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Recent Study Reveals Shocking Cost of Feed Ingredient Approval Process Changes

The Institute for Feed Education & Research recently funded a study regarding the feed ingredient approval process in the U.S. "The Impact of Changes in the Feed Ingredient Approval Process" is complete and the findings reveal a startling financial impact.

In 2007, the Food and Drug Administration Amendments Act was enacted requiring the Food and Drug Administration to create pet food processing and ingredient standards by 2009. However, for the last 35 years, the ingredient approval process was typically run through the Association of American Feed Control Officials in the format of model laws and regulations adopted by states. In 2010, FDA's Center of Veterinary Medicine indicated it would no longer acknowledge the AAFCO process; currently continuing its relationship with the non-governmental organization through only a series of short-term memoranda of understanding, leading to multiple changes in the feed ingredient process and great uncertainty for the future.

The study, conducted by Informa Economics, used qualitative interviews and research to develop an industry survey to identify impacts the ingredient review process has had on the industry, as well as recommendations for improvement.

The study concluded the following:

Key Changes	Key Impacts
■ Increased data requirements	■ Increased costs
■ Process delays	■ Lost revenues resulting from approval delays
■ Uncertainty regarding data requirements and the future of the approval process	■ Disincentives to industry expansion
	■ Hinders innovation
	■ Impedes global competitiveness

Using the key changes and key impacts, a survey was created and conducted with the goal of further defining these areas. A total of 209 respondents--130 completed surveys and 79 partially completed surveys--participated in the survey in February 2016. Survey results revealed:

completed surveys--participated in the survey in February 2016. Survey results revealed:

- A notable shift away from AAFCO to the self-GRAS process, the preferred approval process;
- In pet food manufacturers--7 percent of respondents--GRAS notifications has increased, surpassing self-GRAS as the preferred method;
- Ingredients going through the Food Additive Petition (FAP) process has increased across ingredient manufacturers;
- Feed manufacturers contribute to the most significant submission change--a 0 percent to 55 percent uptick from AAFCO to self-GRAS;
- Feed ingredient approval submissions per respondent are up; while approvals have decreased from 64 percent to 51 percent; and
- Approval flow rate has increased with AAFCO and GRAS, but FAP approval flow rate has declined substantially.

The survey determined the impacts the changes in the approval process will have on industry--a $133,071 estimated cost per ingredient submission. If applied to the 107 ingredients submitted by survey respondents (2010-15), the total increase in direct costs is more than $14 million.

Exhibit 17: Direct Cost Impacts

Respondent Type	Avg. Cost: Current (per ingredient), 2010-2015[a]	Avg. Cost: Past, 2000-2005 (inflation adjusted) [a]	Cost Impact per Ingredient (inflation adjusted)	Number of Respondents [a,b]	Ingredients Submitted, 2010-2015 (excl. self-GRAS)[b]	Respondent Type Weights[c]	Adjusted: Ingredients Submitted, 2010-2015[d]	Estimated Direct Cost Impact (in survey sample)[e]
Feed Manufacturer	175,000	196,683	(21,683)	10	9	8%	8.6	(186,436)
Pet Food Manufacturer	291,667	273,171	18,496	3	6	5%	5.7	106,020
Ingredient Manufacturer	802,083	635,123	166,961	24	71	64%	67.8	11,325,009
Consultant	350,000	229,464	120,536	5	26	23%	24.8	2,994,037
Other	531,250	266,342	264,908	8	0	0%	0	-
Weighted Average[c]	**619,401**	**486,330**	**133,071**	**45**	**107**	**100%**	**107**	**14,238,630**

a/ Only includes respondents providing answers to both time periods.

b/ Number of respondents and number of submissions by respondent type do not sum to the total, as some respondents were categorized as more than one type.

c/ Weighted by percentage of ingredients submitted for each respondent type.

d/Adjusted based on respondent type weights to sum to the total number of ingredients submitted during the current (2010-2015) time period – 107.

e/ Cost per ingredient multiplied by adjusted number of ingredients submitted. Generally, most costs are incurred prior to submission. Therefore, cost impacts are applied to total submissions (not just approvals).

Source: Informa Economics IEG

Additional findings revealed submission process changes have also effected total company revenue, jobs, facility construction and/or expansion, and innovation. Lost revenue was calculated at $1.75 million per ingredient per year of delay in gaining approval.

Survey participants did provide feedback for potential solutions for the industry to consider to fix the mounting ingredient approval process issues indicating:

- FDA should provide clear and specific requirements and documentation for the feed ingredient approval process;
- An increase in ingredient approval resources or staff at FDA is needed; and

- The industry should explore methods to increase resources for FDA ingredient reviews.

The AFIA Ingredient Approval and Definition Committee is currently reviewing the survey results and report and are developing a plan to use the results to advocate for solutions. For more information on the survey results, contact Leah Wilkinson, AFIA vice president of legislative, regulatory and state affairs at (703) 558-3560.