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May 10, 2004

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03-038IF
03-038IF-14

Supplemental Comments on Interim Final Rule on Pork Derived From AMR

Cargill Incorporated, Premium Standard Farms, Smithfield Foods, Inc., Swift & Company, and Tyson Fresh Meats respectfully submit these comments jointly to supplement previous comments made individually in FSIS Docket No. 03-0318IF. We request that these comments be considered notwithstanding that the comment period on this Docket just ended on May 7, 2004.

Our companies are the major manufacturers of pork derived from advanced meat recovery systems (AMR) and thus have an interest in ensuring the availability and viability of this low-cost, wholesome product to consumers. We recognize and respect the agency's decision to issue the AMR regulation as an interim final rule in light of the concerns over bovine spongiform enecephalopathy (BSE). However, in moving rapidly to respond to AMR from bovine raw materials, we fear the issues relative to pork AMR have not been given consideration in their own right. As a result, the application of the rules to pork may not be justified or desirable.

For the reasons discussed below, we respectfully **oppose** those sections of the interim rule dealing with pork derived from AMR in two particulars:

- We ***oppose*** the prohibition on the possible presence of dorsal root ganglia (DRG) in pork AMR because DRG may also appear in hand-derived meat.

- We ***oppose*** the interim calcium limitation because the level selected does not comport with the criteria the agency identified for adopting the level.

- We ***oppose*** the interim iron limitation because the agency's criterion in adopting the level is inconsistent with agency's criteria in setting the calcium limitation.

Dorsal Root Ganglia

In the interim final regulation, FSIS revised the definition of meat to provide, in relevant part, that "Meat may not include . . . any amount of dorsal root ganglia (DRG)." 9 CFR § 301.1, Meat (1)(ii). This revision of the definition was almost exclusively intended to address any food safety issues concerning BSE in cattle. As the agency has conceded, the DRG issue involving pork relates solely to misbranding. 69 Fed. Reg. 1881, col. 3 (January 12, 2004). More specifically, FSIS has determined that the presence of DRG in

AMR pork would constitute misbranding because "DRG [is] not [an] expected constituent of boneless meat." *Id.* at 1,880 col. 2.

FSIS did not articulate the basis, nor provide any data in support of its conclusion that DRG is not an expected constituent, especially when applied to pork. However, it would be fair to characterize the preamble discussion as applying the common sense notion that if the product of an AMR system contains a component which is not found in hand-derived meat, it could be deemed to be an unexpected constituent.

When measured against this standard, we respectfully submit that FSIS erred in determining that DRG would not be present in hand-derived pork. Indeed, as demonstrated herein, DRG may well be found in hand-derived pork.

To illustrate, we are attaching photographs taken of the pork neck. Photo one shows the neck bone. Photo 2 shows the sheath being removed from the spinal canal with the DRG. Photo 3 shows the DRG extending into the meat. Photo 4 shows a DRG in terms of size. Photo 5 shows the DRG in the meat. We respectfully submit that these photos illustrate that DRG can be found in the meat surrounding the spinal column and hence may be incorporated in the finished product during hand-deboning.

Moreover, we have informally contacted several veterinarians and meat scientists to ascertain their views on our conclusion that DRG may become incorporated in hand-derived meat. Although all preferred to conduct a rigorous study before being definitive, they have all agreed that the presence of DRG in hand-derived pork is possible, whether the pork is removed by a Wizzard knife or through more traditional hand deboning.

On the basis of this evidence, we respectfully submit that DRG can be a component of hand-derived meat and hence would not be unexpected. Since it is not unexpected, the presence of DRG in pork AMR would not constitute misbranding under the agency's criterion.

To be clear, we are not asserting that DRG is always contained in hand-derived pork. Nor are we asserting that DRG is always found in pork AMR. For example, we understand that in the FSIS survey of pork AMR recently conducted, the agency analyzed 134 samples and did not find DRG in any samples. However, based on the potential, but unavoidable presence of DRG in hand-derived meat, we respectfully submit that its occasional presence in pork AMR should not, and does not, constitute misbranding.

Accordingly, we request that 9 CFR § 301.2, *Meat* (1)(ii) be amended to read, in relevant part:

> Meat may not include . . . spinal cord, or in the case of beef, dorsal root ganglia (DRG).

Likewise, the AMR regulation, 9 CFR § 318.24(c)(1)(v) should be amended to read:

"(v) *DRG*. If the product is derived from cattle, the product that exits the AMR system contains DRG."

Calcium

Unlike DRG, the definition of meat and the AMR regulation do not impose an absolute prohibition on bone (calcium); rather, the product derived from the system "may not include significant portions of bone, including hard bone . . . ." 9 CFR § 301.2, *Meat* (1)(ii). In terms of hard bone, FSIS has established 130.0 mg of calcium per 100 g of product as what would constitute a "significant portion." 9 CFR § 318.24(c)(1)(i).

Although calcium *per se* is not found at any significant levels in traditional hand-derived meat,[1] FSIS found that the insignificant but unavoidable level of calcium attributable to the AMR process "does not affect the qualitative characteristics of the product and only trivially affect its compositional aspects." 69 Fed. Reg. at 1,879, col. 3.[2] Accordingly, FSIS permitted a low level of calcium. We support that finding – it is the level set with which we have concerns.

According to the preamble, the agency set a level that: (1) could be consistently achieved by industry; (2) would enable production of AMR to be economically feasible; and (3) would create a clear distinction between AMR and mechanically separated (species). 69 Fed. Reg. at 1878, col. 2 & 3. We respectfully submit that the interim maximum calcium level does ***not*** met the first two criteria and the third can be met by a preferable option.

As an initial matter, there is no dispute as to the data, the industry and agency data clearly show the average calcium level of pork AMR is 100 mg/100 g. 69 Fed. Reg. 1878, col. 3. Moreover, "there was a wide variation in individual establishment results." *Id.* We understand that the standard deviation was approximately 30 mg. Hence, what FSIS has adopted as the maximum calcium limitation in the interim final rule is the average plus one standard deviation.

Based on the data, we respectfully submit that the level of 130 mg – representing only one standard deviation from the average – is not a level which could be deemed to represent what can "consistently" be achieved by industry. As a result, the level would not enable production of AMR to be economically feasible since it would result in a consistent "downgrade" to mechanically separated pork, a lower value product. Although the level of 130 mg would create a distinction between AMR and MS pork, we believe our proposed alternative will likewise meet this criterion without the above disadvantages.

We respectfully propose that FSIS apply the principles of good manufacturing practices to the calcium level. In any production process, the manufacturer strives to minimize the

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[1] Lean meat, free of bone, contains less than 20 mg calcium per 100 g of product. Hasiak, R.J. and Harry Marks, Advanced Meat Recovery System Survey Project, 1997 at 9.

[2] Likewise, "a small amount of calcium would not in any appreciable way affect the safety or quality of the product." 69 Fed. Reg. 1,878, col. 1-2.

variations from the average. Under traditional statistical process control, the variations are not to exceed three standard deviations. In the case of calcium, that would mean no single observation should exceed 190 mg/100 g (average of 100 mg plus 3 times the standard deviation of 30 mg). We recognize that the agency may choose to adopt a technology forcing standard as an incentive on industry to improve its process control. Moreover, the traditional application of the three standard deviations would result in a level that exceeded the previous regulatory standard. Accordingly, we would propose a level equal to the average plus two standard deviations, or 160 mg/100 g.

In support of our request, we note that the level is more consistent with operations that have inherent variations and more consistent with the systems approach the agency employs.

We respectfully submit that our proposal meets all three of the agency's goals in establishing the calcium level: (1) it will be consistently achieved by industry; (2) it will enable production of AMR to be economically feasible; and (3) it will create a clear distinction between AMR and mechanically separated (species).

Accordingly, we request that 9 CFR § 318.24(c)(1)(i) be amended to read:

> (i) *Bone solids*. The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 160.0 mg per 100.0 g on any individual observation.

Iron

Like bone (calcium), the definition of meat and the AMR regulation do not impose an absolute prohibition on bone marrow (iron); rather, the product derived from the system "may not include significant portions of bone . . . related components, such as bone marrow . . . ." 9 CFR § 301.2, *Meat* (1)(ii). In terms of bone marrow, FSIS has established 3.5 mg of iron per 100 g of product as what would constitute a "significant portion." 9 CFR § 318.24(c)(1)(i).

However, unlike calcium, FSIS has not chosen to look at ability of industry to achieve the level or whether it is even economically feasible to achieve. Instead, FSIS adopted a totally different requirement – essentially, whether the iron content of the AMR is the same as the iron content of hand derived pork using a complex formula of the iron to protein ratio multiplied by a 10% factor to account for analytical variation. In effect, this level acts more like a prohibition than a tolerance.

We respectfully question why FSIS chose to use a different criterion for iron versus calcium. Admittedly, some of the iron may be an unavoidable consequence of the AMR process, but as noted above, so is the calcium level in AMR. FSIS is treating iron differently than calcium with no articulated reason; in other words, in a seemingly arbitrary manner.

We propose that FSIS employ the same criterion it used for calcium in setting the iron level and use good manufacturing practice principles in setting the compliance parameters. In this regard, we direct your attention to the agency's 1997 Advanced Meat Recovery System Survey Project. There, the researchers noted that:

> The results of this survey approximate those reported in the literature in that the total iron content of the AMRS final meat products was approximately 2 times that of the hand deboned product.[3]

Once again, we respectfully propose that FSIS apply the same principals which it used for bone levels (calcium) – establish a maximum limitation based on the process capability of the AMR equipment with an eye towards a technology forcing standard to encourage maximum process control by the establishments.

Based on the data gathered for this submission and attached hereto, the average iron level is 3.3 with a standard deviation of 0.7. Following our proposed calcium model, the limit should be 4.7 mg/100 g, *i.e.*, the 3.3 average plus two times the standard deviation of 0.7. Interestingly, we do note that previous data submitted to FSIS showed the iron level of hand-derived pork varied from 1.3 mg to 1.9 mg. Even adopting the lowest level of 1.3 mg, when combined with the interim limitation for "excessive iron"[4] of 3.5 mg, our proposed limit of 4.7 mg falls below the total.

We respectfully suggest that our proposal is:

- More consistent with the criteria used by the agency in establishing the calcium level;
- Is a simpler, more direct means of establishing the regulatory maximum; and
- Will not affect the qualitative characteristics of the product and only trivially affect its compositional aspects.

Accordingly, we request that 9 CFR § 318.24(c)(1)(ii) be amended to read:

> (i) *Bone marrow.* The product's added iron content, measured by duplicate analysis on individual samples and rounded to the nearest 10th, is more than 4.7 mg per 100 grams on any individual observation.

Conclusion

We appreciate this opportunity to express our views on the interim final regulation as it applies to pork derived from advanced meat recovery systems and look forward to working with the agency so we can continue to provide consumers with low-cost,

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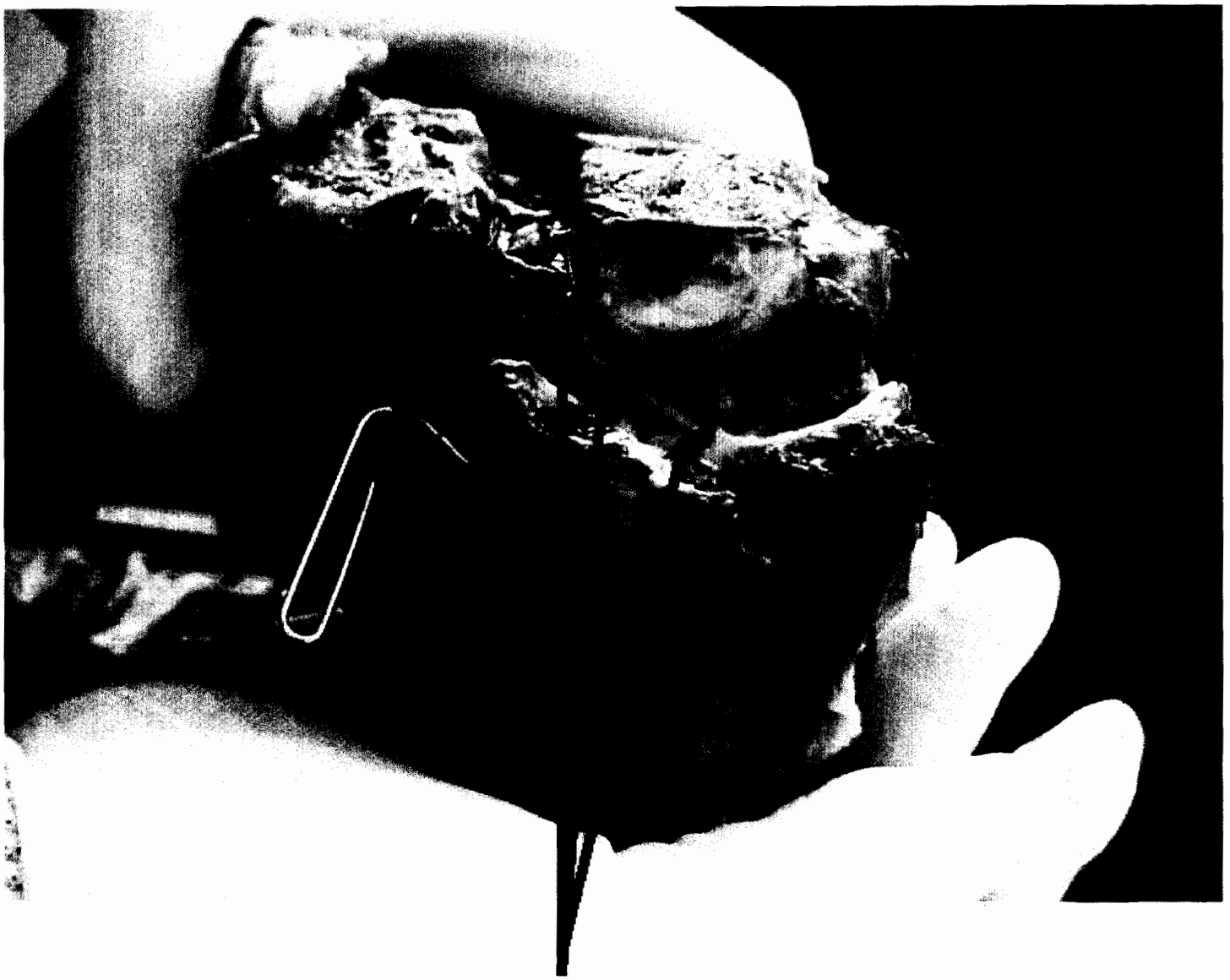
[3] Hasiak, R.J. and Harry Marks, Advanced Meat Recovery System Survey Project, 1997 at 9. The researchers also commented that generally the iron content of AMR is two to three times hand derived.

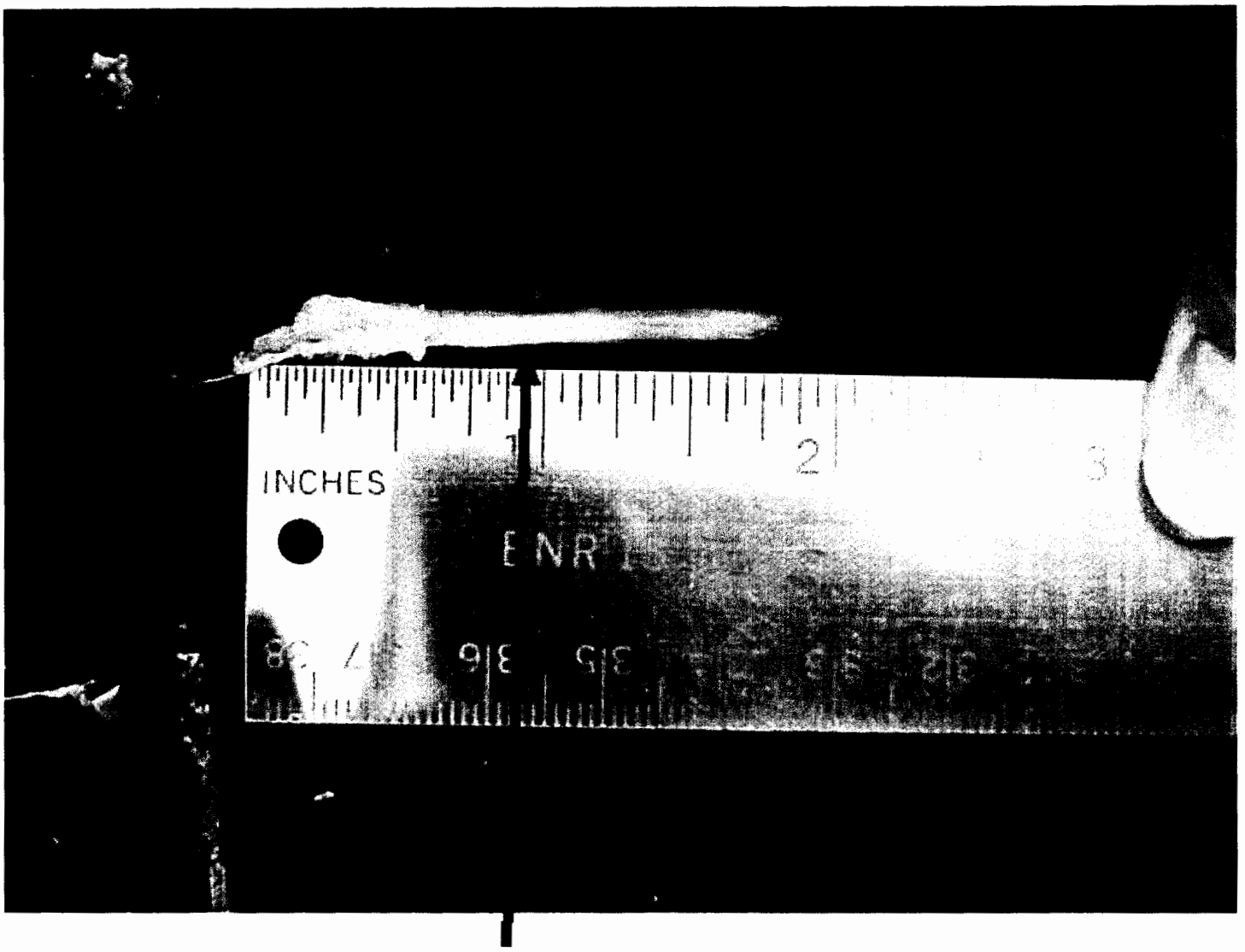
[4] We recognize that the "excessive iron measurement" is in reality a complex formula that does not simply calculate the amount of iron in the pork AMR above the amount naturally occurring in pork.

wholesome, and properly labeled products. We strongly believe that our suggested modifications above will achieve this goal.

Respectfully submitted,

Cargill Incorporated
Premium Standard Farms
Smithfield Foods, Inc.
Swift & Company
Tyson Fresh Meats

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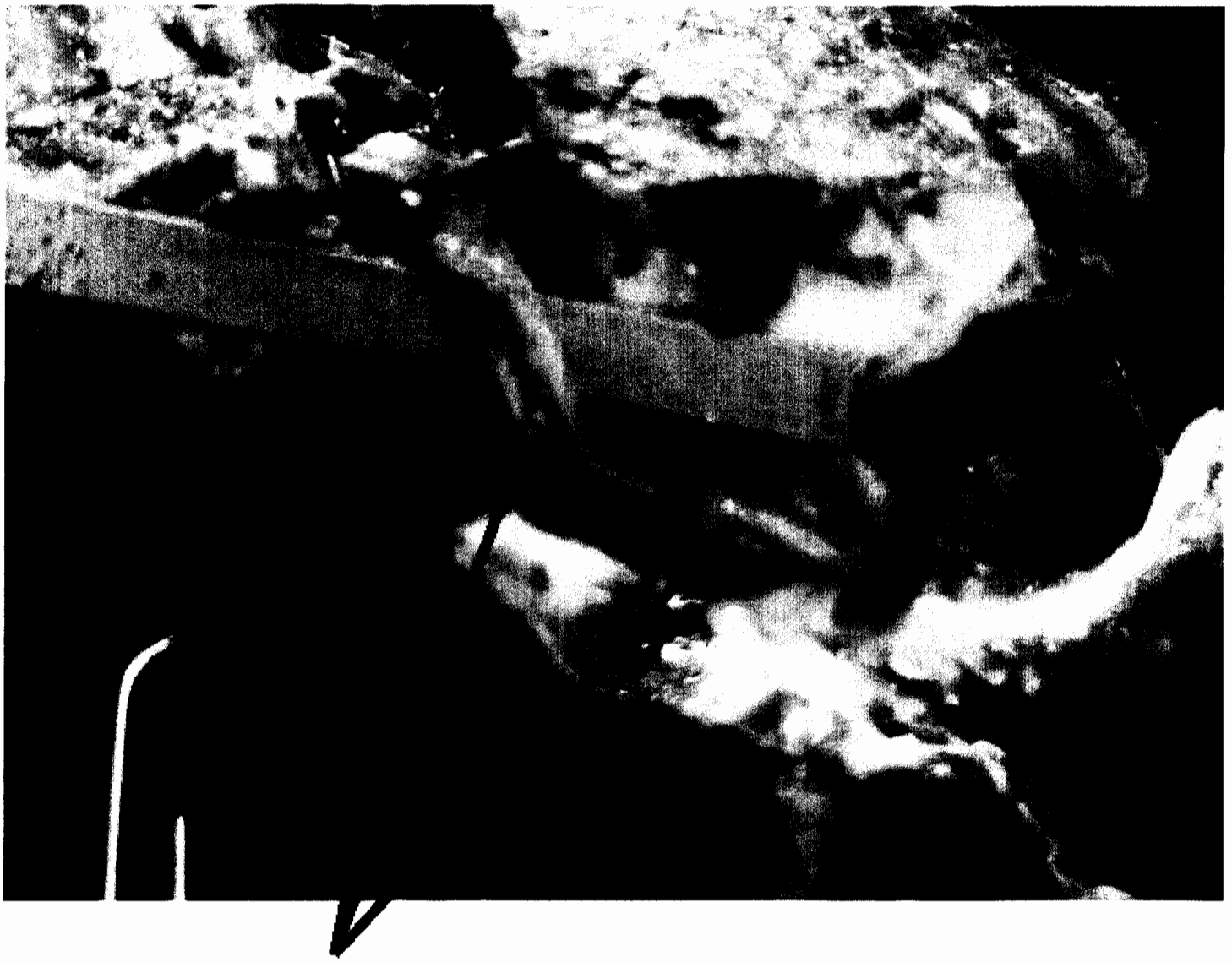

DRG

Summary Stats	
average	3.3
Stdev	0.703136
Min	1.0
Max	5.9

Average + 2 St. Dev		4.744418
Above 4.7%	16	0.012012
Above 3.5%	542	0.406907
Total	1332	

Iron

Plant A	Plant B	Plant C	Plant D	Plant E	Plant F	Plant G
4.9	3.6	2.5	2.8	3.0	2.4	2.2
3.9	3.7	3.0	2.8	3.3	2.35	2.3
5.1	4.3	3.2	2.7	3.6	2.47	2.1
3.4	3.9	3.5	2.7	3.1	2.4	2.2
4.5	3.3	2.9	3.0	3.6	2.61	1.4
5.9	4.1	3.3	2.2	3.3	2.64	1.7
4.0	3.4	3.0	2.8	3.4	2.06	
3.7	3.4	3.2	2.4	3.3	2.04	
4.8	3.7	3.4	3.7	3.5	2.31	
2.5	2.8	2.9	2.6	3.2	2.48	
5.8	2.9	3.5	2.2	4.0	2.08	
3.4	3.8	3.5	2.4	4.1	1.98	
3.0	3.0	3.1	2.8	3.5	1.97	
2.9	3.1	3.6	3.1	3.2	1.87	
4.6	3.1	3.1	3.5	3.6	2.4	
2.9	2.2	3.3	2.4	2.7	2.16	
3.3	2.0	3.0	3.3	3.9	1.99	
2.3	3.2	3.0	2.6	3.0	2.12	
4.3	3.5	3.3	2.5	3.1	2.53	
3.5	4.0	3.0	2.8	3.1	2.63	
3.4	3.0	3.2	3.3	3.3	2.16	
3.9	3.1	2.5	2.8	3.2	2.19	
4.7	2.8	3.5	2.6	4.0	2.15	
5.7	3.3	2.7	3.2	3.4	2.22	
4.2	3.8	3.6	3.1	3.6	2.07	
3.8	3.1	3.7	3.5	3.1	2.03	
4.2	2.8	3.5	2.8	3.3	2.02	
3.9	2.8	3.5	2.2	2.9	2.03	
4.3	2.9	2.7	2.4	4.4	1.81	
2.8	2.8	3.4	3.1	3.6	1.75	
3.7	2.8	2.4	3.3	3.4	2.05	
3.4	4.0	3.5	2.8	3.6	2.09	
4.2	2.6	3.4	2.8	3.0	2.09	
3.2	2.9	2.7	4.4	3.6	2.03	
3.5	3.5	3.1	2.6	4.1	1.9	
2.7	3.0	2.3	4.1	4.2	1.81	
4.9	3.5	2.8	2.8	3.3	1.9	
3.4	3.1	2.8	4.0	3.8	1.88	
4.7	3.5	3.1	2.3	3.1	1.98	
3.1	3.3	2.8	3.1	3.3	1.73	
3.5	3.4	5.2	3.8	3.4		
3.3	3.7	3.0	4.1	4.0		
4.1	3.4	2.3	4.5	2.8		
3.2	4.5	3.1	2.7	2.7		
3.8	4.0	2.5	2.7	3.2		
4.0	3.6	3.5	2.8	3.8		
3.8	4.0	3.0	2.9	3.3		
3.9	2.4	2.9	2.6	2.7		
3.0	4.0	3.6	2.9	2.7		
4.2	3.9	5.8	3.9	3.9		
3.6	3.5	2.9	3.1	3.8		
4.3	2.2	3.9	3.2	3.6		
3.9	3.3	3.5	2.8	3.2		
3.8	2.8	3.1	3.2	4.0		
2.4	3.7	3.4	2.8	3.0		
3.9	4.0	4.0	2.9	3.5		
3.5	2.6	2.8	2.9	3.3		
3.4	2.8	3.1	2.7	3.4		
2.9	2.8	2.6	3.6	2.8		
3.5	5.4	3.6	3.2	4.0		
4.3	2.4	5.5	3.2	3.3		
3.3	4.9	3.1	2.8	3.0		
4.4	3.6	2.6	4.2	3.0		
3.4	4.3	2.7	2.8	2.7		
3.9	3.3	3.1	3.2	3.2		
2.7	3.9	3.4	2.8	3.5		
2.6	2.7	2.7	3.3	3.4		
3.0	4.4	3.1	2.3	3.5		
2.1		2.6	3.2	2.3		
3.8		3.1	3.7	3.0		
4.2		3.0	3.7	3.3		
3.6		3.0	2.1	3.2		
3.4		2.6	2.8	2.6		
3.4			1.8	3.6		
2.7			3.2	3.5		
3.1			2.5	3.0		
3.0			2.7	2.8		
3.1			2.5	3.6		
3.3			2.7	2.7		
2.9			2.7	3.9		
2.5			2.7	3.7		
3.1			3.4	4.0		
3.2			3.8	2.9		
3.1			2.9	4.4		
2.6			2.4	3.7		
3.9			1.0	4.0		
2.5			3.0	3.2		
3.8			3.2	3.8		
2.9			2.4	3.2		
3.1			2.8	3.8		
3.8			1.7	3.5		
3.8			3.1	4.2		
4.0			3.0	3.5		
4.3			2.9	4.3		
3.4			3.1	3.5		
3.8			3.0	3.9		
4.2			3.1	3.1		
3.8			2.9	4.0		
3.8			3.3	3.3		
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4.0			3.1	4.5		
3.8			3.2	3.7		
2.7			3.2	4.1		
4.1			3.8	3.8		
4.2			2.8	4.1		
4.0			4.7	3.1		
4.2			3.5	4.0		
4.4			3.6	4.1		
3.8			3.3	4.3		
3.7			3.8	4.1		
3.8			3.7	3.3		
3.5			4.2	4.1		
4.2			2.8	3.8		
3.8			4.1	3.8		
4.3			2.3	3.0		
3.8			3.9	3.7		
3.7			4.9	4.0		
3.4			4.1	3.7		
4.2			4.1	4.0		
5.1			3.3	3.4		
3.2			4.3	4.1		
4.1			4.2	4.0		
4.4			3.2	3.8		
4.1			4.4	3.7		
3.4			2.7	4.2		
4.0			4.2	3.6		
3.5			4.1	4.0		
4.2			3.4	3.4		
3.7			3.6	2.7		
3.9			3.8	3.4		
3.9			2.5	3.0		
4.8			4.8	3.8		
3.7			4.0	3.0		
4.4			4.5	3.4		
4.1			4.3	3.6		
3.7			4.2	3.5		
2.5			3.4	3.1		
3.7			3.5	3.5		
3.7			3.9	3.8		
4.5			4.8	3.8		
3.0			3.8	3.3		
4.0			4.4	3.4		
4.5			3.2	3.5		
			3.2			
			4.0			
			3.8			
			3.5			
			3.8			
			4.0			
			2.4			
			4.2			
			2.9			
3.7	3.3	3.2	3.2	3.5		

Spec Max: 4.7

%above Spec: 0.026383

Summary Stats

average	3.3
Stdev	0.703136
Min	1.0
Max	5.8
Average + 2 St. Dev	4.744418

bins

	Total	Plant A	Plant B	Plant C	Plant D	Plant E	Plant F	Plant G
0	0	0	0	0	0	0	0	0
0.1	0	0	0	0	0	0	0	0
0.2	0	0	0	0	0	0	0	0
0.3	0	0	0	0	0	0	0	0
0.4	0	0	0	0	0	0	0	0
0.5	0	0	0	0	0	0	0	0
0.6	0	0	0	0	0	0	0	0
0.7	0	0	0	0	0	0	0	0
0.8	0	0	0	0	0	0	0	0
0.9	0	0	0	0	0	0	0	0
1	1	0	0	0	0	1	0	0
1.1	0	0	0	0	0	0	0	0
1.2	0	0	0	0	0	0	0	0
1.3	0	0	0	0	0	0	0	0
1.4	1	0	0	0	0	0	0	1
1.5	0	0	0	0	0	0	0	0
1.6	0	0	0	0	0	0	0	0
1.7	1	0	0	0	0	0	0	1
1.8	4	0	0	0	0	2	0	2
1.9	8	0	0	0	0	0	0	8
2	5	0	1	0	0	0	0	4
2.1	12	0	0	0	0	0	1	11
2.2	9	1	0	0	1	0	5	2
2.3	13	1	2	2	8	0	1	1
2.4	18	1	2	0	8	1	6	0
2.5	10	3	0	3	2	0	2	0
2.6	20	1	3	3	13	0	0	0
2.7	15	3	1	3	2	4	2	0
2.8	34	3	4	4	17	8	0	0
2.9	31	5	6	7	11	1	1	0
3	30	6	4	5	9	6	0	0
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3.4	44	10	7	4	6	17	0	0
3.5	32	10	5	7	2	8	0	0
3.6	43	6	3	8	9	17	0	0
3.7	31	15	4	1	4	7	0	0
3.8	26	8	2	1	5	9	0	0
3.9	28	10	4	1	4	7	0	0
4	34	8	3	1	7	15	0	0
4.1	25	8	4	0	2	10	0	0
4.2	25	11	0	0	8	6	0	0
4.3	17	8	0	0	2	8	0	0
4.4	15	5	3	0	5	2	0	0
4.5	7	1	1	0	2	3	0	0
4.6	4	3	0	0	1	0	0	0
4.7	8	5	0	0	1	0	0	0
4.8	1	0	0	0	1	0	0	0
4.9	5	2	1	0	2	0	0	0
5	1	1	0	0	0	0	0	0
5.1	1	0	0	0	1	0	0	0
5.2	2	2	0	0	0	0	0	0
5.3	2	0	0	0	2	0	0	0
5.4	0	0	0	0	0	0	0	0
5.5	1	0	0	0	1	0	0	0
5.6	0	0	0	0	0	0	0	0
5.7	1	1	0	0	0	0	0	0
5.8	1	1	0	0	0	0	0	0
5.9	0	0	0	0	0	0	0	0
6	1	1	0	0	0	0	0	0

Above 4.7%	16	0.012012
Above 3.5%	542	0.406907
Total	1332