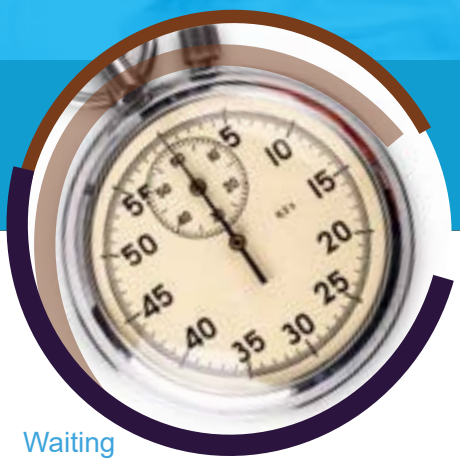
LABORATORY NOTES:
Seven Sins of Product Stability Data



Waiting for new product approvals can be a frustrating time.

So, you have this fantastic new addition to your agricultural chemical product range and are rearing to get it to market. Waiting for the regulatory process to run its course can be frustrating enough, but when you get data rejected, this can result in even longer delays and missed sales opportunities. Many of these delays are avoidable and often stem from poorly conducted stability trials or overseas suppliers not being familiar with the Australian and New Zealand data requirements.

Below, we have outlined seven common pitfalls and how to avoid them:

1. **The formulation tested isn't the one to be commercialised**
Ensure that the supplied data relates to the declared formula to be registered. State it as a fact and cross-reference any formulation batch codes where available.

2. **Trial batch size too small**
The lab batch size should be large enough to be representative of commercial processes. The APVMA requires a batch size of 5 litres (or kilograms).

3. **Trial not conducted in commercial packaging**
If the product is to be sold in 25L HDPE jerricans, then demonstrating its stability in a 20ml glass vial is not particularly helpful. Ideally, the smallest commercial pack should be used for stability trials. A scaled-down pack size, constructed of the same polymer, is also acceptable.

4. **Trial conducted at inappropriate temperature or duration**
If the product failed after 14 days at 54°C, then other conditions are also admissible. The next appropriate equivalent is 8 weeks at 40°C. Demonstrated stability at either of these conditions normally supports a 2-year ambient shelf-life. Other equivalent conditions must be technically justified.

5. **Analytical test methods used for the active were inappropriate**
To effectively monitor any degradation of the active, the test method should be capable of separating out any breakdown products. HPLC and GC are particularly useful for this. Other methods, commonly used for routine product QC testing, may not indicate stability (e.g., UV/Vis).

6. **Analytical test methods used for the active not validated correctly**
The data assessor wants to have confidence that the stability data supplied can be trusted. The APVMA guideline covers criteria to verify whether the analytical method can provide accurate and precise results. The requirements are prescriptive, and the method validation report should be clear and uncluttered so the assessor can tick all those boxes!

7. **The product stability report is too brief or long**
Supply exactly what's required. Make it easy for assessors to review the report and avoid including unnecessary information.

AGCHEM SERVICES

- **New product development.**
- **Trial batch manufacture.**
- **Stability studies to APVMA and ACVM criteria.**
- **Analytical method development and validation.**
- **CIPAC test methods.**
- **Routine quality control testing and shelf-life extension testing.**

GET IN TOUCH

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