

## Plasma Protein Safety<sup>1</sup>

Plasma is a unique functional protein that impacts gut physiology. It contains a complex mixture of proteins, including antibodies, immune proteins, growth factors, enzymes and transferrin among many others.

Based upon extensive, long-term studies by universities and health agencies, Bovine Spongi-form Encephalopathy (BSE) infectivity has not been detected in bovine plasma or serum proteins.

The World Organization for Animal Health

(OIE) and the U.S. Food and Drug Administration (FDA) have specifically noted that plasma and milk proteins are approved to feed to bovine animals. On April 25, 2008, FDA announced the publication of its Final Rule for 21 CFR Part 589.2001 – Substances Prohibited From Use in Animal Food or Feed. Their opinion specifically stated, "FDA is not prohibiting the use of blood and blood products in animal feed because we believe such a prohibition would do very little to reduce the risk of BSE transmission."

Under 21 CFR 589.2000 (Mammalian to Ruminant Feed Rule) the FDA allows ruminant derived products such as *plasma and milk* to be fed to ruminants.

An excerpt from the Final Rule is shown below:

**DEPARTMENT OF HEALTH AND HUMAN SERVICES** 

**Food and Drug Administration** 

21 CFR Part 589

[Docket No. 2002N-0273]

(Formerly Docket No. 02N-0273)

RIN 0910-AF46

Substances Prohibited From Use in Animal Food or

Feed

AGENCY: Food and Drug Administration, HHS.

**ACTION:** Final rule.

PART 589—SUBSTANCES PROHIBITED FROM USE IN

## ANIMAL FOOD OR FEED

- 1. The authority citation for 21 CFR part 589 continues to read as follows: Authority: 21 U.S.C. 321, 342, 343, 348, 371.
- 2. Section 589.2000 is amended by revising paragraph

(a)(1) and by adding paragraphs (c)(4) and (e)(3) to read as follows:

§ 589.2000 Animal proteins prohibited in ruminant

feed.

(a) \* \* \*

(1) Protein derived from mammalian tissues means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in § 589.2001; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

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