

BIOLOGICALLY ACTIVE FOOD SUPPLEMENTS:

RUSSIA



Compliance Deadlines & TraceLink Solution Overview



Want an in-depth look at the new compliance requirements and what you need to do to meet them in time for the deadlines? Watch this webinar for your complete roadmap to compliance.

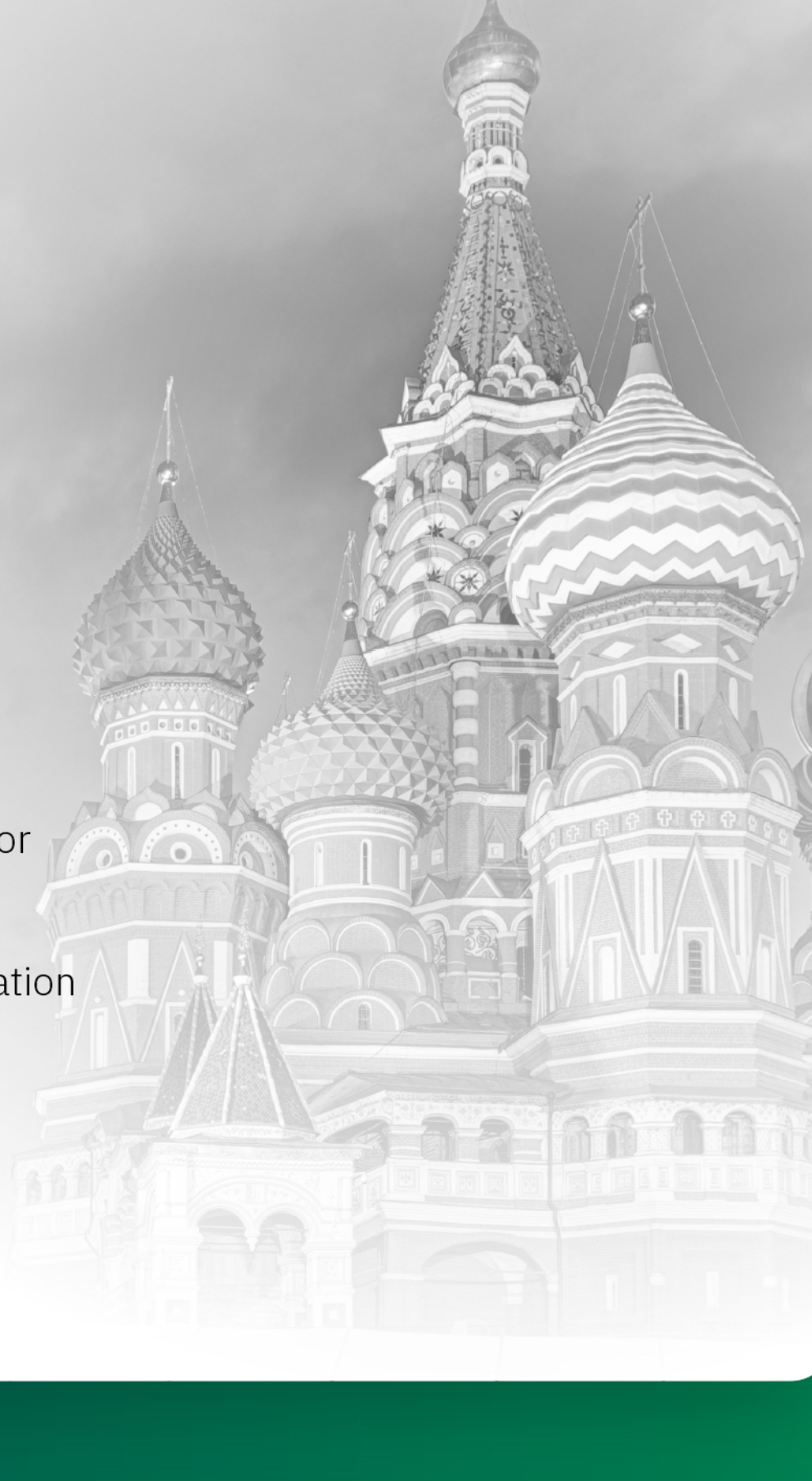


What is the Law?

On May 31, 2023, the Russian government signed Decree 886 into law, which establishes new track-and-trace requirements covering biologically active food supplements (BAFS) such as vitamins and minerals. The law requires the use of Chestny ZNAK, a government information system for monitoring trade goods that is also used for several other product categories, including medical devices.

To comply with the requirements outlined by this regulation, manufacturers, importers, and distributors must be able to:

- ✓ Acquire, receive, and exchange crypto codes with serialization data for biologically active food supplements.
- ✓ Capture key supply chain events such as commissioning and aggregation information from packaging lines and contract packagers.
- ✓ Create properly formatted reports for supply chain events, securely connect to government systems for electronic transmission of compliance reports, and maintain a compliance system of record.



Important Compliance Deadlines

The digital marking and serialization requirements outlined by Decree 886 go into effect over a series of deadlines spanning a two-year period between 2023 and 2025. Failure to comply could result in government fines or penalties incurred from trading partners.

Companies operating in this space must be prepared for six deadlines.

DEADLINE	REQUIREMENT
September 1, 2023	All food supplement products and the entities involved in the distribution of food supplement products must be registered in the Russian government's track-and-trace system (TT GIS).
October 1, 2023	All regulated products must be marked with crypto codes. Utilization, aggregation, and introduction into circulation reports must be submitted to TT GIS.
November 1, 2023	Importers must include the marking codes of consumer packaging and the codes of group packaging units in their customs declarations.
March 1, 2024	All stakeholders must begin reporting product withdrawal from circulation, including at the point of sale.
May 1, 2024	All stakeholders must start using the electronic document exchange system (EDO) to report the sale and receipt of products using GTIN-level reporting.
September 1, 2025	All stakeholders must have implemented unit-level traceability for food supplement products.



Key Capabilities Manufacturers, Importers, & Distributors Need for Compliance

Russia's challenging new food supplement mandates include a high number of supply chain events that manufacturers must monitor for and a complex process for assembling compliance reports.

To meet these requirements and achieve compliance at scale, manufacturers will need a host of new capabilities.

Integration with Critical Internal, Partner, and Government Systems

Serialization and reporting data will need to be exchanged with trading partners and government systems. This includes connecting to the OMS to request and retrieve crypto codes as well as integrating with packaging and distribution partners and the TT GIS for report submission and orchestration.

Supply Chain Event and Product Movement Detection

Companies must be able to monitor for specific supply chain events and product movement so these activities can be reported to the government. Detection of these events must be automated to ensure that the distribution of the product between trade partners is not delayed.

Serial Number and Crypto Code Management

Crypto codes and serial numbers are a core component of Russia's serialization program. Manufacturers will need to be able to simplify and automate the process of requesting and receiving crypto codes from the Russian OMS and creating and allocating crypto code and serial number pairs to line management systems and contract manufacturers and packagers.

Event Triggers for Report Automation

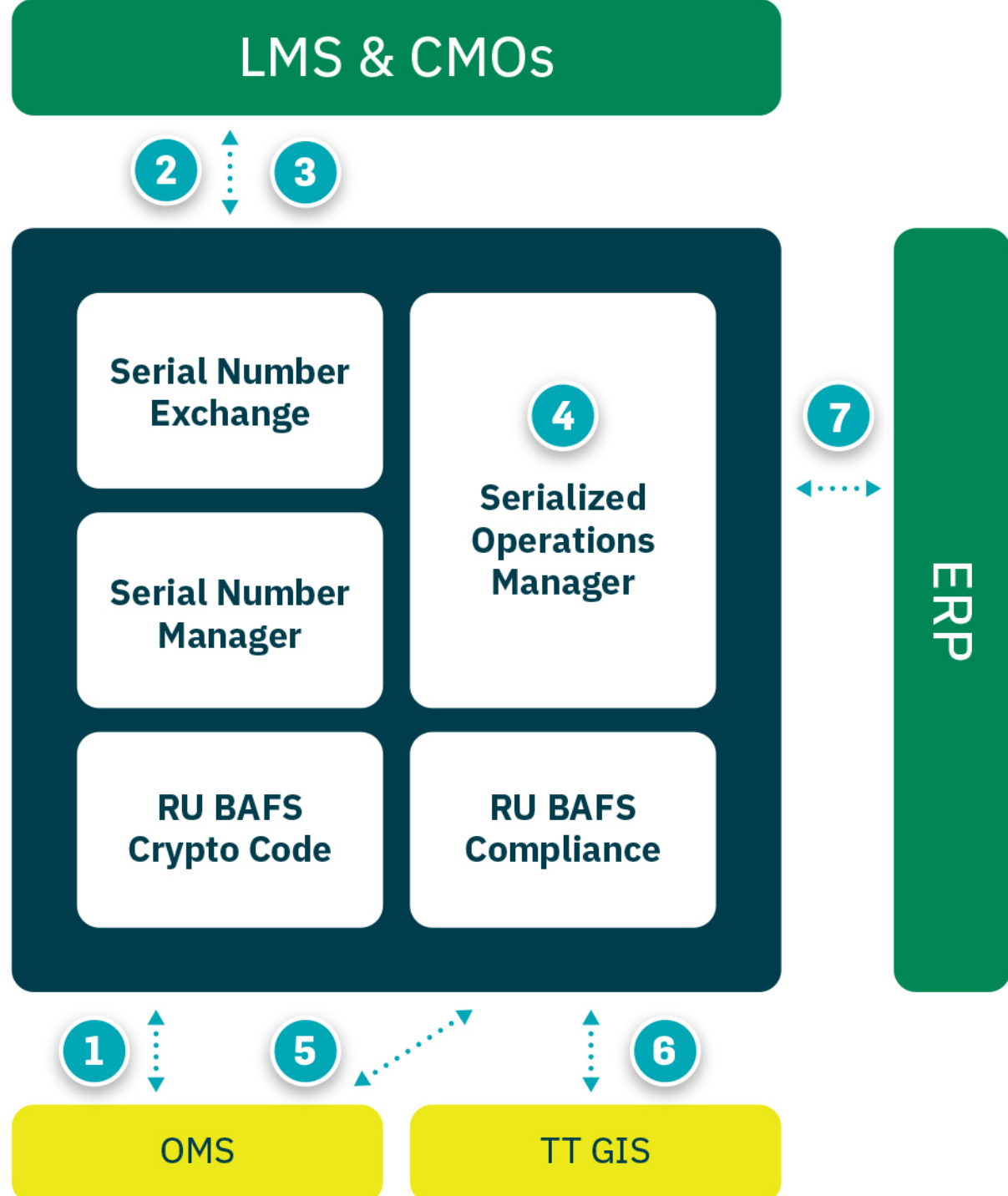
Once a supply chain event or product movement covered by the regulation is detected, companies need to create properly formatted reports and submit them to the TT GIS central system. Given the frequency of these events, companies will need a way to automate the reporting process to minimize the risk of delays and reporting errors.



Reduce the Cost & Burden of Russia BAFS Compliance with TraceLink

TraceLink Russia BAFS Compliance is the ideal solution for meeting the food supplements requirements. The solution comes pre-integrated with business logic to detect specific packaging and supply chain events and workflows for automating compliance reporting. It also simplifies integration with relevant trading partners and government systems through a single connection to the TraceLink network that enables the electronic exchange of serialization and reporting data.

- 1 The Russia BAFS Crypto Code application requests and receives crypto codes from the OMS system.
- 2 Serial numbers and crypto codes are allocated to LMS and CMO partners as required.
- 3 Commissioning and aggregation information is sent to TraceLink once serial numbers/crypto codes have been applied.
- 4 Data is stored in Serialized Operations Manager (SOM) and event triggers send SOM events to Russia BAFS Compliance.
- 5 Russia BAFS Compliance sends utilization and aggregation reports to the OMS system.
- 6 Russia BAFS Compliance sends reports for release to circulation, withdrawal, and other SOM events to TT GIS.
- 7 The SOM API is used to request serialization data from SOM and send it to the customer's ERP for further sale/receipt reporting via the EDO.



Why TraceLink?

TraceLink is the only solution provider proven to effectively manage compliance requirements while tackling multienterprise business challenges at global network scale. With over 130 manufacturers using our Russia compliance solutions, TraceLink has unsurpassed domain expertise covering the most complex serialization requirements in the world.

With just a single integration, the TraceLink network enables organizations to seamlessly exchange serialization data and compliance information with trade partners and government systems across the end-to-end pharmaceutical supply chain.



130+ customers using TraceLink compliance solutions for Russia



930+ distribution and logistics customers and partners



290K+ authenticated and onboarded network members



919M+ regulatory documents processed & exchanged



\$4.7B+ in customer savings by avoiding point-to-point integrations



7.3K+ live CMO connections across more than **1,300** customers



14.9K+ live serialization connections



41.1B+ serial numbers commissioned to date

Get Started on Your Compliance Journey Today

Accessing regulatory information, guidelines, and requirements related to product serialization and traceability in Russia can be difficult, especially for foreign companies with a limited footprint in the country. TraceLink experts are available to help you bridge that gap.

Contact TraceLink at RussiaCompliance@TraceLink.com for more on Russia's food supplements compliance requirements and our solution's capabilities. You can also learn more about [TraceLink Russia BAFS Compliance on our website](#).

ATTENTION TRACELINK CUSTOMERS

Access our customer-only [Eurasian Economic Union+ Innovation Forum](#) for more information about the Russia food supplements compliance requirements and our solution's capabilities.