

Labeling Shrimp Products

NFI Shrimp School
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NATIONAL
FISHERIES
INSTITUTE



Let's start with a question

What do you think is the biggest “problem” with labeling of shrimp products?

Take a minute to type into the chat



Label Requirements Defined By Laws and Regs

Fair Packaging and Labeling Act

Federal Food Drug and Cosmetic Act

FDA regulations (www.ecfr.gov)

FDA policy statements and guidance

State Laws and Regulations



A food shall be deemed misbranded

if its labeling is **false** or **misleading** in any particular

But what is misleading?

FFDCA - SEC 321. Definitions

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

SEC 321(n) in Simple Terms

“... both the presence and the absence of information are relevant to whether labeling is misleading.”

“... food labeling may be misleading if it makes or suggests certain representations, or if it fails to disclose facts that are material in light of representations made or suggested about a food or facts that are material with respect to the consequences that may result from use of the food.”

From FDA Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry (March 2019)
<https://www.fda.gov/media/120958/download>

FDA Guidance from 1994



Label vs Labeling

- Label
 - Display of written, printed, or graphic matter upon the immediate container of a food or affixed to such container.
- Labeling
 - Includes labels and other written, printed, or graphic matter appearing upon a food or any of its containers or wrappers, or accompanying the food (e.g., point of purchase materials).

This also includes websites if referenced on a label

www.ourshrimpisthebest.com

Missing Ingredients



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Label Claims

Chem Free!!

Low fat !!

All Natural!!

Purple!!

Antibiotic Free!!

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Missing Ingredients



Missing Ingredients

Ingredient listings are required for all foods with two or more ingredients

CHAT TIME - What ingredient in frozen shrimp is most often not declared?



INGREDIENTS: SHRIMP, WATER, SALT, SODIUM TRIPOLYPHOSPHATE (TO RETAIN MOISTURE).

Missing Water

Ingredient listings are required for all foods with two or more ingredients

Water added in making a food (regardless of the source) **is an ingredient** and must be identified in the list of ingredients.

This includes water used to incorporate dry ingredients (i.e., batter mix, salt, sodium tripolyphosphate and non-phosphate moisture retention agents).

The only exception is if the added water is subsequently removed by cooking or other means during processing

FDA's Compliance Policy Guides Explain the Regulations

CPG Sec. 555.875 Water in Food Products (Ingredient or Adulterant)

(<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074565.htm>)



Missing Moisture Retention Ingredients

Ingredients that are “natural”, “natural sounding” (ie., citric acid, sodium bicarbonate) and GRAS are still ingredients and must be listed.

Exception: If an ingredient is present at an incidental level and has no functional or technical effect in the finished product, then it need not be declared on the label.

What are the exceptions?

FDA's regulations exempt:

Incidental additives that are present in a food at insignificant levels **and** do not have any technical or functional effect in that food."

There are 2 types of "incidental additives"

- ingredient[s] of another ingredient
- processing aids

21 CFR 101.100(a)(3)

What is an “Ingredient of another Ingredient”?

“Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.”

Example

When making a breaded fish product and you use the following breading mix:

Seasoned Fish Fry Breading Mix

Corn Meal, Corn Flour, Salt, Monosodium Glutamate, Spices, Citric Acid, Garlic, Paprika, **Tri-Calcium Phosphate (to prevent caking)**.

21 CFR 101.100(a)(3)(i)

What is a processing aid?

FDA's Definition

“Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.”

21 CFR Sec. 170.3 Definitions (o)(24)

So processing aids don't have to be labeled?

ONLY TRUE IF -

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

OR

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

OR

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels **and** do not have any technical or functional effect in that food.

21 CFR 101.100 (a)(3)(ii)(a), (b), and (c)

What is “insignificant”?

FDA gives a clue –

For sulfiting agents – it is insignificant if there is no detectable amount of the agent present. “Detectable” is the limit of detection – 10 ppm.

$$10\text{ppm} = 0.001\%$$

21 CFR 101.100 (a)(4)

Incidental Additives, Processing Aids & MRAs

The components of a phosphate or non-phosphate blend designed for moisture retention purposes would not meet the regulatory requirements that allow for an exemption of labeling because:

1. MRAs have a functional or technical effect in the finished product.
2. Ingredients in MRA blends contribute significantly to increase the sodium content of the product.

Either one would disqualify the ingredient as “incidental.”

Why Does it Matter?



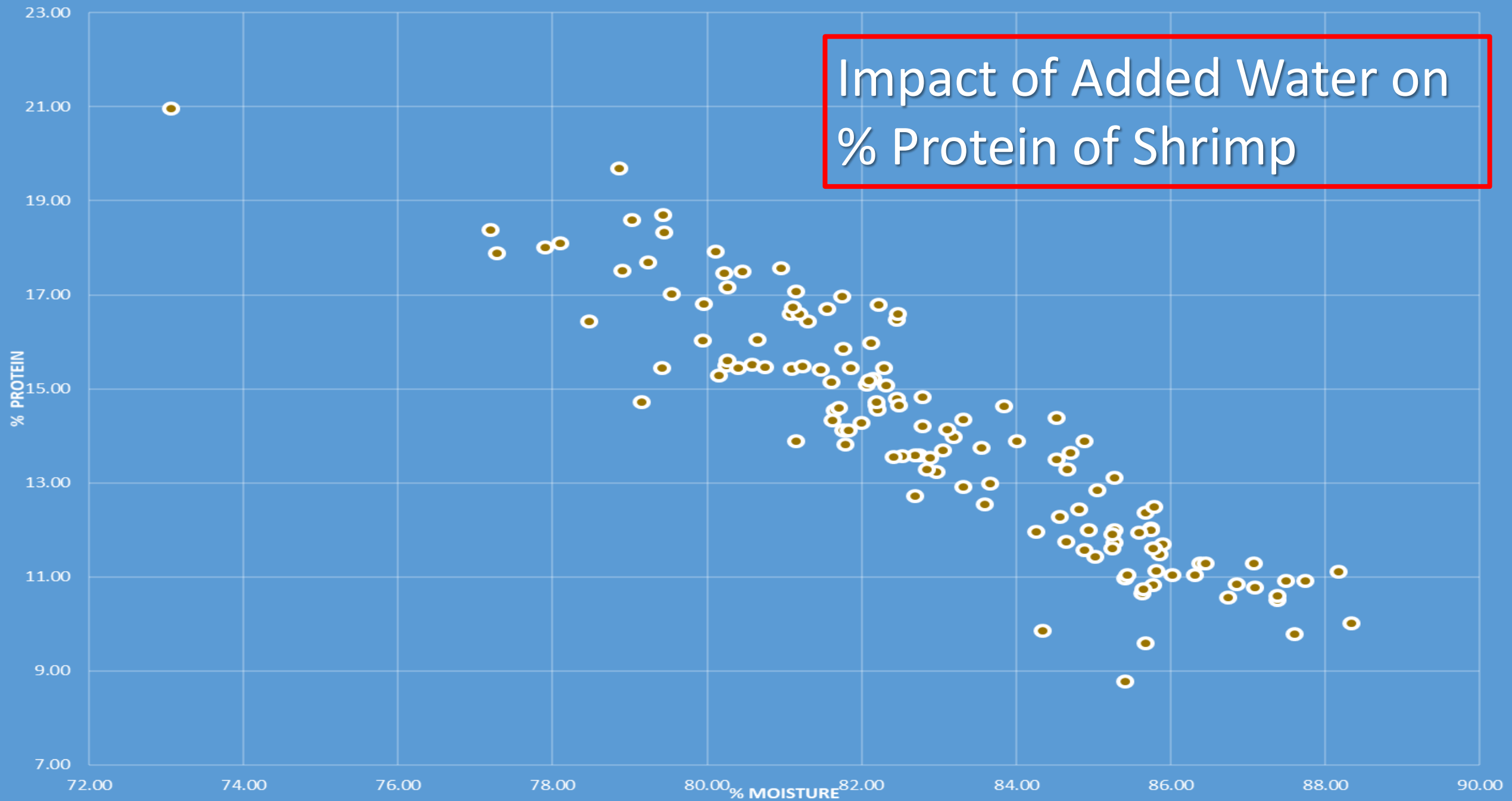
Impact of Water and Ingredients used in Processing

- Protein - Added water will reduce the percentage of proteins in the product, thus lowering this beneficial nutrient.
- Moisture Retention Agents (phosphate and non-phosphate blends) - Increases sodium content of the product, as the solution is absorbed into the product.

	Moisture	Protein	Sodium
Raw Shrimp - untreated	78%	20 g	119 mg
Raw Shrimp - treated	83%	14 g	566 mg

Per 100g - Source USDA National Nutrient Database for Standard Reference
Legacy Release, April 2018

SHRIMP



Missing Ingredients – The Bottom Line

1. Moisture retention ingredients are not processing aids because they have technical or functional effects in the product.
2. Water is an ingredient

NFI Labeling Policy

All ingredients added to fishery products must be declared in the ingredient statement.



Time for a Poll



Time for a Poll

FDA has very clear regulations on label claims
and statements.

Yes

No

Both

Don't know

Label Claims

Chem Free!!

Low fat !!

All Natural!!

Purple!!

Antibiotic Free!!

What you're really
saying is ...

Buy my shrimp because the other guy's shrimp
is **not**:

Chem Free!!

Low fat !!

All Natural!!

Purple!!

Antibiotic Free!!

With Every Label Statement

Ask

Is the statement false?

Is it true?

Is the statement misleading?

Remember, a truthful statement could also be misleading.

Is this false? Is this misleading?



Our shrimp is !



Is this false? Is this misleading?



Disclosure statement is required when any of the following exists:

Total Fat > 13.0 g

Saturated Fat > 4.0 g

Cholesterol > 60 mg

Sodium > 480 mg

“See nutrition information for sodium and cholesterol content”



Is this false? Is this misleading?

Is there a difference in meaning between these 2 statements?



Is this false? Is this misleading?

Is there a difference in meaning between these 2 statements?



“Low Fat” implies you did something to the food to make it low fat.

Is this false? Is this misleading?

Our shrimp is !



Healthy, low fat and delicious,

Healthy – there are specific rules

Raw, single-ingredient seafood

- Total fat less than 5g
- Sat Fat less than 2g
- **Cholesterol less than 95mg**
- Sodium less than 480mg
- At least 10% of RD or DRV of one or more of vit A, vit C, calcium, iron, protein or fiber

Other Products*

- Total fat less than 3g
- Sat Fat less than 1g
- **Cholesterol less than 60mg**
- Sodium less than 480mg
- At least 10% of RD or DRV of one or more of vit A, vit C, calcium, iron, protein or fiber

*different limits apply to meal or main dish products

21 CFR 101.65(d)(2)

Is this false? Is this misleading?

Our shrimp is !



Healthy, low fat and delicious,

Cholesterol > 200mg per serving
Sodium > 500mg per serving

Clear as Mud?

It's about to get muddier!



Is this false? Is this misleading?

- Shrimp Raised in India. Raw product repackaged in the US.
- What if the shrimp are cooked in the US?
- What if the shrimp are breaded in the US?



Four Federal Agencies cover COOL



CBP rules apply to all imported products
(19 CFR 134)



USDA Agricultural Marketing Service (AMS) applies to unprocessed seafood sold at retail
(7 CFR 60)



FDA covers geographical label designations and truthful and not misleading labels/labeling



Federal Trade Commission defines "Made in the USA"

Need to understand how each applies to your product

CBP Ruling on “Substantial Transformation”

Product	Processing Steps	Ruling	Reference
Raw shrimp	Beheading, peeling, de-veining, freezing, repackaging	Not a substantial transformation	N247131
Raw shrimp	Peeling, de-veining and repackaging foreign-origin shrimp	Not a substantial transformation	HRL 731472
Raw shrimp	Freezing and packaging headed (without heads) shrimp	Not a substantial transformation	HQ 563123
Cooked shrimp	Thawing, washing, grading, cooking	Not a substantial transformation	HQ 731763
Breaded shrimp	Breading	Substantial transformation	HQ 563104

Made in the USA

FDA requires labels to be truthful and not misleading.

Federal Trade Commission requires “advertising” to be truthful and not misleading.

- Product must be “all or virtually all” made in the United States
- Guidance document “Complying with the Made in USA Standard” helps to define what is **misleading**
- OK to qualify the claim to make it **truthful** and not **misleading**.

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“Processed in the U.S. with globally sourced shrimp”

Is this false? Is this misleading?

Shrimp Raised in India. Raw product repackaged in the US. **FALSE**

- What if the shrimp are cooked in the US?
FALSE
- What if the shrimp are breaded in the US? **TRUE, BUT MISLEADING**



Is this false? Is this misleading?



No antibiotics ever

No added hormones

On frozen shrimp

Failure to Reveal Material Facts



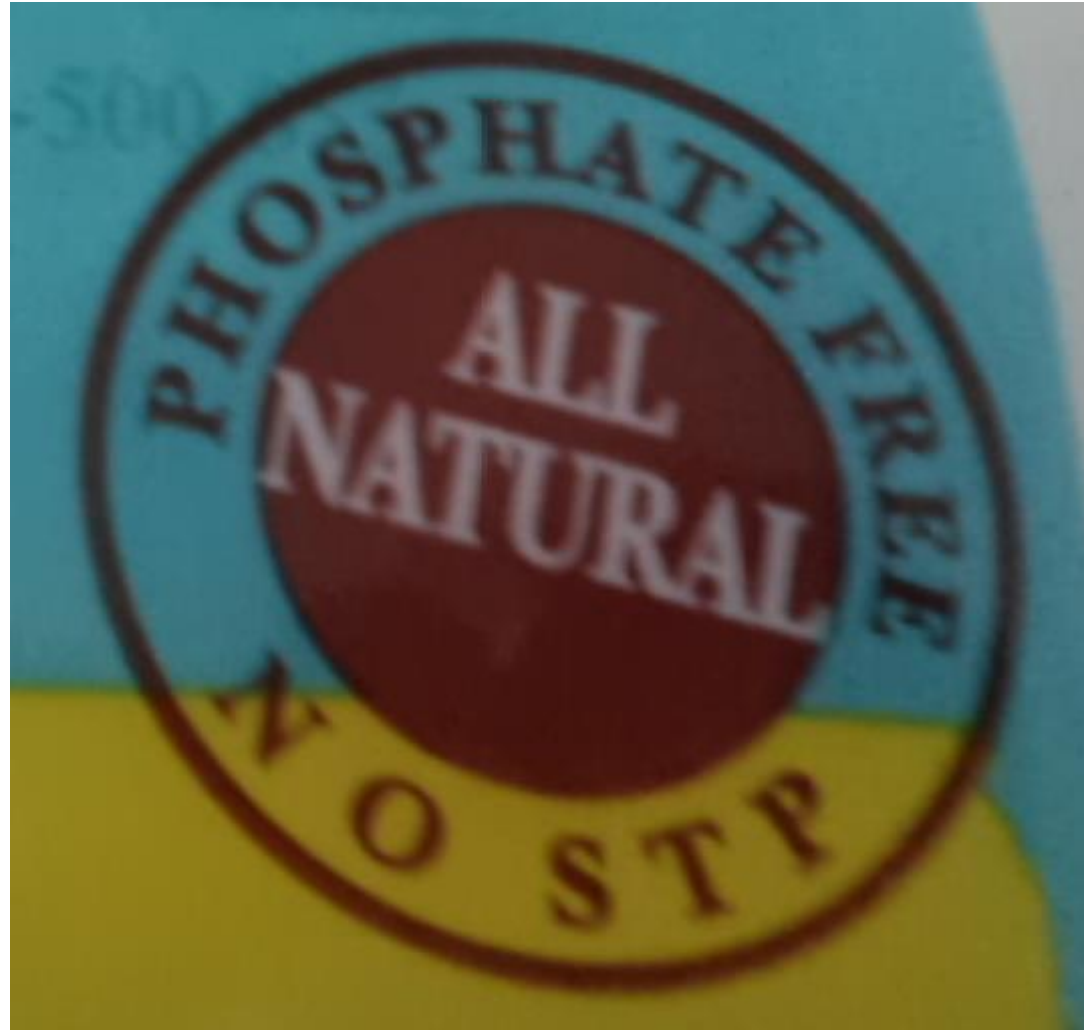
Remember: labels can be misleading if they fail to reveal important facts.

There are no antibiotics or hormones approved for use with raising shrimp so - no shrimp should be processed with antibiotics or added hormones.

Statement is misleading because implies that this shrimp differs from other shrimp.

Is this false? Is this misleading?

As seen on a bag of
frozen shrimp



Phosphate Free

“Phosphate free” is **false**.

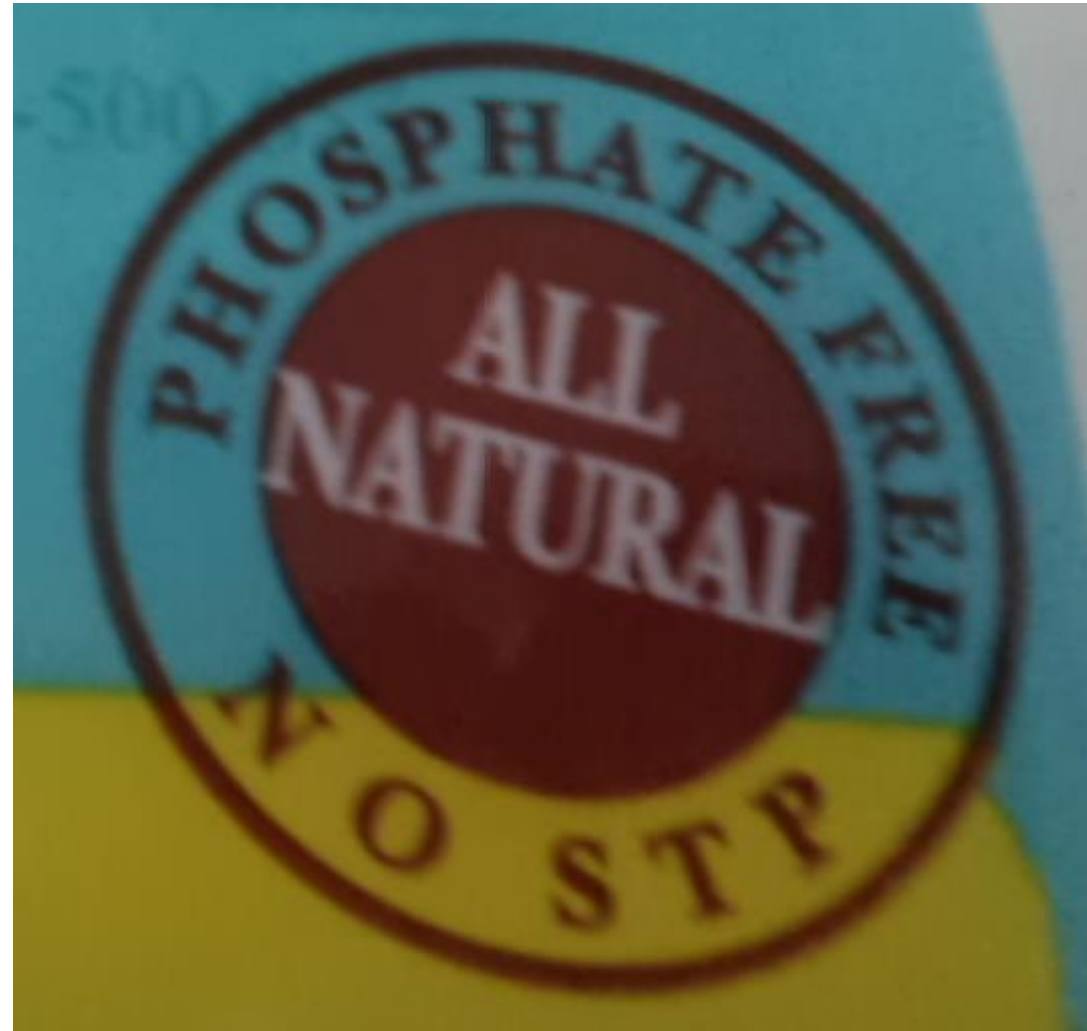
All shrimp naturally contains phosphates.

A more accurate statement would be “no added phosphates”.

Is this false? Is this misleading?

As seen on a bag of frozen shrimp

Ingredients: Shrimp, Water, Salt, Sodium Bicarbonate, Sodium Carbonate, Citric Acid



No STP

“No STP” is meaningless and potentially **misleading** to the consumer because STP is not the common or usual name for the ingredient sodium tripolyphosphate on a label.

A better statement would be “no added sodium tripolyphosphate”.

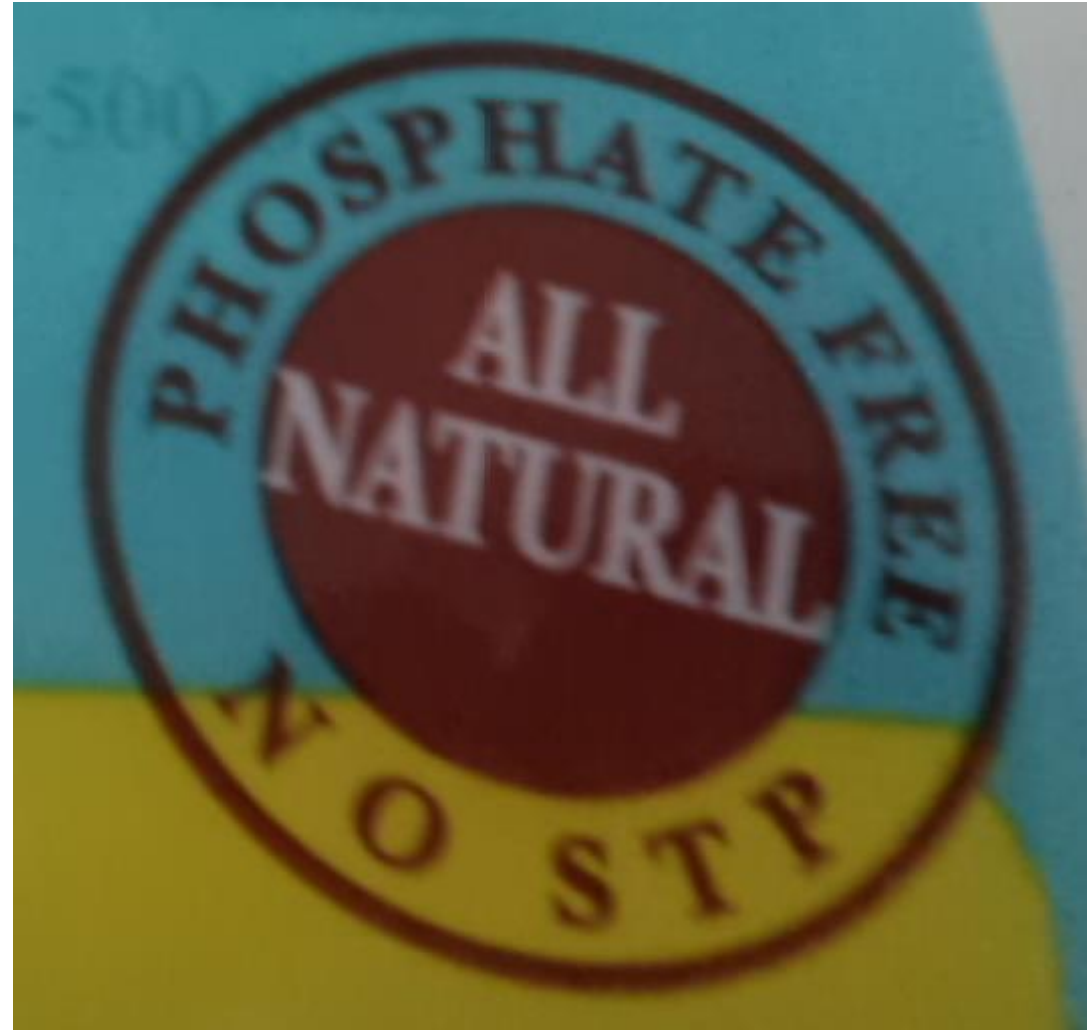
The statement could also be considered **misleading** because it implies that sodium tripolyphosphates are a negative addition to shrimp, especially when non-phosphate moisture retention ingredients are being used to perform the same function.



Is this false? Is this misleading?

As seen on a bag of frozen shrimp

Ingredients: Shrimp, Water, Salt, Sodium Bicarbonate, Sodium Carbonate, Citric Acid



All Natural

There is no regulatory definition of “natural”

FDA’s policy for use of the term natural is the product does not contain any added:

- Color of any source
- Artificial Flavors
- Synthetic (man-made) substances



Natural

A natural sounding ingredient does not necessarily mean it qualifies as “natural”. Ingredients can be formulated in different ways – sometimes by a natural process and other times synthesized

Misuse of the term “natural” on a label can cause the product to be **misbranded**.

And became fodder for a class-action lawsuit.

Class Action Lawsuits

Newman's Own Pasta Sauces

“all natural” claim but products contain citric acid, “a non-natural, chemically processed ingredient”

Barilla Pasta Sauces

“No Preservative” claim but product contains citric acid, a preservative.

Does it Really Matter?

Bottom line: all aspects of labels must be truthful and not mislead the consumer



With Every Label Statement

Ask yourself:

Is the statement false?

Is it true?

Is the statement misleading?

REMEMBER:

A truthful statement could also be misleading.





Questions?

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Quiz Time – is this misleading?



	Sophie's Kitchen Breaded Vegan Coconut Shrimp	Brand X Coconut Shrimp
Serving Size (g)	110	110
Calories	286	243
Total fat (g)	22	11
Saturated Fats (g)	9	2.5
Sodium (mg)	352	467
Carbohydrate (g)	22	24
Protein (g)	2.2	10.7

Quiz Time – is this misleading?



Must state “imitation” if it is nutritionally inferior to the food it is mimicking.