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Reduction of False Positives in the Chili Candy Analysis Method for Filth Using a Newly Developed Correction Factor

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Abstract

In the examination of chili candy for filth using the current method and mathematical formula, it was observed that product samples containing small amounts of filth elements were disproportionally violative. After examining numerous regulatory samples, there was clear indication that it would be necessary to re-evaluate the mathematical formula to reduce false positive results. The original formula calculation is based entirely on the dry weight of recovered chili powder in the product. The formula failed to take into account the loss of soluble material from the chili powder at two critical phases: during candy production, and during processing for filth analysis. This paper provides a means to account for the lost soluble material from the chili powder and adds a correction factor to the original formula to address the high rate of false positive results.

Keywords: chili candy, correction factor, method, weight lost, extraneous material analysis

1. Introduction

In the growing, harvesting and processing of raw agricultural products into manufactured commodities, it is nearly impossible to produce them so that they are free of any defects. These defects typically are naturally occurring, non-hazardous and often pose more of an aesthetic issue then a true health hazard. That being said, aesthetic issues can be very disconcerting to consumers and can lead to consumer complaints. The U. S. Food and Drug Administration (FDA) has been given the authority by the U. S. Congress to establish the maximum level of defects allowed on these aesthetically disconcerting elements in Title 21, Code of Federal Regulations, Part 110.110. These defect levels have evolved into the, “Food Defect Action Levels: levels of natural or unavoidable defects in foods that present no health hazards for humans”.

The Food Defect Action Levels (DAL) were developed for individual food commodities and encompass all aspects of the manufacturing process of the product, beginning at the farm level, including any relevant scientific data surrounding the product. They take into account the insect and animal pests typically associated with the product. The aesthetics of the product to the consumer also play a role in the defect action levels, sometimes referred as “the ick factor”. These defects normally are not hazardous in nature.

Chili candy is any semi-soft to hard sugar candy with typical candy components of colors and flavors, containing varying amounts of chili pepper powder. The candy typically comes in one of two forms: either wrapped in individual cellophane wrappers, or placed on a lollipop stick and wrapped in cellophane.

The Southwest Import District (SWID) of the FDA, with the FDA Center of Food Science Safety and Applied Nutrition’s (CFSAN) concurrence, has determined that the chili pepper contributes all of the recovered filth elements to this product. Therefore, the filth analysis is centered on the chili pepper present in the product.

The FDA laboratories have examined numerous regulatory samples over the years using the current calculations on candy coated with chili powder. This has led to a high violation rate of chili candy products and the placement of this product on Import Alert 33-12 [3]. This violation rate seemed excessively high and it was determined by the FDA that both the formula and analysis needed to be re-examined with regard to this product.

The purpose of this paper was to see how much chili material was lost during analysis and to generate a correction factor to compensate for the lost chili material, giving a more reasonable assessment of the product being evaluated. This new correction factor would reduce errors that are inherent in the original equation. It would also reduce false positive samples, by presenting a more accurate DAL equivalent (DALe). An important consideration when analyzing chili-candy samples is

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Weight of Chili (g)	Weight of Sugar (g)	Amount of Water (ml)	Amount of HCL (ml)	Weight of Filter Paper (g)	Paper + Chili after Air Drying (g)	Weight of Dry Chili (g)	Weight of Lost Chili (g)	% Remaining Chili	% Lost Chili
25.02	75.02	500	0	3.56	23.45	20.01	5.01	79.98	20.02
25.01	75.02	500	0	3.51	23.69	20.27	4.74	81.05	18.95
25.00	75.02	500	0	3.51	24.54	21.03	3.97	84.12	15.88
25.01	75.00	500	0	3.34	21.44	18.10	6.91	72.37	27.63
25.01	75.00	500	0	3.59	19.17	15.58	9.43	62.30	37.07
10.01	90.00	500	0	3.58	10.15	6.57	3.44	65.63	34.36
10.01	90.03	500	0	3.39	9.96	6.57	3.44	65.63	34.36
10.03	90.02	500	0	3.38	9.62	6.24	3.79	62.21	37.79
10.00	90.02	500	0	3.63	9.78	6.15	3.85	61.50	38.50
10.00	90.01	500	0	3.46	9.49	6.03	3.97	60.30	39.70
5.02	95.03	500	0	3.49	6.82	3.33	1.69	66.33	33.66
5.01	95.02	500	0	3.49	7.27	3.78	1.23	75.44	24.55
5.01	95.01	500	0	3.57	7.18	3.61	1.40	72.06	27.94
5.01	95.02	500	0	3.37	6.65	3.28	1.73	65.47	34.53
5.01	95.01	500	0	3.42	6.36	2.94	2.07	58.68	41.32
1.00	99.00	500	0	3.54	4.14	0.60	0.4	60.00	40.00
1.00	99.01	500	0	3.57	4.22	0.65	0.35	65.00	35.00
1.00	99.01	500	0	3.63	4.18	0.55	0.45	55.00	45.00
1.00	99.01	500	0	3.54	4.14	0.60	0.40	60.00	40.00
1.00	99.00	500	0	3.59	4.15	0.56	0.44	56.00	56.00
					AVE	7.32	2.94	***66.45**	34.11
					2STD	14.59	4.83	16.81	19.06

Figure 1: The effect of filth analysis on varying formulations of chili candy product (Chili powder + sugar) and the amount of chili tissues recovered using water. Results are compared to the original amount of chili used in each formulation. The amount of chili powder ranged from a high level of ~25 g to a low level of ~1 g. An average recovery (or correction factor) was determined to be 66% utilizing water only, with the range in 2 STD ± 16.8% for all levels of chili expected in the candy product.
* **Value utilized for corection factor presented in Figure 5.**

to check the ingredient statement on the package label. The sample may contain "chili powder" or "chili resin", the latter of which is a flavoring agent (A. Barnes, personal communication, January 8, 2007). These correction factors are only valid for candies where "chili powder" is an actual ingredient, and not for products with chili resin.

2. Materials and Methods

Chili candy is analyzed for filth using a two-step method. A typical sample usually consists of 6 portions or subsamples. The candy is first dissolved using the current ed. Association of Analytical Chemist (AOAC) 971.34 (a) "Filth in Candy", method using 100 (g) of product, in 1 (L) of water, with 15-20 (ml) Hydrochloric Acid (HCl), (Certified ACS Plus), Fisher Scientific (Fair Lawn, New Jersey) added. In step 1, the dissolved product is washed over a #230 sieve. Endecott's Laboratory Test Sieve, (London, England) and the remaining sieve overs are transferred to pre-weighed filter paper, dried and weighed again to determine the average amount of chili present per subsample. The sieve overs consist of undissolved chili tissues and filth elements. For heavily spiced product, these overs cannot be plated directly for examination, as the material on the plates would be too thick and difficult to examine microscopically.

After weighing, the recovered dried chili material is examined as is using the AOAC current ed. 978.22 (B) (c) "Light Filth in Capsicums (Ground)", methods (H. G. Semey, personal communication, April 5, 2007). The plates are examined microscopically for filth elements, and the average number of filth elements calculated based on a mathematical formula derived by FDA Dallas District Office of Compliance (D. Floyd, personal communication, May 4, 1998). The formula is: 25g (a/b g) = x, where a is the total number of insect fragments or rat/mouse hairs found by count in the sample, b is the total amount of remaining dried capsicum material in grams and x is the calculated total number of insect fragments or rat/mouse hairs per 25 (g).

The formula is evaluated against the FDA's Compliance Policy Guide 525.200, "Capsicum Pods, Ground Capsicums Excluding Paprika, Ground Paprika Adulteration with Insect and Rodent Filth, Mold, Mammalian Excreta" for 25 (g) of ground capsicums (cayenne, red pepper, etc.), excluding paprika [1]. The DAL for ground capsicum is based on an average of 6 subsamples, and establishes the following limits: >6 rat/mouse hairs or >50 insect fragments per 25g product [2]. Because this DAL is based solely on the ratio of contaminants

Weight of Chili (g)	Weight of Sugar (g)	Amount of Water (ml)	Amount of HCL (ml)	Weight of Filter Paper (g)	Paper + Chili after Air Drying (g)	Weight of Dry Chili (g)	Weight of Lost Chili (g)	% Remaining Chili	% Lost Chili
25.00	75.01	500	20	3.51	18.05	14.54	10.46	58.16	41.84
25.00	75.01	500	20	3.64	17.03	13.39	11.61	53.56	46.44
25.00	75.01	500	20	3.53	17.76	14.23	10.77	56.92	43.08
25.01	75.00	500	20	3.53	17.32	13.79	11.22	55.14	44.86
25.00	75.00	500	20	3.59	18.07	14.48	10.52	57.92	42.08
10.00	90.00	500	20	3.54	8.52	4.98	5.02	49.80	58.02
10.01	90.01	500	20	3.56	8.58	5.02	4.99	50.15	49.85
10.01	90.01	500	20	3.58	8.05	4.47	5.54	44.66	55.34
10.01	90.01	500	20	3.34	8.99	5.65	4.36	56.44	43.56
10.01	90.01	500	20	3.40	8.63	5.23	4.78	52.25	47.75
5.00	95.00	500	20	3.60	6.21	2.61	2.39	52.20	47.80
5.00	95.00	500	20	3.57	6.15	2.58	2.42	51.60	48.40
5.00	95.01	500	20	3.46	6.32	2.86	2.14	57.20	42.80
5.01	95.00	500	20	3.47	6.21	2.74	2.27	54.69	45.31
5.00	95.00	500	20	3.46	6.19	2.73	2.27	54.60	45.40
1.00	99.00	500	20	3.48	3.96	0.48	0.52	48.00	52.00
1.00	99.01	500	20	3.39	3.83	0.44	0.56	44.00	56.00
1.01	99.00	500	20	3.44	3.90	0.46	0.55	46.00	55.00
1.00	99.00	500	20	3.46	3.87	0.41	0.59	41.00	59.00
1.00	99.00	500	20	3.44	3.92	0.48	0.52	48.00	52.00
					AVE	5.58	4.68	***51.61**	48.83
					2STD	10.64	8.08	10.08	11.06

Figure 2: The effect of filth analysis on varying formulations of chili candy product (Chili powder+ sugar) and the amount of chili tissues recovered using 0.4% HCl in water. Results are compared to the original amount of chili used in each formulation. The amount of chili powder ranged from a high level of ~25 g to a low level of ~1 g. An average recovery (or correction factor) was determined to be 52% using 0.4% HCl in water, with the range in 2 STD ± 10% for all levels of chili expected in the candy product.
* **Value utilized for corection factor presented in Figure 5.**

to chili powder, inaccurate recovery of the chili powder (overestimation/underestimation) can adversely influence the laboratory analytical findings and decision.

To simulate the general matrix of the candy, granulated table sugar and chili powder were combined to form 100 (g)/sub in the following portions: 75 (g) sugar, WinCo (Boise, Idaho) with 25 (g) chili powder, K. L. Trading Company (Brisbane, California), 90 (g) sugar with 10 (g) chili, 95 (g) sugar with 5 (g) chili, and 99 (g) sugar with 1(g) chili. We then analyzed 5 replicates for each of the sugar-chili combinations using current ed. AOAC 971.34(a) method. To test solvent and/or acid effects on the chili material, the sugar-chili mixtures were dissolved into one of the following solvents or solvent combinations: water, water and 20 (ml) HCl (4:1), Fisher Scientific, (Fair Lawn, New Jersey), 40% isopropyl alcohol, (Certified ACS Plus) Fisher Scientific, (Fair Lawn, New Jersey) or 40% isopropyl alcohol and 20 (ml) HCl (4:1). In all cases, the dissolved product was thoroughly washed over a #230 sieve, using current ed. AOAC 970.66B (a) techniques. The residue on the sieve was transferred to pre-weighed, wetted, qualitative P8 fluted filter paper, Fisher Scientific, (Fair Lawn, New Jersey) lining a Büchner funnel, Fisher Scientific, (Fair Lawn, New Jersey). The filter paper and filtrate were then held on a watch glass in a standard laboratory fume hood for up to 24 hours, until the paper and chili powder were dry to the touch. The filter paper and chili were weighed and the values recorded in Figures 1-4.

3. Results and Discussion

The current DAL guidelines are based on an assessment of filth elements present in 25 (g) of, dried chili powder. Whereas, the chili powder recovered from chili candy is processed through an acidified pre-treatment (current ed. AOAC 971.34 (a)), and washed over a #230 sieve to remove all extraneous soluble matter. During this sieving process, oils, starches, and all other digestible materials from the chilies are rinsed away, leaving behind insoluble chili material and filth elements. The chili remaining for analysis after processing has lost a substantial portion of its original mass.

Using the current methods and mathematical formula, it was observed that product with small amounts of filth elements were disproportionally violative. After examining numerous regulatory samples, it was evident that the current procedures should be re-evaluated to reduce false positive results. The original formula calculation was based entirely on the dry weight of unprocessed chili powder in the product. The formula failed to take into account the loss of soluble material from the chili pow-

Weight of Chili (g)	Weight of Sugar (g)	Amount of 40% IPA (ml)	Amount of HCL (ml)	Weight of Filter Paper (g)	Paper + Chili after Air Drying (g)	Weight of Dry Chili (g)	Weight of Lost Chili (g)	% Remaining Chili	% Lost Chili
25.00	75.00	500	0	3.46	19.66	16.22	8.78	64.88	35.12
25.00	75.00	500	0	3.52	20.37	16.85	8.15	67.40	32.60
25.00	75.01	500	0	3.46	18.83	15.37	9.63	61.48	38.52
25.00	75.00	500	0	3.51	22.11	18.60	6.40	74.40	25.60
25.01	75.01	500	0	3.44	21.52	18.08	6.93	72.29	27.71
10.00	90.03	500	0	3.44	11.75	8.31	1.69	83.10	16.90
10.00	90.00	500	0	3.44	11.37	7.93	2.07	79.30	20.70
10.00	90.01	500	0	3.47	11.49	8.02	1.98	80.20	19.80
10.00	90.01	500	0	3.45	11.59	8.14	1.86	81.40	18.60
10.00	90.01	500	0	3.42	10.89	7.47	2.53	74.70	25.30
5.00	95.01	500	0	3.45	7.39	3.94	1.06	78.80	21.20
5.00	95.01	500	0	3.44	7.29	3.85	1.15	77.00	23.00
5.00	95.01	500	0	3.42	7.51	4.09	0.91	81.80	18.20
5.01	95.05	500	0	3.39	7.68	4.29	0.72	85.63	14.37
5.00	95.01	500	0	3.43	7.48	4.05	0.95	81.00	19.00
1.01	99.01	500	0	3.44	4.23	0.79	0.22	78.22	21.78
1.00	99.01	500	0	3.43	4.30	0.87	0.13	87.00	13.00
1.00	99.01	500	0	3.45	4.24	0.79	0.21	79.00	21.00
1.01	99.01	500	0	3.46	4.24	0.78	0.23	77.23	22.77
1.01	99.01	500	0	3.45	4.25	0.80	0.21	79.21	20.79
					AVE	7.46	2.79	***77.20**	22.80
					2STD	12.53	6.41	13.08	13.08

Figure 3: The effect of filth analysis on varying formulations of chili candy product (Chili powder+ sugar) and the amount of chili tissues recovered using 40% isopropanol. Results are compared to the original amount of chili used in each formulation. The amount of original chili powder ranged from a high level of ~25 g to a low of ~1 g. An average recovery (or correction factor) was determined to be 77% using a 40% IPA treatment, with the range in 2 STD of ± 13% for all levels of chili expected in the candy product
* **Value utilized for corection factor presented in Figure 5.**

der at two critical phases during candy production and processing for filth analysis. Figures 1-4 contain the raw data representing the actual dry weight recovery of chili powder for multiple concentrations subjected to each of four extraction conditions. The final correction factors proposed are presented in Figure 5, by determined dissolution method; (x 2sd) determined by calculation.

As most candy samples would be examined using the current ed. AOAC 971.34 "Filth in Candy" method, which prescribes dissolving the product in "boiling HCl (1+70)" which translates to 14.28 (ml) HCl in 1 (L) water. It is common practice and easier to dispense the acid separately, the acid can vary from 15 to 20 (ml)/sub. Using 20 (ml) HCl, the correction factor would be 0.52 with a variance of 2 sd ± 0.10, or to give a worst case scenario, 0.62, rounded to a 0.6 correction factor (CF). The corrected formula the analyst would use is:

$$25\ (g)\ [a\ /\ (b\ (g)/CF)] = x,$$

where a is the total number of insect fragments (IF) or rodent hairs (RH) found by count in the sample, b is the total amount of remaining dried capsicum material in grams, CF is from Figure 5 and depends upon the solvents used and 2 sd to increase the confidence level, and x is the calculated total number of IF or RH per 25 (g). The analyst would apply the standard DAL calculation to determine the limit x for IF or RH. The DAL number for IF is 50, while the DAL number for RH is 6. Finally, the analyst would compare the calculated values against the 6 sub average of the DAL to determine if the sample was violative or not. It is recommended for chili candy samples to follow the current ed. AOAC 971.34(a) method with the water acid combination, if the plates are going to be heavy with chili, proceed with the current ed. AOAC 978.22 method. Apply the 0.60 correction factor to the dry weight of the recovered capsicum material retained on the #230 sieve to determine the DAL equivalent (DALe) levels for IF or RH.

Example:

For a chili coated lollipop candy product, the analyst analyzes 6 subs, first by AOAC current ed. 971.34(a) "Filth in Candy", using 100 (g) product with 15-20 (ml). HCl added to the water. The analyst dries the #230 sieve overs, then after weighing, the overs from each subsample were examined by AOAC current ed. 978.22(B) (c) "Light Filth in Capsicums (Ground)". The Analyst examined the plates and recovered an average of 10 IF and 1 RH per sub and the average dry weight of the recovered overs was 4.0 (g).

To calculate the DALe, the analyst first has to calculate the amount of chili that was present in the original product. In the

Weight of Chili (g)	Weight of Sugar (g)	Amount of 40% IPA (ml)	Amount of HCL (ml)	Weight of Filter Paper (g)	Paper + Chili after Air Drying (g)	Weight of Dry Chili (g)	Weight of Lost Chili (g)	% Remaining Chili	% Lost Chili
25.02	75.04	500	20	3.40	19.66	16.26	8.76	64.99	35.01
25.01	75.01	500	20	3.41	19.59	16.18	8.83	64.69	35.30
25.01	75.02	500	20	3.40	18.71	15.31	9.70	61.22	38.78
25.03	75.01	500	20	3.46	17.44	13.98	11.05	55.85	44.15
25.02	75.04	500	20	3.42	21.71	18.29	6.73	73.10	26.90
10.00	90.02	500	20	3.42	10.45	7.03	2.97	70.30	29.70
10.01	90.02	500	20	3.41	10.26	6.85	3.16	68.43	31.57
10.00	90.02	500	20	3.38	11.19	7.81	2.19	78.10	21.9
10.01	90.02	500	20	3.45	10.79	7.34	2.67	73.33	26.67
10.02	90.01	500	20	3.42	10.81	7.39	2.63	73.75	26.25
5.01	95.01	500	20	3.43	6.91	3.48	1.53	69.46	30.53
5.00	95.02	500	20	3.42	7.29	3.87	1.13	77.40	22.60
5.00	95.00	500	20	3.37	7.22	3.85	1.15	77.00	23.00
5.01	95.01	500	20	3.44	7.03	3.59	1.42	71.65	28.34
5.00	95.02	500	20	3.38	6.92	3.54	1.46	70.80	29.20
1.00	99.02	500	20	3.39	4.22	0.83	0.17	83.00	17.00
1.00	99.02	500	20	3.42	4.13	0.71	0.29	71.00	29.00
1.00	99.00	500	20	3.47	4.27	0.80	0.20	80.00	20.00
1.00	99.02	500	20	3.48	4.27	0.79	0.21	79.00	21.00
1.00	99.01	500	20	3.51	4.29	0.78	0.22	78.00	22.00
					AVE	6.93	3.32	***72.05**	27.95
					2STD	11.83	7.14	13.55	13.54

Figure 4: The effect of filth analysis on varying formulations of chili candy product (Chili powder + sugar) and the amount of chili tissues recovered using 0.4% HCl in 40% IPA. Results are compared to the original amount of chili used in each formulation. The amount of original chili powder ranged from a high level of ∼25 g to a low of ∼1 g. An average recovery (or correction factor) was determined to be 72% using a 0.4% HCl in 40% IPA, with the range in 2 STD of ± 13.5% for all levels of chili expected in the candy product.
* **Value utilized for corection factor presented in Figure 5.**

Solvent and/or acid solution	Recovered Chili	2xSTD	Calculated Sum CF	Rounded CF
Water alone	0.66	+ 0.17	0.83	0.8
Water and 20 ml HCl (4:1)	0.52	+ 0.10	0.62	0.6
40% Isopropyl Alcohol	0.77	+ 0.13	0.90	0.9
40% Isopropyl Alcohol and 20ml HCl (4:1)	0.72	+ 0.14	0.86	0.9

Figure 5: Comparison of the solvent and acid effects on varying formulations of chili candy product (Chili powder+ sugar) and the correction factor applicable to each type of analysis. To add a measure for the worst case scenario (highest solvent and/or acid effect), 2 STD were added to the average recovery to calculate the correction factor to be applied to an analysis (rounded to nearest significant digit). The chili analyzed by the AOAC chili powder method to determine the amount of filth recovered, then compared to the DAL, using the correction factor to help calculate how much chili was in the product to a 99% confidence level.

example above, given 4 (g) dry weight of recovered material (after going through the candy procedure), from the HCl column in Figure 2, this represents an average of 52% remaining chili, with a worst case scenario (2 STD) of +10% or a total of (52%+10%=) 62% remaining chili. The CF would be 0.60; therefore 4 (g). divided by 0.60 yields a total of 6.67 (g). original chili in the product. To get the DALe/gram IF or RH, the analyst would use the calculated chili equivalent in the formula above, i.e.

For insects: 25 (g) [10 IF/ (4.0 (g)/0.60)] = 37.48 IF/25 (g) average,

And for hairs: 25 (g) [1 RH / (4.0 (g)/0.60)] = 3.75 RH/25 (g) average.

Rounded, the DALe value for the product analysis yields an average 37 IF, with 4 RH per sub, which does not exceed the

DAL level; hence the sample would be acceptable.

This outcome would be completely different, if the above example was used with the current recognized formula: total filth element found/total amount of ground Capsi, i.e.

For insects: (10 IF/4.0 (g) x 25 (g)) = 62.5 IF/25 (g) average,

And for hairs: (1 RH/4.0 (g) x 25(g)) = 6.25 RH/25 (g) average

Rounded, the DAL value for the product analysis yields an average 62 IF, with 6 RH per sub, which exceeds the DAL level; hence the sample would be violative.

The use of the DALe on chili candy samples would have a dramatic outcome on samples. It would reduce the amount of false positive samples and could lead to the cancellation of Import Alert 33-12.

4. Declaration of Conflicting Interest

The authors declare that there is no conflict of interest. Research was funded by U. S. Food and Drug Administration.

5. Disclaimer

The views expressed are those of the authors and should not be construed to represent the views and policies of the U. S. Food and Drug Administration. Any reference to a specific commercial product, manufacturer, or otherwise, is for the information and convenience of the public and does not constitute an endorsement, recommendation of favoring by the U. S. Food and Drug Administration.

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7. Article Information

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