DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 24 1996

Nabil W. Said, Ph.D.
Director of Research and Development
Insta-Pro ® International
10301 Dennis Drive
P.O. Box 3600
Des Moines, Iowa 50322

Dear Dr. Said:

We have utilized the results of our review of the following information to develop a response to your request for an opinion on whether the dry extrusion process is an acceptable method of processing by-products:

Your three-page letter dated July 24, 1996, to Dr. Dan McChesney of my staff. Enclosed with this letter was:

- A paper, "Extrusion of Alternative Ingredients...An Environmental and A Nutritional Solution," presented at the Poultry Science Association 85th Annual Meeting in Louisville, Kentucky on July 8-12, 1996 (REF 69.1016; 20 pages).

The one-page letter dated July 10, 1996, from Duncan P. Nesbitt, President of Powell Technologies, Inc. to Dr. Dan McChesney. Enclosed with this one-page letter was:

- UPDATE Insta-Pro ® Extrusion Technology on twelve different topics (REF 6002-6013), an UPDATE on "Purposes of Extrusion" (REF 49.1001), and an UPDATE on "The Dry Extrusion Process" (REF 49.1002).
- A paper, "Extrusion Processing of Ingredients and Feed," presented at The International Symposium of Feed Production in Curitiba -PR Brazil on September 16-17, 1995 (REF 59.1011; 16 pages).
- A reprint of the article, "Garbage is turned into gold: Hatchery recycling plant typifies new joint ventures," that appeared in the Des Moines Sunday Register (Sunday, March 3, 1996, Section 4G).
- "Turning Costly Waste into Valuable Feed," a six-page promotional brochure, and
- A one-page specification sheet on Insta Pro Model 2500 Extruder.

At this time, the FDA Center for Veterinary Medicine would not object to the use of the dry extrusion process for processing various by-products as acceptable feed ingredients provided that:

1. There was adequate documentation to show that the appropriate levels of temperature (minimum of 140° C), residence/dwell time (approximately 30 seconds) and pressure (an atmospheric pressure differential of approximately 40 atmospheres as the product exits the extruder) were attained for each batch produced.

2. The moisture was reduced to about 10% prior to cooling and storing the finished product.

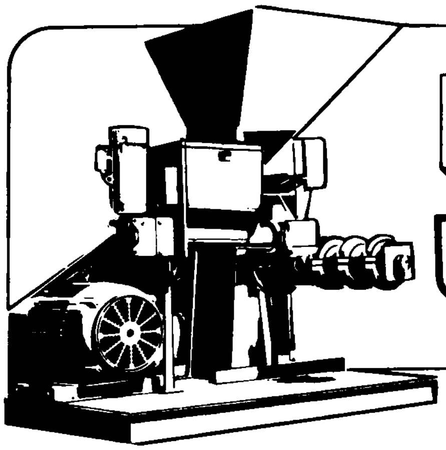
3. The finished product met a feed definition established by the Association of American Feed Control Officials, Inc. and is not in conflict with other federal or state regulations (e.g., the USDA regulations in 9 CFR 166 regarding the feeding of garbage to swine).

4. The finished product was appropriately labeled.

If you have any questions concerning this letter, please don't hesitate to call us at 301-594-1724 or send a facsimile to 301-594-1812.

Sincerely,

George Graber, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine



Insta Pro® UPDATE

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MICROBIOLOGIC EVALUATION OF DEAD BIRD MEAL

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The process of dry extrusion as an alternative for dead bird disposal has been proposed. The extrusion process provides the potential for animal carcasses, viscera, etc. to be processed and utilized as potential feed ingredients. Because of the nature and condition of the starting material being utilized (dead birds) the question arises "Is it safe to feed dead bird meal to poultry?" The objective of the work reported below was to determine if dead bird meal has the potential for carrying or spreading infectious disease agents.

To determine the effectiveness of the extrusion process to sterilize the starting material (dead birds) a number of tests were performed on pre- and post-extruded material. In our initial studies pre- and post-extruded material was cultured for bacteria and molds. Several samples were collected and inoculated onto culture media routinely used for growing bacteria and molds. In each case, the cultures from the pre-extruded samples were overgrown with bacteria and molds but the cultures from the post-extruded samples were negative. These results strongly suggested that the extrusion process was an effective way of sterilizing feed ingredients.

Although the preliminary studies were encouraging there were still questions about the ability of the extrusion process to inactivate viruses, coccidia, certain bacteria (in particular **Salmonella spp.**) and the effect of "other things" that may escape through the extrusion process and potentially have detrimental effects on the turkey poult. Further studies were designed to address these questions. The experimental design was similar in all the studies in that a preparation of avian infectious disease agents was prepared and added to the pre-extruded materials. Following extrusion, the material was evaluated for the presence of these agents and/or the material was fed to turkey poults and the poults were evaluated for signs of disease and the presence of these agents. The infectious agents which were used included **Salmonella typhimurium,** coccidia, turkey rotavirus and turkey astrovirus. These infectious agents were prepared in one large volume and added to the pre-extruded material as it was entering the extruding machine. The post-extruded material was then collected in sterile containers and taken back to the laboratory for further evaluation.

At the laboratory, the post-extruded material was cultured for the presence of bacteria and molds, and was examined for the presence of coccidia. In each case the result was negative. In preparation of the feeding trials, groups of poults were placed into presterilized containment isolators. There were four groups of birds as follows: controls, which received only feed and sterile water; post-extruded group, which received post-extruded material incorporated into the feed; post-extruded/culture group, which received post-extruded material incorporated into the feed and were given a bolus of culture media from a 48 hour culture of post-extruded material; infectious agent group, which received the combination of infectious agents given orally at the time of placement. These trials were done using commercial poults and were repeated using specific pathogen free (SPF) poults.

In each experiment the results were the same. Those birds which received the infectious agents died within the first week of the experiment. Those birds which received the extruded material in the feed and the culture material displayed no signs of ill health and appeared as healthy and performed the same as control birds. At necropsy, there were no visible signs or lesions of disease. **Salmonella** cultures were negative and no viruses or coccidia could be demonstrated from the intestinal tract.

From the experimental trials described above, it was concluded that (under the conditions by which the extrusion process was carried out in these studies) feed materials subjected to the extrusion process would not pose a potential problem of transmitting infectious agents.

blended mixtures had significant numbers of CFU/g of sample. The extruded products, however, were free of aerobic microorganisms (Table 6). Tadtiyanant *et al.* concluded that high temperature-short time extrusion is a feasible disposal method for converting these poultry industry residuals into high quality feedstuffs.

Froning and Bergquist [3] fed extruded eggshells and technical egg white to a commercial flock of laying hens. They reported that the rate of lay was significantly higher ($P < .05$) for those birds receiving the extruded product compared to the control group (Table 7). No differences in mortality, feed conversion, breaking strength, or shell thickness were found. They concluded that extrusion technology may provide an avenue for better utilization of eggshells as well as other waste from egg processing plants.

Patterson *et al.* [4] extruded a blend of offal and condemned birds with inexpensive ingredients such as wheat middlings, barley, cassava. The resulting new ingredients were incorporated into broiler diets at 5, 10, and 20% and performance compared with a corn-soybean meal control diet. They reported (Table 8) that all extruded products except the 20% barley/by-product blend resulted in equal broiler performance at a lower cost than that of the control diet. They also reported that ensiling poultry by-products was a viable method of preservation before extrusion.

Blake *et al.* [5] investigated the feasibility of extruding turkey processing plant offal and farm mortalities. When those by-products were co-extruded with soybean meal, the nutrient composition of the resulting product compared favorably to that of soybean meal (Table 9). Furthermore, they presented the results of a digestibility trial and a complete analysis of one of the resulting ingredients (30/70 turkey mortality/soybean meal) (Table 10). This information was used in formulating diets for a turkey feeding trial. The results of this trial indicate that the substitution of up to 100% extruded turkey meal for soybean meal had no effect on growth performance and feed efficiency (Figure 1). Similar results were obtained when extruded turkey meal replaced soybean meal in a broiler trial (Figure 2).

Lyons and Vandepopuliere [6] processed ground spent hens alone or in combination with wheat middlings in a fluidized bed dryer followed by steeping or extrusion. All heat treatments supported equal or better broiler performance to 21 days of age (Table 11). Steeping resulted in a marked reduction in aerobic plate colonies, coliform, yeast, and mold. Extrusion of spent hens and wheat middlings product, however, achieved the greatest reduction of aerobic plate colonies (Table 12).

THE MICROBIOLOGICAL QUALITY OF EXTRUDED BY-PRODUCTS

Because of the nature and conditions of the starting material (mortalities), the question arises: Is it safe to feed dead bird meal to poultry?" Reynolds [7] conducted studies to answer this question.

A preparation of avian infectious disease agents containing *Salmonella typhimurium*, coccidia (*Eimeria tenella*), turkey rotavirus, turkey astrovirus, and *Streptococcus faecium* was added to the pre-extruded material. After extrusion, the mortality meal was tested for microorganisms (Table 13). Furthermore, feeding trials were conducted with turkey poults. At necropsy, there were no visible signs of lesions of disease. Salmonella cultures were negative, and no viruses were isolated from the intestinal tract. Reynolds [7] concluded that extruded products in feed posed no risk of transmitting infectious agents.

Other by-products that have been extruded and tested include feathers and offal, turkey litter, broiler litter, partially dehydrated layer manure, farm mortalities, dissolved air flotation, restaurant grease, fish waste, eggshells and unsalable eggs, cheese trimmings, tallow, and other food industry by-products.

Commercial extrusion operations are being installed in the United States and the rest of the world to pursue the idea of upgrading and complimenting conventional rendering. Such operations seek to consistently produce ingredients of the highest quality with regard to both nutrition and microbiological safety.

TABLE 6. Aerobic plate counts of dead poultry, feathers, eggshells, hatchery waste, and deboning residual mixtures before and after extruding

SOURCE	BEFORE EXTRUDING			AFTER EXTRUDING		
	Exp. 1	Exp. 2	X	Exp. 1	Exp. 2	X
	CFU/g of Sample)					
Broilers, 3 wk[A]	2.0×10^5	4.0×10^6	2.1×10^6	0	0	0
Broilers, 4 wk[A]	2.0×10^5	3.0×10^6	1.6×10^6	0	0	0
Turkey, 6 wk[A]	4.5×10^6	8.0×10^5	2.6×10^6	0	0	0
Turkey, 12 wk[A]	3.2×10^4	6.0×10^5	3.2×10^5	0	0	0
Feathers[A]						
Untreated	5.0×10^5	3.5×10^5	4.2×10^5	0	0	0
Treated[B]	3.5×10^5	2.8×10^5	3.2×10^5	0	0	0
	Exp. 3	Exp. 4	X	Exp. 3	Exp. 4	X
Eggshells[C]						
Source A	8.5×10^5	3.9×10^8	2.0×10^8	0	0	0
Source B	1.5×10^5	1.1×10^9	5.6×10^8	0	0	0
Hatchery Solids[D]						
Source C	6.9×10^8	2.5×10^{10}	1.3×10^{10}	0	0	0
Source D	2.2×10^8	3.9×10^9	1.9×10^9	0	0	0
Hatchery Reconstituted[E]						
Source C	4.0×10^7	1.7×10^8	1.0×10^8	0	0	0
Source D	1.5×10^6	2.2×10^9	1.1×10^9	0	0	0
Mechanically debonded residue[F]	2.2×10^8	5.6×10^7	1.4×10^8	0	0	0

[A]Mixtures of 75% soybean meal (48% CP) and 25% dead birds or feathers (wet basis).

[B]Treated by proteolytic enzyme premix (2.5% wet basis). Enzyme Premix No. 1955 provided by Insta-Pro International, Des Moines, IA.

[C]Ground corn and centrifuged eggshells in a 25:75 ratio (wet basis).

[D]Ground corn and centrifuged hatchery solids in a 40:60 ratio (wet basis).

[E]Ground corn, centrifuged hatchery solids, and liquid in a 65:19.6:15.4 ratio (wet basis).

[F]Ground corn and mechanically deboned residue in a 73.2:26.8 ratio (wet basis).

TABLE 7. Effect of feeding extruded eggshells on shell quality, rate of lay, feed conversion, and mortality

TREATMENT GROUP	BREAKING STRENGTH[A]	SHELL THICKNESS[A]	RATE OF LAY (HEN HOUSED)[B]	FEED CONVERSION	MORTALITY/ 1000 BIRDS
	kg	mm		kg feed/dz eggs	
Control	4.44^a	0.384^a	62.4^b	1.89^a	1.5^a
Extruded	4.54^a	0.394^a	64.2^a	1.77^a	2.1^a

[A]Breaking strength and shell thickness were measured on 2 replicates of 30 eggs each (a total of 60 eggs/treatment).

[B]Weekly averages were taken over a 12-wk period.

[a,b]Values within the same column with no common superscript differ significantly ($P < .05$).