Common Pitfalls in Submissions: Industrial Perspective

• NUMBER ONE – Preregistration meeting
  – If Microbial: be aware of history of similar strains
  – If Biochemical: Meeting MAY be necessary for classification. Registrant to submit rationale and documentation

• When possible – use Joint Reviews with US EPA, PMRA and maybe DPR
Common Pitfalls in Submissions: Industrial Perspective

• Learn who your RAL will be and work with that person.
• Request waivers when appropriate
  – Scientific rationale needed
  – If joint review, may not be accepted by all Agencies
  – Ensure that all waiver requests and responses are sent to OTHER Agencies
• Send dossier by courier or hand-deliver: do not use regular mail if possible – use correct address, departmental numbers, etc.
Common Pitfalls in Submissions: Industrial Perspective

Regarding the dossiers:

- Format per 86-5 and comparable in Canada
- Use all needed and proper forms – on internet
- Change fonts to aid readability
- Use only clean copies, xerox carefully – good margins, etc.

- Keep CBI in separate, clearly marked section
- No CBI in cover letters (help the Agency by keeping CBI to minimum)
- Double, and then triple check for errors – use independent person
Common Pitfalls in Submissions: Industrial Perspective

• Tolerances – or exemption from requirement of a tolerance
  – Maybe eligible for waiver of fees
  – Use recent FR notices as a pattern

• Efficacy
  – Required to submit to PMRA and DPR, may be required with BPPD (Public Health)
  – Data may include: 2 years; phytoxicity; dose rate response; statistical significance.