TRACEGAINS

Five Things to Expect from DSHEA 2.0

A New Era of Compliance

Table of Contents

Introduction

It's almost unheard-of for an industry to ask for more regulation. But that's exactly what several major players in the dietary supplements and natural foods space have done in recent years. Current regulations, industry insiders argue, haven't kept pace with a changing world.

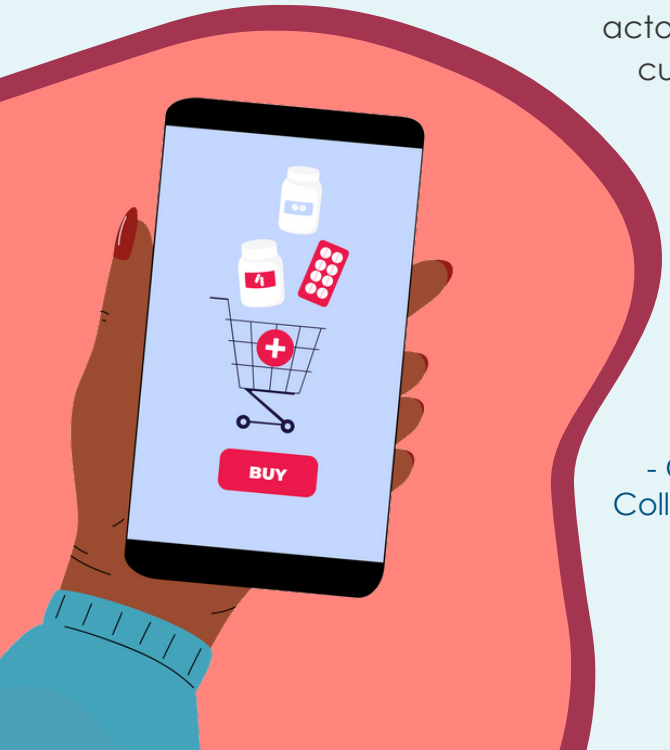
More than 26 years ago, when Congress passed the Dietary Supplement Health and Education Act of 1994, the industry began to break into the mainstream with $4 billion in annual sales and roughly 4,000 product offerings.

The Industry Has Evolved

Today, experts estimate there are between 50,000 and 80,000 unique nutritional supplements on the market worldwide, generating over $170 billion in sales in 2020. With the US market growing 12% in 2020, reaching a record $52 billion.

"I'm concerned that changes in the supplement market may have outpaced the evolution of our own policies and our capacity to manage emerging risks," then-Food and Drug Administration Commissioner Dr. Scott Gottlieb told the Washington Post in 2019.

Some would argue Gottlieb greatly underestimated the situation. Despite success, bad actors pose a significant threat to the industry's reputation. Stakeholders insist more current and robust regulations can eliminate bad actors while also increasing consumer confidence in nutritional supplements.



"Additional regulatory oversight could be favorable to both consumers and responsible actors within the industry, although the overall impact of that oversight will largely depend on the modifications that the agencies make first and the methods they will use to implement their actions."

- Christine Burdick-Bell, Steering Committee Chair, Dietary Supplements Quality Collaborative (DSQC)

Regulators are Paying Attention

The pandemic has led to a record number of consumers turning to supplements to boost immunity. "From March to May 2020, just about any ingredient in the immune category was flying off shelves," Healthy Directions Vice President, Product Development & Quality Assurance Irfan Qureshi told Nutritional Outlook. "Going forward, savvy consumers will have the ability and wherewithal to focus on those that have more robust substantiation and science, and it will be these ingredients that rise to the top."

More Regulations Ahead

But the forecast is not all optimistic. Regulators have turned their attention to the supplements industry in recent years with a renewed focus. And as Democrats take back the White House and Senate, industry insiders expect a heavier regulatory hand in the years ahead.

"Every regulated industry recognizes the need for increased vigilance whenever the Democrats are in charge of the White House and both houses of Congress. The Democrats are more prone to propose new regulations since they are, as a rule, more protective of consumers and more willing to place more burdens on the industry if they think that supports consumers. The last time the Democrats were in charge of all the levels of government, Congress passed the Food Safety Modernization Act in 2010 (signed into law in January 2011)."

- Michael McGuffin, President, American Herbal Products Association (AHPA)

2020'S MOST POPULAR SUPPLEMENTS

1. Vitamin D
2. Fish Oil/Krill Oil/ Algae Oil/Omega-3
3. Magnesium
4. Multivitamins
5. COQ10/Ubiquinol/ MitoQ
6. Vitamin C
7. Probiotics
8. Zinc
9. Curcumin/Turmeric
10. B-Complex

Source: ConsumerLab.com

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

What Is DSHEA?

The Dietary Supplement Health and Education Act of 1994 (DSHEA) is the federal law regulating the safety and sale of nutritional supplements in the US. DSHEA moves regulation for supplements under the FDA and clearly defines what constitutes a dietary supplement. Under DSHEA, manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. The FDA is responsible for taking action against unsafe dietary supplements after they reach the market.

DSHEA Highlights:

- Reaffirmed the status of nutritional supplements as a food category and created a specific definition for nutritional supplements.
- Established that dietary supplements are not regulated as food additives.
- Created two categories of supplements ingredients "grandfathered," before 10/15/1994, considered safe for consumer use, and "new," which require the submission of a New Dietary Ingredient Notification to the FDA at least 75 days before marketing the new ingredient.
- Confirmed supplements must comply with current Good Manufacturing Practices (cGMPs) and authorized the FDA to establish separate cGMPs for supplements, which they did in 2007, and began enforcing them in 2010.
- Provided the FDA with additional enforcement authority, including the ability to remove products that the agency considers unsafe through:
  1. An "imminent hazard" clause that allows the FDA to immediately remove a product it considers an immediate safety risk, AND
  2. A "significant or unreasonable risk" clause that allows removing a product considered an unacceptable risk of illness or injury.

What Does the COVID-19 Task Force Signal?

Dr. David Kessler vs. the Industry

Soon after his election, President-elect Joe Biden announced his 13-member COVID-19 Task Force, including co-chair Dr. David Kessler, who industry insiders identify as a vocal critic of nutritional supplements and natural products.

Kessler campaigned against DSHEA in 1993, lobbying to limit the health claims supplements manufacturers could make. He also testified in Congress later that same year, calling supplements manufacturers "snake oil salesmen."

After President Bill Clinton signed DSHEA into law, then-FDA Commissioner Kessler so disapproved he instructed the FDA not to enforce the new law.

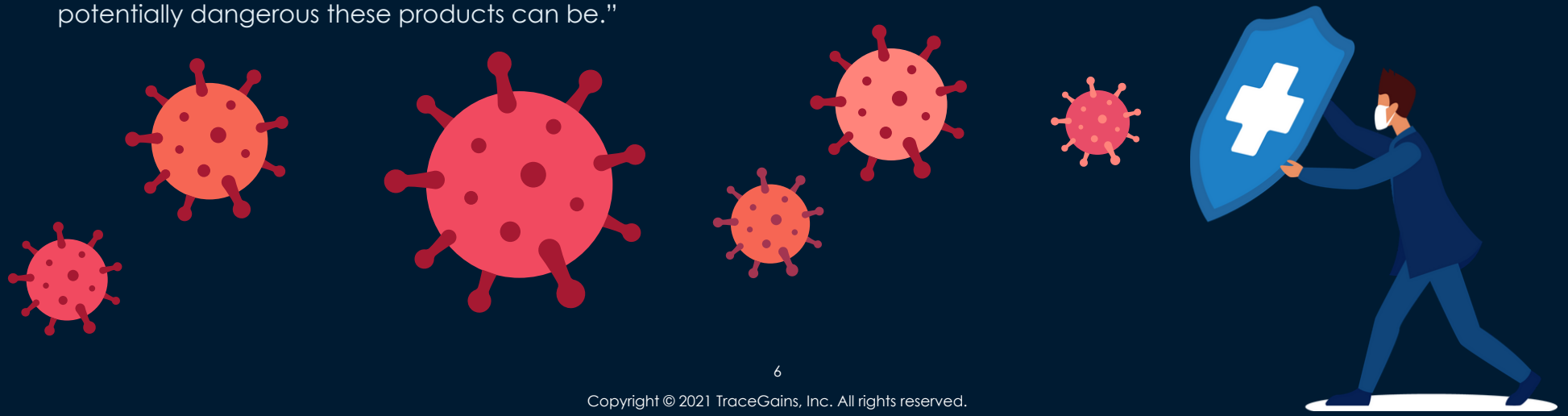
In a 2000 New England Journal of Medicine editorial, Kessler wrote, "Congress has shown little interest in protecting consumers from the hazards of dietary supplements, let alone from the fraudulent claims that are made. Nor does the public understand how potentially dangerous these products can be."

Kessler, who President Biden also tapped to lead the federal government's COVID-19 vaccine efforts, worries industry experts that his pessimistic take on supplements could turn the administration against the industry. Others fear President Biden could even nominate Kessler to resume his role as head of the FDA.

DSHEA 2.0 Is On the Horizon

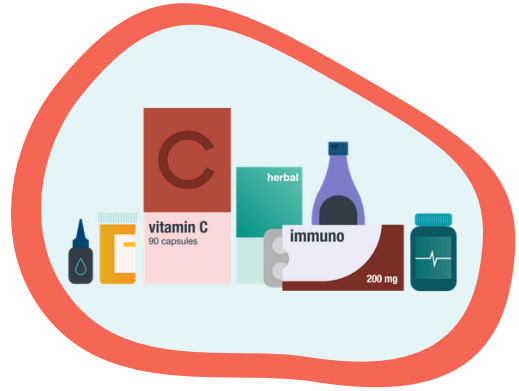
Regardless of who is running the agency, there is little doubt that an updated DSHEA is on the horizon. While trade groups in the industry remain divided on what form this should take, regulators concerned about the spread of fraudulent claims and consumers worried about transparency have been pushing for change.

There are five pillars likely to form DSHEA 2.0, ranging from the introduction of a mandatory product registry to strengthening FDA enforcement.



FIVE THINGS TO EXPECT FROM DSHEA 2.0

No. 1 A Mandatory Product Registry



The FDA has put a mandatory product registry in its annual budget request for each of the last two years. According to that request, "This proposal would require all products marketed as 'dietary supplements' to be listed with FDA and give FDA authority to act against non-compliant products and the manufacturers and/or distributors of such products. This would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products, improve transparency and promote risk-based regulation."

Building on CRN's OWL Database

Although a mandatory product registry has long been the third rail of regulation on nutritional supplements, the industry already has a voluntary, self-regulated database, the Supplement OWL (Online Wellness Library), launched by the Council for Responsible Nutrition (CRN) in 2017 and updated in 2021. The Supplement OWL "serves as a resource for consumers, businesses, and regulators to identify products, their ingredients, and the companies who market them, and permit registry users to examine and evaluate labels and other product information."

According to CRN's VP of Scientific and Regulatory Affairs, Luke Huber, the OWL database contained information on 9,000 individual labels and continues to grow at last count. OWL entries contain a product image, a label, and various data fields, including ingredients, dosage form, label claims, and contact details. CRN requires companies to submit their labels and provide contact information for manufacturing and packaging facilities that are only accessible by the FDA.

"Broad industry participation in the Supplement OWL is critical," Huber explained. "This self-regulatory initiative serves as a model for mandatory product listing, proposed by FDA, and supported by CRN and other responsible stakeholders in the industry."

CRN updated the Supplement OWL "to ease the entry of product information and improve overall user experience," CRN reported in its most recent update, "including the addition of a self-service portal and new tools within the registry to add, edit and remove products more easily."

Other enhancements include multi-factor authentication for participants to add more security for participating companies; a multi-version component to help companies efficiently enter product information for multiple versions of the same product in circulation; and a supplier feature for brand owners to designate their contract manufacturers as a business user with administrative capabilities on their behalf," according to CRN.

NO.1 A MANDATORY PRODUCT REGISTRY

Industry Trade Groups Disagree

Trade groups like CRN and the Dietary Supplements Quality Collaborative (DSQC) support a mandatory product registry approach. "The FDA doesn't really have a way to know what's out there [in the market], and it's hard to regulate what you can't see," DSQC Chair Christine Burdick-Bell told Natural Products Insider.

Consumer groups, like the Center for Science in the Public Interest (CSPI), also want to see a mandatory product registry. "The FDA should require mandatory product listing and registration so that it can track dangerous products and repeat offenders, identify hazards in dietary supplements, and anticipate safety issues," CSPI Director of Strategy and Program Laura MacCleery said in a recent webinar. "This should include important safeguards so that products that are not legal to bring to market are not listed, and retailers must verify the registration via a QR code."

Industry supporters, including CRN CEO Steve Mister, argue a registry would:

- Build a more robust marketplace of responsible companies.
- Make it easier for consumers to recognize trustworthy products.
- Help the FDA identify products in a crisis.
- Encourage compliance with Good Manufacturing Practices (GMPs).
- Shore up the industry's reputation with critics.

Critics of the registry, including trade groups like AHPA, push back with claims that:

- It would impose an undue burden on companies, especially smaller operators.
- The FDA doesn't do enough to enforce the regulations already in place.
- Regulators would take advantage of the database to essentially turn it into a tool for premarket review.
- It would serve as a launchpad for plaintiffs' attorneys eager to pursue class-action suits.

A Mandatory Product Registry Is Likely Inevitable

According to multiple industry insiders, it's not about whether, but when, the nutritional supplements industry gets a mandatory product registry. The best way for stakeholders to prepare for this eventuality is to adopt digital records management, which will make any transition to a national registry smoother.

Mandatory product registration is a good start and would help to catch us up with the rest of civilization," Alkemist Labs CEO Elan Sudberg wrote in a blog post. "Yes, it'd be painful, but it'd also be extra painful for those unscrupulous players we're trying to remove."

FIVE THINGS TO EXPECT FROM DSHEA 2.0

No. 2 Modernize Adverse Event Reporting

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 requires dietary supplements manufacturers, packers, and distributors to report Serious Adverse Events (SAEs) to the FDA via the electronic MedWatch Form 3500A within 15 business days of receiving the complaint. Companies also must keep records of non-serious adverse events for six years.

However, in March 2020, the FDA offered further guidance that allowed companies struggling with employee absenteeism due to the pandemic to store SAEs and report them to the FDA within six months "after the restoration of normal activities."

The FDA defines a serious adverse event as a situation that results in any of the following outcomes:

- Results in death.
- A life-threatening experience.
- Inpatient hospitalization.
- A persistent or significant disability or incapacity.
- A congenital anomaly or congenital disability.
- Requires medical or surgical intervention to prevent an outcome described above.

The Center for Food Safety and Applied Nutrition Adverse Event Reporting System (CAERS) database is publicly available and includes:

- Demographic and administrative information and the CAERS report ID number.
- Product information from the case reports.
- Symptom information from the reports.
- Patient outcome information from the reports.

But it's not as simple as that. Critics of the existing system say more data and context is needed to prevent confusion.

NO. 2 MODERNIZE ADVERSE EVENT REPORTING

Experts Point to Gaps in Current SAE Reporting

There are many who believe the current requirements for SAE reporting are not only insufficient, they cause confusion. According to SafetyCall International Co-Founder Dr. Richard Kingston, FDA adverse event reporting (AER) doesn't typically include:

- Information on underlying medical conditions.
- Concomitant use of medications.
- The exact ingredients involved.

Missing AER Data

"Even though FDA makes AER data available, fields that may prevent misinterpretation of the data are omitted, including FDA's assessment of causation," Kingston said. "Similarly, studies analyzing emergency department visits and exposures reported to poison control centers fail to provide proper context by not considering the rarity of events in comparison to the billions of servings used by consumers."

Worse still, consumer advocates claim the FDA often omits product names to promote better reporting. Consumer reports found that more than 19,700 products in the database, 15% of the total, had redacted the product names. The FDA has accelerated this practice in recent years, and "in 2019, alone, filed twice as many reports as in the first decade of CAERS operation, which was launched in 2003."

Insufficient communication between national and international regulators monitoring potential public health risks exacerbates the problem.

Advocates argue DSHEA 2.0 should include more robust SAE reporting, which would require the addition of the following:

- A more comprehensive approach to data collection.
- Improved coordination between regulatory agencies.
- Better public healthcare education.
- Additional dietary supplement research.

More Proactive Supplements Makers

With this new approach, supplements manufacturers should be prepared to take a more proactive, systematic, and scientific approach to product safety.

Consumer watchdog CSPI, however, would like to see this go a step further, as MacCleery said, "Supplement companies should report all adverse events linked to their products by having to report all events, and not merely those they self-designate as 'serious.' In addition, labeling should include a 1-800 number for consumers to directly report adverse events to the FDA." These additional practices would go a long way toward improving transparency between consumers and dietary supplements producers.

No. 3 Fixing the Generally Recognized as Safe (GRAS) Provision

When launching products, supplements manufacturers must inform the FDA of any new ingredients they use. To counter the industry's fears of wholesale pre-market reviews, the FDA issued guidelines in 2016, which allowed dietary supplements manufacturers to avoid this notification process by declaring new ingredients as "generally recognized as safe" (GRAS).

What is the GRAS Rule?

Under an earlier FDA rule, regulators could grant an ingredient the GRAS designation if it meets basic guidelines for food additives. Members of the scientific community could demonstrate it wasn't harmful.

The rule addresses the types of scientific evidence that can be used to demonstrate safety as well as the role of publications in evaluating whether the scientific evidence of safety is 'generally available and accepted. "The GRAS criteria require the safe use of ingredients in human and animal food be widely recognized by the appropriately qualified experts," the FDA guidance reads.

Eliminating the GRAS Loophole

Critics claim this allows manufacturers to circumvent the spirit of the law by hiring experts to say that a new ingredient qualifies under the GRAS provision.

MacCleery of the CSPI argued that Congress never intended to allow companies to self-determine the safety of an ingredient. The only reason they allowed DSHEA to defer ingredients in the food supply was that regulators expected these ingredients to undergo a nominal review.

The FDA should revise its guidance documents and rules to prohibit supplement companies from using the GRAS loophole to secretly self-affirm that new ingredients and uses are safe without FDA review," she said. "A New Dietary Ingredient review (NDI) should be required for every novel ingredient in supplements, and the FDA should be directed to revise, by a certain date, its guidance and rules to strengthen the NDI review process."

No. 4 Mandate Supplement-Drug Interaction Label Warnings

Dietary supplements can either enhance or irritate the effects of prescription and over-the-counter medications. St. John's Wort is the most notable example of this type of reaction. The problem is widespread, since more than a third of American consumers take some form of dietary supplement along with prescription medication, according to FDA research. And most of those consumers don't tell their doctors they're taking a supplement.

Although there are at least a half dozen websites that describe drug-supplement interactions, most consumers are unaware of the potential risks. For this reason, consumer advocacy groups are increasingly calling for drug-supplement interaction warnings on product labels. Supporters say it's a simple fix that would help educate consumers while keeping them safe. However, opponents counter that dietary supplements makers already face a daunting list of label requirements.

"Dietary supplement and functional food companies must carefully evaluate product liability issues when crafting product labels, claims, and warnings," Rubin explained. "In determining whether to include an herb/drug interaction warning on product labeling, a variety of issues should be evaluated, including, but not limited to: (1) the likelihood of a potential interaction; (2) the potential severity of a potential interaction; (3) whether the interaction is well known by the general population or scientific community; (4) whether drug product labeling already warns against ingestion of the herb or dietary supplement; and (5) the level of the herb present in the dietary supplement."

Paul D. Rubin, Partner of Patton Boggs Food and Drug Practice Group, suggests manufacturers consider four crucial factors when drafting supplement-drug interaction warnings.

1 Think About The User

Warnings should be clear, concise, and written in plain language, assuming professional advice may not be available.

2 Offer Relevant Information

Include information regarding the probability of potential adverse events, including the possible severity.

3 Prominence is as Critical as Content

The interaction warning isn't worth much if the company doesn't display it prominently enough.

4 Consult a Physician, Maybe?

Experts insist including a disclaimer to consult a physician on the label, with no language, might be insufficient.

No. 5 Stronger Office of Dietary Supplement Programs (ODSP) and FDA Enforcement

DSHEA established the Office of Dietary Supplement Programs (ODSP) to "strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population."

But industry insiders maintain ODSP needs more funding and staff, especially since it remains one of the smaller divisions of the FDA, despite the booming industry it regulates.

With sufficient resources for more robust enforcement, Burdick-Bell says ODSP can better protect consumers "from intentionally adulterated or misbranded products marketed as dietary supplements."

CSPI's MacCleery echoed that sentiment in a recent webinar, "The dietary supplement division is under-resourced and cannot keep pace with the large numbers of producers and products," she said. "Its budget should be doubled, and enforcement attention focused on tainted supplements.

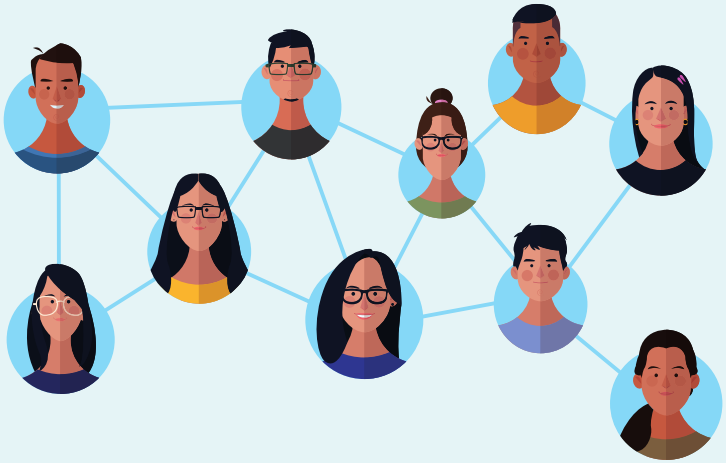
ODSP Acting Director Cara Welch announced in March that the agency chose three primary 2021 objectives, "safety, product integrity, and informed decision-making."

"We're also focused on making internal improvements to improve ODSP's operations, including implementing a reorganization of ODSP to maximize the value of new positions funded by increased appropriations and establishing a blueprint for future office growth and continued success," Welch added.

A More Proactive FDA

More than anything, industry insiders want an FDA that does more than it has over the last few years. Guidance has fallen off to a trickle, and the agency – along with Congress – has made no movement on clarifying the legal status of CBD and hemp.

"We saw so little activity this past year. We were all clamoring for CBD to be resolved. FDA's activity lately has not been good, frankly speaking," the Natural Products Association Daniel Fabricant told Nutritional Outlook. "They haven't been strong on things we need them to be strong on. We'd like to see that change—but we don't want to see overreach. We're glad to see inspections back up and running, but there really hasn't been any discussion on what that means, what that entails, and how the gaps are being filled. The agency at some point needs to be a lot more transparent, and I hope that's what happens in 2021, but I don't have a good feeling about that."



FIVE THINGS TO EXPECT FROM DSHEA 2.0

TraceGains Facilitates DSHEA Compliance

TraceGains provides networked regulatory compliance, quality assurance, and product development solutions to supplement makers and brand owners that want to reduce supply chain risk, speed up business processes, and take control of data. TraceGains helps companies more efficiently comply with DSHEA.

With TraceGains, you can transform a tangled web of manual and disconnected supplier, sourcing, quality assurance, document management, and product development steps into a highly automated and orchestrated digital workflow that's tracked for a complete audit trail.

Network connectivity gives teams instant access to more than two million supplier-provided documents. Teams leverage existing supply chain data, specifications, and product-related data to build claims. And a library of over 300,000 digitally integrated scientific studies lets teams search by health condition, study type, journal ranking, or published date range. Once teams locate the documentation they need, they directly link it to the ingredient or claim, ensuring all associated formulas or recipes contain the appropriate documentation.

Alerts remind your team to conduct real-time tasks alongside automated steps to improve consistency, eliminate errors, enable measurements, and vastly increase outcome reliability and quality. And all of this is visible to everyone on the team with any connected device.

About TraceGains

Founded in 2008, TraceGains connects people and information so teams can work smarter. As a global technology company, TraceGains provides networked innovation, quality, and compliance solutions to consumer brands that want to reduce supply chain risk, speed up business processes, and take control of data. On average, companies find 80% of their suppliers already on TraceGains Network, allowing them to connect and collaborate instantly.

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