USA market for Sacha Inchi

NEXT STEP FOR THE INDUSTRY?

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How to enter the USA market

- I am do not have all of the answers
- I am here to make suggestions to pull the industry forward so all can benefit
- Sacha Inchi is “not” the perfect product, however, it has potential and the opportunities need to be explored.
- Care must be taken to keep supply in line with demand. It is important that people produce what they can sell not sell what they produce.

GRAS

- **What does "GRAS" mean?**
- "GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, **among qualified experts**, as having been **adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.**

What are the criteria for GRAS status?

- The use of a food substance may be GRAS either through **scientific procedures** or, for a substance **used in food before 1958, through experience based on common use in food.**
  - General recognition of safety through **scientific procedures** requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is **based upon published studies**, which may be corroborated by unpublished studies and other data and information.
  - General recognition of safety through experience based on common use in foods requires a **substantial history of consumption for food use by a significant number of consumers**.

Requirements

- **In what way are the criteria for the use of a substance to be GRAS similar to that for the approved use of a food additive?**

  Regardless of whether the use of a substance is a food additive use or is GRAS, there must be **evidence that the substance is safe under the conditions of its intended use.**

- FDA has defined "safe“ as a reasonable certainty in the minds of **competent scientists that the substance is not harmful under its intended conditions of use**. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

In what way are the criteria for the use of a substance to be GRAS different from that for the approved use of a food additive?

- A GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use. The data and information relied on to establish the safety of the use of a GRAS substance must be generally available (e.g., through publication in the scientific literature) and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. Thus, the difference between use of a food additive and use of a GRAS substance relates to the widespread awareness of the data and information about the substance, i.e., who has access to the data and information and who has reviewed those data and information.
  - For a GRAS substance, generally available data and information about the use of the substance are known and accepted widely by qualified experts, and there is a basis to conclude that there is consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.

If an ingredient is GRAS for one use, is it GRAS for all uses?

- Not necessarily. It is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption.
- A determination of the safety of the use of an ingredient includes information about the characteristics of the substance, the estimated dietary intake under the intended conditions of use, and the population that will consume the substance. Dietary intake of a substance depends on the food categories in which it will be used and the level of use in each of those food categories.

Must FDA approve GRAS substances?

- No. If the use of a food substance is GRAS, it is not subject to the premarket review and approval requirement by FDA.

Does FDA currently have a program to affirm that one or more uses of a food substance are GRAS?

At this time FDA is not committing resources to the review of GRAS affirmation petitions.

- **What is the GRAS notification program?**

The GRAS notification program is a voluntary procedure that is intended to providing a mechanism whereby a person may inform FDA of a determination that the use of a substance is GRAS, rather than petition FDA to affirm that the use of a substance is GRAS. The submitted notice includes a "**GRAS exemption claim" that includes a succinct description of the substance, the applicable conditions of use, and the statutory basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food).** A GRAS notice also includes information about the identity and properties of the notified substance and a discussion of the notifier's reasons for concluding that the substance is GRAS for its intended use.

How long will it take to receive a response from FDA?

Their goal is to respond to most GRAS notices within 180 days.

- **If we submit a GRAS notice about a food substance, must you wait until you receive a response from FDA before I market that substance?**

  No. If we are correct in determining that the intended use of Sacha Inchi is GRAS, use of the ingredient is not subject to any legal requirement for FDA review and approval. The decision to submit a GRAS notice is voluntary, and FDA's response to a GRAS notice is not an approval. We may market a substance that you determine to be GRAS for a particular use without informing FDA or, if FDA is so informed, while FDA is reviewing that information. The FDA recognizes, however, that some firms prefer to know that FDA has reviewed its notice of a GRAS determination, without raising **safety or legal issues, before marketing**.

Can the use of a substance be GRAS even if it is not listed by FDA?

- Yes. Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of the GRAS.
- **The use of a substance is GRAS because of widespread knowledge among the community of qualified experts, not because of a listing or other administrative activity.**

The problem with promotion of Omega's

- "Pharmacy companies may invest tens or even hundreds of millions of dollars in developing a single patented new drug. …since Omega 3 fatty acids are natural substances….they are unattractive to pharmacy companies…without a corporate sponsor, the Omega-3 fatty acids are likely to remain pharmaceutical orphans….As awareness of the health benefits of the Omega-3's grows, perhaps the public itself will compel the medical profession to incorporate them in routine practice."
  - Dr. Andrew L. Stoll – The Omega-3 Connection

Problems

- USA companies have liabilities without GRAS status
- Companies reluctant to import without assurance of customs clearance
- Market without GRAS status is limited

Eliminate the problems

- “Be your own importer” for trial shipment
- Shield the importers from risk
- Prove importing is possible and achieve GRAS status

Recommendations

Activity	Cost
Open USA importing and marketing arm	$600
Work with Dr. Luis Cisneros-Zevallos of Texas A&M on GRAS paperwork	$20,000
Get Liability insurance for product	$1,000 - $6,000
Make commercial shipment of drum and bottles to USA	Cost
Clear customs	?
If customs not cleared return shipment	Cost
Work with Texas A&M to do more research and tests	$30,000 - $100,000
Establish industry marketing strategy and fund	?