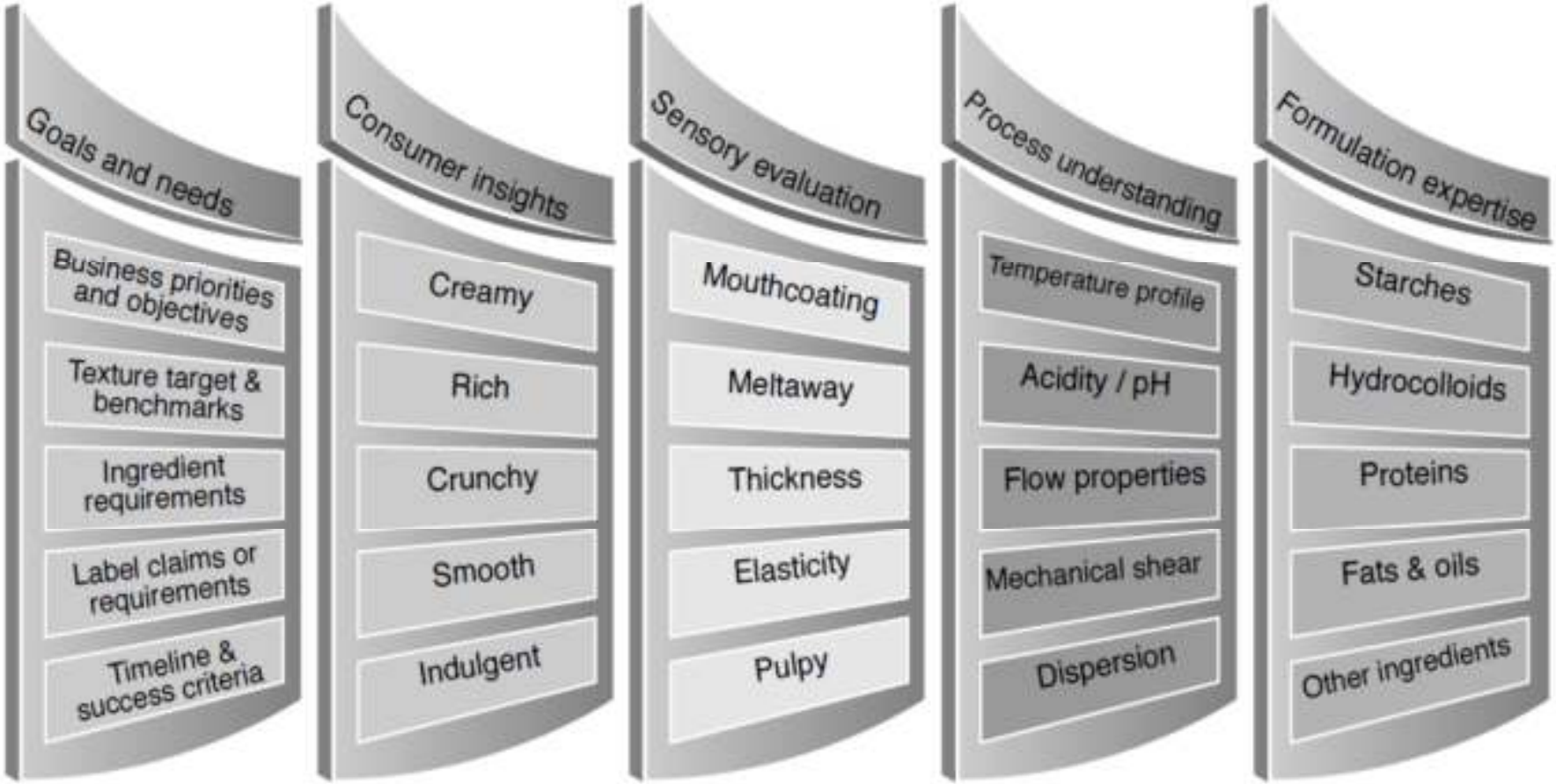
Consumer terms- Inner layer

Integrated terms- Layers 2 and 3

Fundamental/measurable terms – outside layer

TEXICON: The Texture Lexicon (Source: Copyright © 2013 Ingredion Inc.) from Food Texture Design and Optimization, Eds. Y. Lal Dar and J. Light, published 2014 © 2014 by John Wiley & Sons, Ltd. (Redrawn with permission.)

Sharing Tools/Technology/Methods?



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Looking ahead-- in vitro mouthfeel assessments (including palatability (taste-masking) and swallowability)

- ***Where are the challenges and opportunities in a multi-disciplinary setting?***
- ***What could be the likely next steps?***