Breakout Group 1A

Question 1) What parts of the definition for comprehensive do you agree with? [There are 8 parts to the draft definition of comprehensive.]
With the definition of comprehensive- that it covers the full scope of facilities involved in the production of feed ingredients

Part 1) It would apply to the whole range of feed products, including all ingredients and finished feeds,
We agree - under definition of comprehensive

Part 2) use ingredients approved and/or recognized by an established regulatory agency or entity whose members are charged with a responsibility of enforcing laws regulating the production, labeling, distribution, or sale of animal feeds,
Disagree

Part 3) cover the complete range and variety of facilities involved in animal feed production,
Definition of comprehensive – lack of consensus

Part 4) have the flexibility to be process- or product-oriented, depending on the situation,

Part 5) address feeds produced for food and non-food animals,
Agree

6) Cover all known hazards, and be applicable to hazards not yet identified,
Disagree as written

Part 7) address both human and animal health issues
Agree

Part 8) acknowledge and coordinate regulatory authorities at all levels, including local, state, tribal and federal, involved in feed safety.
Agree

Question 2) What parts of the definition for comprehensive do you disagree with? Why? [see description of the 8 parts in Question 1 above]
Part 1 – N/A
Part 2 – However, appears to be a gap – will cover under Q4 (gaps)
Part 3 – Disagree: "Range of and variety of Facilities" and "Animal Feed Production" need more precise definition
Part 4 – will address later
Part 5 - N/A

Part 6 – Would better define hazard and change to "all known hazards reasonably likely to occur"
Part 7 – N/A
Part 8 – N/A

Question 3 – Differentiate between process-oriented approach and product-oriented approach to feed safety?
Process – Where testing is performed; GMP/SOP performed
Product – Ingredient and final product oriented

Question 4) Does the proposed definition for comprehensive contain any gaps? Is it too broad? If you answered yes to either question, please explain why?
Part 1 – No Gap
Part 2 – The word "Entity" is too broad. (Could be an Alien)
Is AAFCO excluded from this point?
Are foreign county regulators included?
(There are multiple Regulatory Agencies which come to different end points)
Part 3 – Gap in definition of what facility meant
Need to be better defined what "animal feed production is?"
Where does it begin? (crops in the field)
How do you find all these firms?
How do you incorporate transportation?
Part 4 – "Depending on the situation"
Q – Does firm establish whether it is process or product control e.g. with Regulatory Agency following through to make this comprehensive for everyone
Part 5 – No GAPS
Part 6 - See disagree statement
Parts 7 and 8 – No GAP
Overall: Comprehensive Enforcement Ability

<u>Questions 5 – 8:</u>

Question 5) Do you agree with the identified gap? Why?

The AAFCO OP, a non-federal listing, is a source of information on permitted ingredients/additives in animal feed... A Compliance Policy Guide (CPG) that (1) explains the relationship between FDA and AAFCO and (2) establishes a policy whereby FDA would recognize the ingredients defined in the OP as acceptable for use in animal feed is being developed to address this potential barrier. We are also considering the promulgation of a regulation in addition to a CPG. A regulation would be more binding than a CPG and less subject to variation in interpretation. The CPG would, however, define the relationship between AAFCO and FDA.

Question 6) Do you disagree with the identified gap? Why?

Question 7) What gap(s) have we missed?
Question 8) What solution(s) do you recommend to fill the gap(s)

1) Cost of OP, availability to all
2) Agree there needs to be a CPG defining "clearly" the relationship between FDA and AAFCO.
3) Transparency for new approvals (there is no public availability)
4) FDA – Regulation into CFR
5) Acceptability of human food GRAS ingredients; The process is not defined
6) No market protection for new feed ingredients
7) Regulation is written; easy of accessibility to everyone

Resolutions:

1) Can FDA recognize definitions that are not freely available to everyone?
2) FDA contract for providing this access to O.P
3) We agree!
4) Without legal ramifications, publish on FDA website
5) Define the process
6) Ask Congress to amend FD&C Act to provide patent protection for new ingredients – A Recognized Miracle!
7) Self Explanatory