

# One-Day BADI Training Course

**Area: Food Supplements and Regulatory Developments in the European Union Date: March 27, 2026**

**Organizer: Bulgarian Association for Drug Information (BADI)**

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## Bulgarian Association for Drug Information (BADI) is organising

**ONE DAY TRAINING COURSE - 27.03.2026 - Free for BADI Members**

- 1. New dossier' evaluation approach of food supplements presented by the Bulgarian Agency for Food Safety. Examples from the practice**  
*Dr. Kamen Nikolov (Head of Department in the Food Control Department at the Central Directorate of the Bulgarian Food Safety Authority)*



- 2. Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024 amending Regulation (EC) No 1234/2008 as regards the examination of variations the terms of marketing authorisations for medicinal products for human use**

*Assos. Prof Lyubina Todorova, Director of Marketing Authorisation Department of Medicinal Products; Bulgarian Drug Agency (BDA)*

*Silvia Tsvetkova - Chief Expert, Validation and Community Procedures Division, Marketing Authorisation of Medicinal Products Dept. Bulgarian Drug Agency (BDA)*



- 3. View of the industry - Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024**

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## Event Overview

The Bulgarian Association for Drug Information (BADI) held a one-day specialized training course focused on the current regulatory requirements and the dynamically developing regulatory framework in the field of food supplements and variations of medicinal products.

Over 90 experts from the Bulgarian Medicines Agency (BAMA), the Bulgarian Medicines Executive Agency (BDA) and the Bulgarian Food Safety Agency (BFSA) participated in the training, who presented practical guidelines, updates to the regulatory framework and strategic considerations, consistent with the current legislation of the European Union.

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## Lecture 1

### **Main Highlights from the BFSA**

Presented by **Dr. Kamen Nikolov**, Head of Department, Food Control Directorate, Central Office of the Bulgarian Food Safety Agency

#### **1. Digitalization of regulatory procedures for food supplements**

A key element of the training was the presentation of the upcoming introduction of a system for electronic submission of applications through a web-based interface integrated with the BFSA register.

#### **Main features:**

- AI-assisted submission process aligned with the existing regulatory procedures
- Automated check for completeness and compliance of the documentation



Providing real-time guidance during the submission process and development of a webchat system for communication with applicants. Expected impact:

- Reduction of administrative inconsistencies
- Optimization of processing timelines
- Alignment with EU digitalisation policies

Limitations and risks:

A system that is not sufficiently optimized may lead to additional administrative burden, despite **the intended goals of digital transformation.**

### 1. Updates to the EU Novel Food Catalogue

Significant changes were presented concerning the eligibility of ingredients used in food supplements, in accordance with the EU Novel Food Catalogue.

**Examples of restrictions include:**

- *Agaricus subrufescens* only the fruiting body is permitted
- *Ajuga turkestanica* → prohibited
- *Apigenin* ( $\geq 98\%$ ) → prohibited
- *Crithmum maritimum* → prohibited
- *Jasminum sambac* → prohibited
- *Lignosus rhinocerus* → prohibited

**Regulatory implications:**

- Increased compliance requirements
- Need for product reformulation
- Restriction on the use of insufficiently characterized ingredients



### Regulatory and market impact

A clear trend toward increased regulatory control is observed.

**For marketing authorization holders/operators:**

- Need for continuous monitoring of regulatory changes
- Increased risk of non-compliance
- Greater need for specialized regulatory expertise

**For the market:**

- Shift toward well-characterized and safe substances
- Restriction of misleading or borderline products
- System weaknesses – lack of a unified information system to support the structuring of an online catalogue of validated food supplements

So, the direction is obvious: cleaner market, fewer “creative” products, and a lot more pressure on anyone trying to stay compliant. Also, no central system... which is impressive, considering how much everyone talks about digitalization like it's already solved

## **Lecture 2**

**Speakers from Bulgarian Drug Agency (BDA)** – Assoc. Prof. Dr. Lyubina Todorova, Director of the “Marketing Authorization” Directorate, and Silvia Tsvetkova, Expert in the “Validation of EU Procedures” Department

### **Reform of the Variations Regulation (EU) 2024/1701**

The second part of the training focused on the key amendments to the regulatory framework for variations of medicinal products, delivered by speakers from the Bulgarian Drug Agency (BDA).

Main elements of the reform:

- Introduction of a new classification system: E, Q, C, M
- Reduction in the number of categories (from 23 to 16)
- Introduction of new regulatory tools:
  - Super-grouping
  - Work-sharing procedures
  - Annual Type IA update

Fewer categories, more “tools,” new letters to memorize. The kind of simplification that somehow still requires a workshop to explain.

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### **Annual Type IA update – a key regulatory instrument**

The Annual Type IA update represents a significant element of the reform. Core principle:

- The first implemented variation determines the regulatory submission deadline (9–12 months)
- Subsequent variations do not alter the established timeline
  - Regulatory risk:
- Significant risk of non-compliance with deadlines in the absence of adequate tracking and management systems

Elegant in theory. In practice, one missed internal trigger and suddenly you’re explaining to regulators why your “simple” Type IA quietly turned into a compliance issue. Timing stops being a detail and becomes the whole game.

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### **Transition to portfolio-based variation management**

The reform reflects a shift from managing individual variations to an integrated, portfolio-based approach.

#### **Observed trends:**

- Increase in grouped variations
- Expanded use of work-sharing procedures
- Need to adapt internal processes

In other words, instead of juggling one problem at a time, now you juggle ten... but in a more “structured” way. Efficiency, they call it. The kind that quietly demands better systems, tighter coordination, and fewer mistakes than humans usually enjoy making.

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## **Digitalisation and practical limitations**

Although a significant portion of submissions is carried out electronically (e.g. via CESP), full digitalisation remains only partially implemented. There are plans for not only centralised procedures, but also others to transition to a web-based format, although no specific timeline has been set.

### **Main issue:**

- Limited use of qualified electronic signatures, leading to continued reliance on paper documentation

### **Conclusion:**

There is still a mismatch between digital regulatory tools and their practical implementation.

So yes, “digital transformation” is happening... right alongside printers, scanners, and someone signing things with a pen like it’s 2003. Progress, just with a nostalgic twist.

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## **Overall conclusion**

The training highlighted two key trends in the development of the regulatory framework.

1. Short version: everything is getting more digital and more controlled at the same time. Because apparently one layer of complexity just wasn’t ambitious enough. **Digitalisation of processes**  
→ Increased efficiency and optimization of administrative procedures
2. **Enhanced regulatory control**  
→ Stricter requirements and reduced flexibility in product development

### **Key takeaway:**

- Optimisation of administrative processes
- Increased complexity in strategic decision-making

Efficiency goes up, flexibility goes down, and somehow everyone ends up working more anyway. Beautiful system.

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## **About BADI**

The Bulgarian Association for Drug Information (BADI) continues to support the development of regulatory expertise by providing specialized training, facilitating knowledge exchange, and engaging with leading experts in the field. It also serves as a platform for independent yet professional dialogue between stakeholders, regulatory authorities, industry, and academia.

We extend our gratitude to all lecturers and industry representatives who participated

