

## FACT SHEET

# DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT



## WHAT IS DSHEA?

Congress passed The Dietary Supplement Health and Education Act of 1994 in response to a increased pressure to regulate dietary supplements and provide consumer education. DSHEA established a new regulatory framework for dietary supplements, in part by distinguishing them from drugs and food additives.

In short, DSHEA, which moves regulation under the jurisdiction of the Food and Drug Administration, clearly defines what constitutes a dietary supplement. Additionally, under DSHEA, dietary supplement companies are responsible for substantiating the safety of the ingredients used in making supplements.

Companies are also responsible for determining that any representations or claims made about their products are substantiated by adequate evidence to show they're not false or misleading.

**DSHEA defines dietary supplements as products taken by mouth that contain a “dietary ingredient” and can include:**

- vitamin and mineral products
- “botanical” or herbal products
- amino acid products
- enzyme supplements

## HOW DOES TRACEGAINS ENSURE DSHEA COMPLIANCE?

TraceGains helps companies efficiently comply with the dietary supplement CGMPs mandated by DSHEA. Specifically, TraceGains implements standardized processes and tools to assist supplement makers in qualifying suppliers and their raw materials, in part by building upon the Standardized Information on Dietary Ingredients (SIDI™) Work Group's recommendations.

The SIDI Work Group is a coalition of three industry trade associations—the Consumer Healthcare Products Association, the Council for Responsible Nutrition, and the United Natural Products Alliance—and a number of their member representatives. The SIDI Work Group has published a set of material datasheet templates, for both botanic and non-botanic ingredients, which are included in TraceGains and expanded on — making it easy to build and compare raw material specifications and streamline the qualification process. The primary goal is to standardize the process of qualifying and managing suppliers and their raw materials to increase efficiency (for both customers and suppliers) and ensure compliance with federal regulations.

## LEARN MORE ABOUT TRACEGAINS

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