

Functional Beverage Summit 2003

Federal Regulations and Areas for Clarification

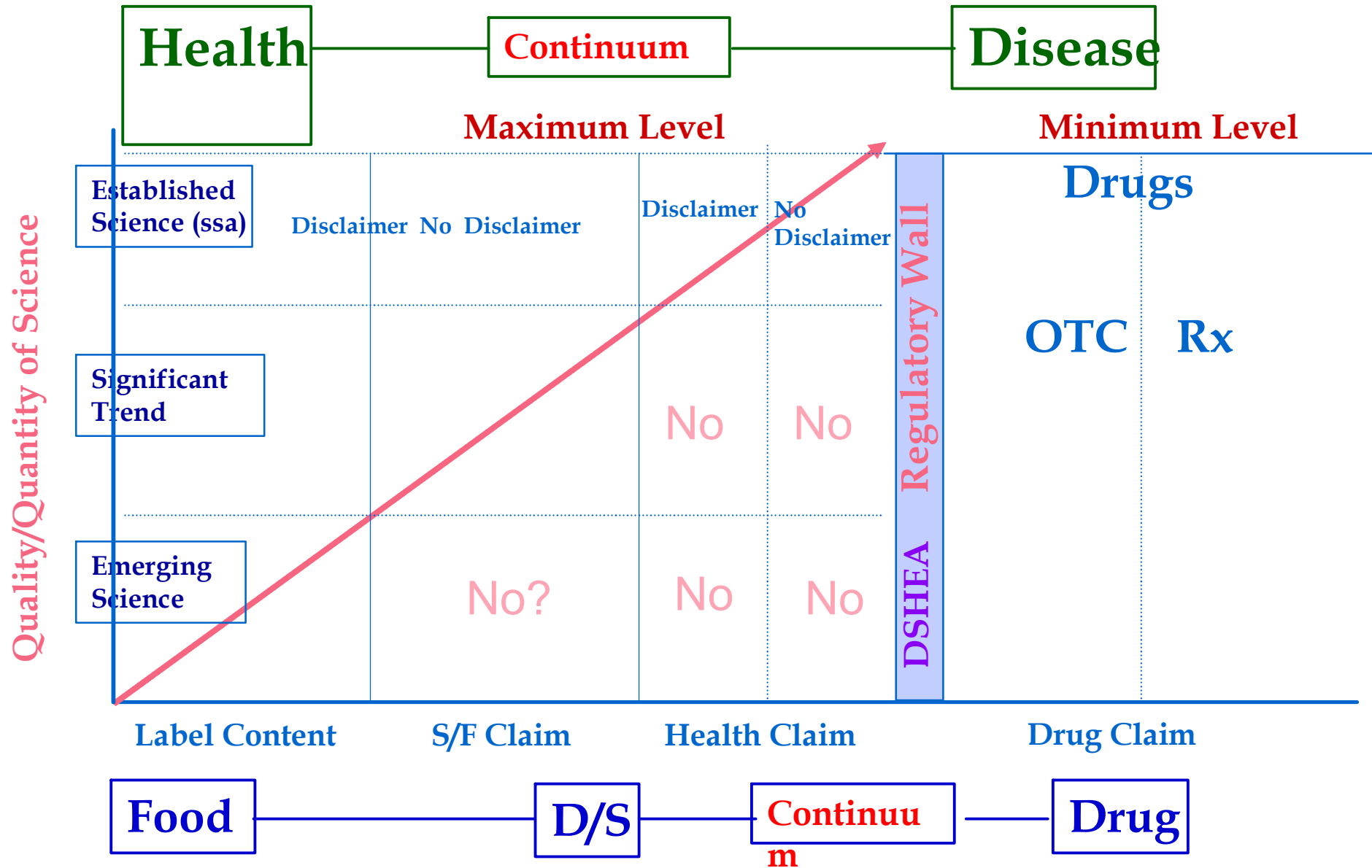
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- **Structure/Function Claims for foods and beverages**
- **Non GRAS ingredients and their use in beverages**
- **Label claims and the extension of these claims to website promotion...**

whose jurisdiction is it anyway, FDA or FTC?

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Claims: Conventional Foods and Dietary Supplements

1. HEALTH CLAIMS

- NLEA act: DS, Food
- FDAMA: Food

Authoritative statement of science by body of US government or NAS

- QUALIFIED HEALTH CLAIMS: DS
- QUALIFIED HEALTH CLAIMS: Conventional Food

2. STRUCTURE/ FUNCTION CLAIMS: DS and FOODS

3. NUTRIENT CONTENT CLAIMS: DS, Foods

Describe level of nutrient: “good source”, “high”, ”free”

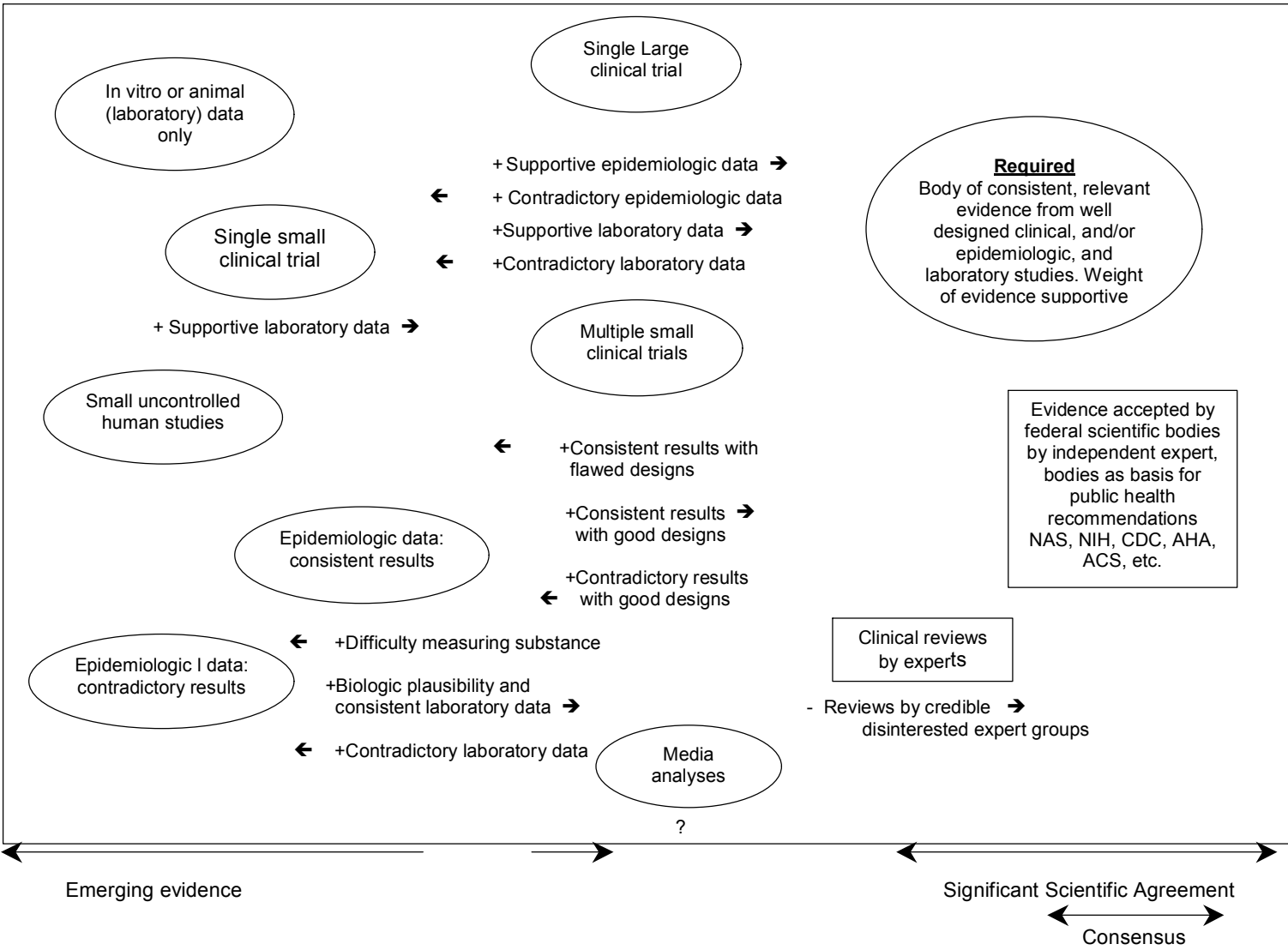
Used for substances with established daily values

4. PERCENTAGE CLAIMS: DS

Describe simple percentage statements

(40% omega-3 Fatty Acids, 10 mg per capsule)

Schema for Assessing Strength and Consistency of Scientific Evidence Leading to Significant Scientific Agreement



Structure -Function Claims on Foods

Good News and Bad news

- Good news is that S/F claims can now be used on both food and DS
- Pearson/Shalala qualified Health Claims can NOW be used on dietary supplements AND conventional foods!!!!
- *Claims must be truthful and not misleading*
- *Marketer must have substantiation in the files before making any claim*
- *Claims can not suggest to “treat, prevent, mitigate, diagnose any disease or disease symptom” (= drug claim) cf. Health Claims, and can not “imply” to treat a disease*
- FDA believes that structure/function claims in foods should derive from “**nutritive value**”, an as yet undefined value by FDA, or are recognized nutrients that have taste, aroma, or a technical effect. What about coffee, sterols?
- FDA more problematic than FTC in that there is no guidance re procedure nor substantiation requirements
- FDA have not yet defined procedure for submitting a Qualified Health Claim


























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Non GRAS Ingredients in foods.

- GRAS determination is required for ingredients used in foods, this can be either Self Determination with Notification or Without Notification to FDA
- Dossiers and Expert panels conclusions need to be in the files as substantiation
- The dossier and safety assessment needs to be specific for the use you wish to pursue regarding food category(ies) and dosage.

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Nutraceuticals/Functional Foods/Drugs

	<u>Dietary Ingredient</u>	<u>Food Ingredient</u> FA GRAS		Functional Food	<u>Drug</u> Prescription/ Orphan	<u>Drug</u> OTC
Exposure Population Duration	Unlimited Lifetime	Unlimited Lifetime	Unlimited Lifetime	Unlimited Short/Long	Limited Short/Long	Unlimited Short/Long
Safety						
Animal						
Human						
History of Use						
Charac- terization						
Analytical Method Detection						
Risk/ Benefit	No Risk	No Risk	No Risk	No Risk	Risk	Little Risk

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New and Old Dietary Ingredients in Foods

- DSHEA defines safety standards for dietary supplements
- Exposures are derived as unit dosages per label instructions or under ordinary conditions of use and are generally chronic in duration, although intermittent exposures can occur and may be important for some potential adverse outcomes.
- Data upon which a safety determination is made is quite variable in quality and quantify (e.g., history of use, case reports, minimal laboratory animal data).
- Significant uncertainties - exposure (e.g., timing & amounts), hazard identification (e.g., relevance of animal studies), dose/response, relevance of endpoints.
- Burden of proof to establish a safety concern resides with the FDA.

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The Internet: Labeling or Advertising?

- It all depends!
 - Web content (product info or claims) **with** direct link to label, likely labeling (FDA)
 - Third party literature, within product/company website **with** direct linkage (FDA)
 - Third party literature **NO** direct link or metatab (FDA????)
 - Product website linked to other websites discussing diseases/treatments ??????

Key Issues: Pertains to any information especially claims

- Claim type; Health Claim, S/F claim
- Truthful NOT misleading
- Balanced literature/supportive materials
- Require FDA Disclaimer
- Direct linkages
- “Two click rule”, need to be at least two mouse clicks away, i.e. **NOT** direct linkage