ANALYTICAL VARIANCE UPDATE

2019 AAFCO Mid-Year Meeting Monday,
August 5, 2019
Louisville, GA
AAFCO Vision & Mission (Adopted 2018, from 2019 OP)

Vision: To be the trusted leader, building collaboration and regulatory uniformity, to safeguard animal feed.

Mission: AAFCO provides science-based resources as the cornerstone to continuously advance animal feed regulatory programs.

AAFCO PT Program AV Work Group Charge

1. Survey state regulatory programs regarding use of the OP analytical variances (AVs) in their states
2. Provide Technical Report to document the need for removal of the current published AVs, e.g. limitations and liabilities
3. Recommend, to the Board, guidance language to replace the AV Section in the OP
State Regulatory Programs Survey on Use of the Analytical Variances (AVs) from the Official Publication

From Steve Stewart, Minnesota Dept. of Agriculture

<table>
<thead>
<tr>
<th># of Respondents</th>
<th>Description</th>
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<tbody>
<tr>
<td>28</td>
<td>Total Surveys</td>
</tr>
<tr>
<td>26</td>
<td>Use AVs</td>
</tr>
<tr>
<td>1</td>
<td>Explicitly do not use AVs</td>
</tr>
<tr>
<td>1</td>
<td>Unclear</td>
</tr>
<tr>
<td>16</td>
<td>Exclusively use 1AV as basis</td>
</tr>
<tr>
<td>10</td>
<td>Use multiples of AVs or other modifications as basis</td>
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If AAFCO no longer provided AVs, how would you determine a “failed” analyte and/or the need for enforcement?

- Additional research would need to be done by (STATE) to determine appropriate AVs to use. We would likely continue to use the current AAFCO AVs until new guidelines could be established between the laboratory and regulatory programs.
- Develop our own criteria or method criteria if available
- Good question, further discussion would be needed
- Good question. We do not have an answer now.
- I am not sure how the state of ______ would handle failers if AAFCO did not provide AVs.
- I am not sure, we would have to do some research. We may keep the current AV's being used.
- It would be difficult without another measure to be put into place
- Not sure.
- Not sure. Would likely develop a manner similar to fertilizer, which is specified in Department rule. There is another variation of fertilizer investigational allowances in the Uniform State Fertilizer Bill Section 26, Subpart 6.
- Our internal method variability would be applied.
If AAFCO no longer provided AVs, how would you determine a “failed” analyte and/or the need for enforcement?

- Tolerances are determined by Director of Feeds based on AAFCO guidelines and historical agency documentation.
- Utilization of measurement uncertainty data associated with a given analyte.
- We request a continuation of AVs in the AAFCO publication.
- We would attempt to use the AV associated with the testing method, however I can see there being push-back from industry, because more samples will fail. If we get a significant amount of push-back, our executive staff may force us to go with the AVs that would were last published by AAFCO, which would come out of date pretty quick.
- We would continue to use our own regulations but I would strongly recommend keeping AV's in OP.
- We would have to generate an analytical variance ourselves, based on risk assessment, B.M.P. and industry practice.
- We would have to re-evaluate or reporting methods to determine the best course for our state.
If AAFCO no longer provided AVs, how would you determine a “failed” analyte and/or the need for enforcement?

• We would likely establish our own allowable variances.
• We would likely use our lab's measurement of uncertainty (MU) as a starting point and use some multiple of the particular analyte's MUs, based on economic or human/animal safety.
• We would utilize the AV's as written in our Administrative Rules. Although we use the AV's that AAFCO has provided and updated in the OP we do not reference that we adopt AAFCO AV's.
• We would write in AAFCO's Current AVs into (STATE) law.
• Would appreciate the continued use of AAFCO AV be used for the laboratory. However, would like to see AAFCO come up with a result strategy for each or every analyte possible to that would consider sampling error. If there's a strategy that could be presented at annual meeting with industry in the room and one that everyone could agree upon, then it would be more consistent across the country instead of each state having different policies.
• Yet to be determined. I would be concerned that there could be considerable differences between state policies.
Have you heard of the proposed use of investigational allowances?

- Don't really understand the concept
- Have heard of, but do not know about it
- Heard of this but don't really understand the meaning and what is really being proposed. Is it posted in the Feed Bin?
- I suspect they may use a similar criteria, but different name.
- I would like to see investigational allowances added to the OP but not to replace AV's.
- I've heard of but not seen a proposal that I can remember.
- Only preliminarily. Would like to learn more about it.
- Use from AAPFCO for fertilizer
- Why is this proposed change being announced through a survey?
Other notes or comments

• Do not remove AVs from AAFCO. There are so many testing methods out there and so many variances. It makes taking enforcement action much smoother when you are using an industry standard. If AAFCO doesn't want to keep the AVs, then investigational allowances could be used. If neither are used, then AAFCO should cite a nationally acceptable source states could use for a reference when taking enforcement action.
• I would like to see a statement giving detailed reasoning why AAFCO would remove AV's from the OP.
• (STATE) relies very heavily on the published AVs for determination of sample failure. We understand the reasoning behind the proposed changes but we would hope the decision to remove the published AVs would not be made lightly as it will have far-reaching impacts on states' feed programs.
• Moistures and Ash Weights are provided for samples, but no enforcement action is taken on them.
• Should be implemented over a time period.
• We will validate any new models with our data to see if they work.