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Compliance certification system development as a priority criterion for improving product competitiveness

Sofia A. Tsareva

Candidate of Chemical Sciences, Associate Professor
Yaroslavl State Technical University, Yaroslavl, Russia
E-mail: tsarevasa@ystu.ru

Yana V. Denisova

Candidate of Economics, Associate Professor
Kazan National Research University, Kazan, Russia
E-mail: yana-denisova@inbox.ru

Alexandra I. Semyonova

Master's student
Yaroslavl State Technical University, Yaroslavl, Russia
E-mail: alexa.semionova2013@yandex.ru

Varvara A. Selezneva

Certification specialist
OOO DKS RUS, Yaroslavl, Russia
E-mail: seleznevava@mail.ru

Abstract. The paper characterises the elements of compliance certification in the context of ensuring independent conformity assessment and improving product quality. The authors described the features of adapting a new model of compliance certification on the example for a regional certification body, which go beyond the traditional conformity assurance system. The paper discusses the essence of the compliance certification system, levels and types of compliance system, and prerequisites for its adaptation in certification. The research recommendations for the development and implementation of compliance certification in manufacturing plants are based on the results of a single-factor variance analysis. It allows ones to assess the production process reproducibility. The study of manufacturing process stability reveals the potential inclusion of vegetable fats in the products under study. The authors analysed the reproducibility using an event tree. This tree identified the main production control parameters. The authors show the risk of added vegetable oils presence in the raw materials at the homogenisation, pasteurisation, and fermentation stages. The analysed data on statistical stability and reproducibility assessment suggest the necessity to provide conditions for the software development and implementation for monitoring of production processes in order to implement the principles of compliance certification on the basis of the selected production enterprise. The implementation of compliance certification system increases the competitiveness of products, ensuring reliability and quality.

Keywords: certification compliance system, organisation activity, certificate of conformity, confirmation of conformity, one-factor variance analysis, statistical stability and reproducibility of technological processes.

JEL codes: C13, L15, L64

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Introduction

In recent years, there has been a global trend of increasing product competitiveness. It consists in increasing requirements to the ways of proving product conformity. Compliance certification is a new direction of professional activity in conformity assessment introduced by international certification bodies into Russian organisations. There is nothing surprising in such borrowing in the era of business globalisation, especially since this practice provides consumer confidence in the transparency of the conformity confirmation

procedure. Certification is one of the prevailing confirmations of compliance with the requirements of various types and categories of standards, as well as directives and technical regulations (Bataeva & Cherepanova, 2017). Certification as a confirmation of conformity is based on the use of a significant number of measuring methods, testing, and control of product quality and safety. This determines the necessity of compliance control, requiring compliance with the established rules of internal interaction, procedures, and decision-making process to international requirements, identification, and assessment of compliance risks (Gvozdeva, 2010).

The application of the fairness doctrine in certification ensures, primarily, the quality and competitiveness of products, as well as their safety in the market. The national certification system of the Russian Federation has standardised approaches to various methods of conformity confirmation. In particular, standardised schemes of conformity confirmation have been developed. They based on different methods of proving conformity. For example, analysis of production or mandatory confirmation of conformity of products with the involvement of accredited bodies (certification bodies, testing laboratories) or the manufacturer's measures to ensure the release of products meeting the requirements of technical regulations, priorities its own production control (Aydynov & Grosheva, 2020).

Moreover, despite the introduction of standardised certification schemes, there are still unscrupulous certification bodies and testing laboratories committing the following violations:

– they don't take product samples;
– they don't analyse the production;
– they form an unrepresentative sample when certifying a batch of products (too small volume and/or incorrect type representatives), as a result, the test results do not provide a true representation of the entire batch of products' safety;
– they do not perform tests or perform them incompletely;
– they use incorrect test methods.

Therefore, control over the certification market requires more drastic measures. Namely, changes to legislative and regulatory documents are introduced and prerequisites are created to maintain transparency of activities within the sphere of conformity assessment. Over the last year, global changes in the legislation on technical regulation have been introduced. Federal Law No. 460 amended Federal Law No. 184 "On Technical Regulation". The main part of these changes goes on to the statute book on 21 June 2021.

The amendments officially introduced new terms "invalid declaration", "invalid certificate", "invalid test report". According to the Law, the invalidity of a declaration and certificate is a reason for control and supervisory authorities to terminate their validity in the prescribed cases. The adoption of amendments to the Federal Law on Technical Regulation was followed by a number of by-Laws.

The State adopted Decrees No. 934 and 936 of the Russian Government on 19 June 2021. These Decrees determine the procedure for invalidating test reports, declarations of conformity, and certificates of conformity. The procedure provides for cases for protocols, certificates and declarations to be declared invalid from the date of issue/registration, to be suspended or terminated. Certificates and declarations will be recognised as invalid not only as a result of non-conforming products identification, but also as non-compliance with mandatory conformity assessment procedures.

Decrees No. 934 and 936 allowed RusAccreditation to recognise certificates, declarations and test reports invalid. Now RusAccreditation assesses the completeness and correctness of the data transferred to the FSIS; the correctness of the selected conformity assessment scheme; identifies cases of violation by the first party of the declaration of conformity; cases of issuing conformity certificates in violation of the mandatory rules of conformity assessment by an accredited person, and performs other control functions[1].

All these measures are aimed at combating unscrupulous certification bodies and ensuring the distribution of reliably tested and safe products. The focus of these measures is shifted from product surveillance to compliance with mandatory conformity assessment rules and procedures. Applicants must

[1] *The World information-analytical and scientific-technical journal "Russian Engineer". Available at: https://mtz-transmash.ru/files/presscentr/publikacii/2021/rusinzh-112021.pdf4. (accessed: 12.10.2023).*

be ready to answer not only for their own actions, but also for the activities of certification bodies and testing laboratories providing certification and testing services. In fact, the product may be qualitative and safe, but due to violations committed by both the applicant and the certification body or testing laboratory, the certificate or declaration may be invalidated retroactively. Therefore, such products may have to be withdrawn from the market anyway.

The invalidation of conformity certificates and conformity declarations from the date of their issue/registration provides huge risks of financial losses for the manufacturer. This may include product recall, impossibility to sell residual goods, impossibility to fulfil supply agreements, loss of contracts, reputational losses. In order to avoid risks and financial losses, it is necessary to understand the issues of conformity assessment and consciously choose only reliable partners when performing certification. However, changes in the legislative sphere and the new procedure for declaration registration starting from 01.01.2021, as well as the control by the state authorities, cause a lot of questions among the stakeholders about finding a solution and recovery.

Therefore, the national certification body ROSTEST made a prompt decision to develop methodological principles for adapting the compliance certification system. "Compliance" is an effective tool for risk minimisation. In general terms, compliance is ensuring fulfilment of regulatory and legislative requirements in certain areas. US experts R. J. Burby, R. J. May, R. K. Paterson believe that "compliance" is the fulfilment by an economic entity of the requirements adopted in the appropriate order by the legislative authorities (Burby, May & Paterson, 1998). G. Governatori interprets it as the degree of compliance of business processes with those requirements both at the legislative level and within the organisation itself (Governatori et al., 2017). The international standard ISO 37301:2021 defines compliance as the activity of fulfilling by an organisation all its obligations to ensure norms conformity[2]. Compliance management in the sphere of technical regulation in the Russian market is a new, unexplored, and important phenomenon.

The "Compliance" service is the fulfilment of the current legislation in the field of technical regulation in terms of mandatory requirements for products, processes, rules, and procedures for first party conformity assessment (confirmation). The accreditation of the national certification body ROSTEST allows it to assess the products and processes. Compared to certification, within the framework of compliance, in addition to fulfilment of the current legislation in terms of mandatory requirements for products and processes, the correctness of the first party's application of the necessary rules and procedures – from product identification, development of a test plan to the adoption and registration of a declaration – is also assessed[3].

There are several types of compliance certification:

– compliance in the field of conformity with the established product requirements and the processes of design (including surveys), production, construction, installation, commissioning, operation, storage, transportation, sale, and disposal related to product requirements;

– compliance in procurement activities;

– compliance in the area of managing conflicts of interest (objective decision-making).

The compliance system developed by ROSTEST also has several levels (see Table 1).

Compliance is conducted beforehand at the stage of product market circulation. Based on the results of the conducted analysis on the first party's compliance with the norms of legislation in the sphere of technical regulation, a report on product compliance (compliance report) is issued. This document may form the basis for a declaration and will strengthen the evidence base.

By assessing, ROSTEST guarantees the structural format and logical control in the FSIS of RusAccreditation will be passed and the declaration will be reliable.

ROSTEST is ready to provide support to customers in case of questions from supervisory authorities at the stage of products market circulation in relation to conformity assessment. It was performed within the

[2] *ISO 37301:2021 Compliance management systems — Requirements with guidance for use. Available at: https://cdn.standards.iteh.ai/samples/75080/98db41625e0445a193a12f005dd5f30b/ISO-37301-2021.pdf. (accessed: 12.10.2023).*

[3] *Russian Union of Dairy Industry Enterprises. Available at: https://2023.dairyunion.ru/news/tpost/ubah57byk1-lyudmila-manitskaya-posetila-laboratorii. (accessed: 12.10.2023).*

framework of compliance before the declaration was adopted[4].

Table 1 – Compliance system levels

Level 1	
Version 1. Product Compliance	Version 2. Compliance certification of products
Compliance analysis and preparation of a product compliance report	Compliance analysis and issuance of a product compliance certificate
Result of the work performed	
Product conformity report signed by an expert. It serves a supplement to the evidence base formed, which will make the registration of the declaration justified and legitimate. Product conformity reports are accepted by all supervisory authorities	Product conformity report and certificate of conformity on a strictly accountable form. The certificate of conformity will increase the credibility of the product among inspection organisations, retailers, and end consumers, and minimise risks in case of supervisory measures
Level 2	
Version 1. Compliance of process	Version 2. Compliance certification of process
Compliance analysis and preparation of a process compliance report (taking into account the requirements of declaration schemes 1d, 3d, 5d, 6d on production control)	Compliance analysis and issuance of a conformity certificate for the process (taking into account the requirements of declaration schemes 1d, 3d, 5d, 6d for production control)
Result of the work performed	
A process conformity report includes mandatory product requirements. They will allow the third party to assess the processes and provide an opinion that will allow non-conformities to be identified and eliminated in advance.	A process conformity report and certificate of conformity on a strictly accountable form. The Certificate of Conformity is a full third party assessment of the processes and will provide additional assurance to inspection organisations and the end user.
Levels 3 and 4	
Development and assessment of compliance with the standards and requirements for the organisation management system, including compliance of products and processes with the compliance management system as a whole, including the provisions of ISO 19600.	

Source: Russian Union of Dairy Industry Enterprises, 2023

Few companies in Russia have yet been certified to the ISO 19600:2014 standard. It defines the principles of the compliance system. These include large business companies, such as MTS, Sberbank, Sibur, Aton, SUEK. The practice of certification to ISO 37001:2016 is even rarer in Russian business. Companies confirmed their anti-corruption compliance programmes in accordance with the above-mentioned international standard, and conducted a compliance assessment in accordance with ISO 19600:2014. Compliance standard certification is gradually becoming in demand, and a number of companies are in the process of preparing or undergoing compliance assessments. For example, TMK (Pipe Metallurgical Company) and Severstal.

Methods

The Yaroslavl State Institute for Quality of Raw Materials and Food Products (YaO YaGIKSPP) was chosen as the object of our study. The Institute has accreditation certificates in the national system of the Federal Accreditation Service for all areas of food testing and certification. Today, more than three quarters of

[4] *ROSTEST. Compliance. Available at: https://rtmsk.ru/uslugi/komplaens. (accessed: 12.10.2023).*

all regional food products are tested and received certificates of conformity[5] in the laboratories of YaGIKSPP.

The State Budget Institution of YaO YaGIKSPP established the Rules of functioning of the voluntary certification system "Yaroslavl Quality" and the Procedure of control over the use of certificates and marks of conformity in the voluntary certification system "Yaroslavl Quality". Producers using the "Yaroslavl Quality" mark on their products commit to annually provide certified food products for inspection control on the quality of goods produced[6].

In order to increase the certification process efficiency of the studied object, the prerequisites for adapting the principles of compliance certification have been created. Compliance certification will help to increase the level of confidence in the results of conformity assessment of products, processes, management systems, personnel in the National Certification System. It also allows ones to make activities transparent and accurate, reduce the number of appeals by increasing the reliability of the results of confirmation of compliance. Compliance certification systems are based on the following laws and regulations:

1. Federal Law "On Technical Regulation" No. 184-FZ.
2. GOST R 53603-2009 Conformity assessment. Schemes of product certification in Russian Federation.
3. GOST R ISO/IEC 17065-2012 Conformity assessment. Requirements for bodies certifying products, processes and services.
4. Federal Law of 25.12.2008 No. 273-FZ "On Anti-Corruption".
5. Federal Law No. 115-FZ of 07.08.2001 "On Anti-Money Laundering".
6. Administrative Offences Code of the Russian Federation of 30.12.2001 No. 195-FZ.

In general, the certification procedure is considered to be rather long and labour-intensive, involving a large number of certification body employees. The problem of risk analysis in the activities of the certification body has become particularly relevant with the introduction of the standard GOST R 56275-2014 Risk Management. Guidelines for good practice in project risk management (Berezina, 2014).

Certification bodies should consider the risks associated with implementing certification in a professional and impartial manner. Moreover, the operating system should also have a process for identifying, analysing, handling, and documenting conflict of interest risks arising during the certification process. However, the certification body of the Yaroslavl State Institute for Quality of Raw Materials and Foodstuffs adheres to impartial ways of proving conformity. For instance, they use certification schemes based on the analysis of production – the analysis of the implementation of the production control programme. This study identified the reasons for non-compliance with the industrial control programme using the expert method and Ishikawa diagram (see Fig. 1). The construction of the Ishikawa diagram ensures the reliability of the obtained data on the basis of their statistical validity.

The most important factors are non-compliance with confidentiality and impartiality rules by the certification body employees, problems in setting up the equipment, inaccurate measuring instruments, and the use of incomplete/outdated/incorrect documentation.

Hence, the main principles of compliance certification are confirmation of compliance at the place of production. Therefore, to implement the principles of compliance certification, stability and reproducibility assessment of technological processes of products manufacturing certified in the certification body YaO YaGIKSPP on the basis of single-factor analysis of variance was also conducted. In general, analysis of variance is possible if the results of observations are independent random variables obeying the normal distribution law with equal variance (Berezina, 2014). Analysis of variance is based on the property of variance additivity, i.e., the total variance of the indicator of interest is equal to the sum of its constituent partial variances.

The problem of one-factor analysis of variance (OVA) is posed as follows. Assume, the influence of factor x on a technological process or some quality indicator is studied. During the experiment the factor is maintained at u levels. At each level of the factor, m duplicate (parallel) experiments are conducted. The results of a single-factor experiment from Uxm observations are presented in the form of an observation

[5] *Yaroslavl State Institute of Raw Materials and Food Quality. Electronic resource. Available at: URL: https://yagik.ru (accessed: 16.10.2023).*
[6] *Federal Law "On Technical Regulation" No. 184-FZ (last edition). – Introduction. 2002-12-27 (in Russian)*

matrix (Frolova, 2017; Dedkov, 2011). However, the analysis of variance of the experimental observations (Nisaif, 2021) allows us to assess the influence of a factor only as a whole. The conclusions obtained can be applied only to the given experimental material at a given systematisation. Thus, for example, when changing the range of variation of the studied factor or the main (base) point, the assessment of the influence of the latter may change.

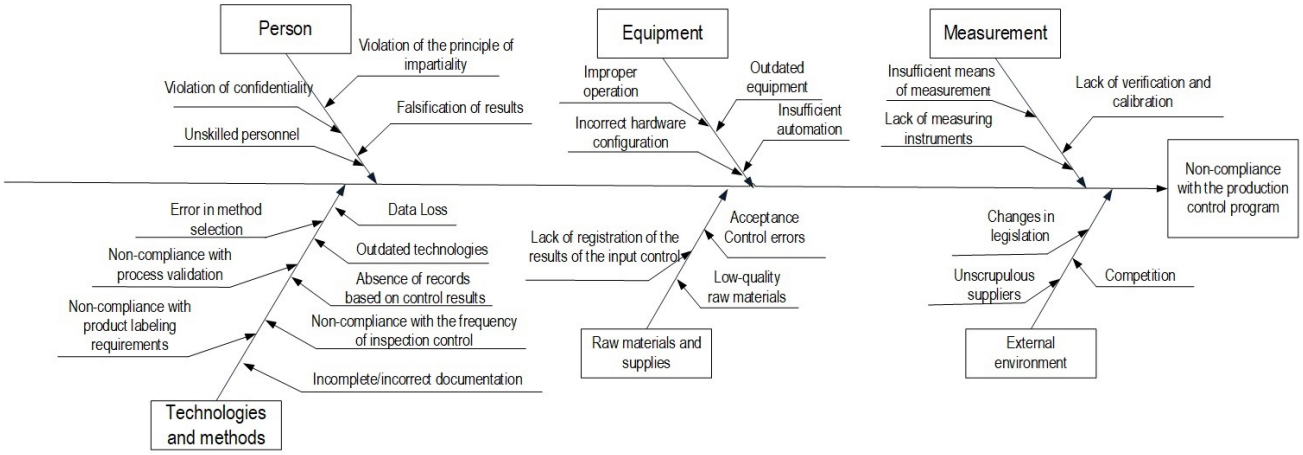

Figure 1. Ishikawa diagram to identify reasons for non-compliance with the production control programme
Source: composed by the authors

Results

Statistical stability and reproducibility of the production process was assessed on the example of production of dairy products (ryazhenka). This is the most common product group under certification of the certification body named above. Preliminary to determine the reproducibility of the process in the study was used such a methodological technique as an event tree. It represents the hierarchical structure of the technological process. On the basis of the shown event tree, it is possible to generally understand the reasons for the risks of producing low-quality products (see Fig. 2). It determines the transparency of the certification procedure.

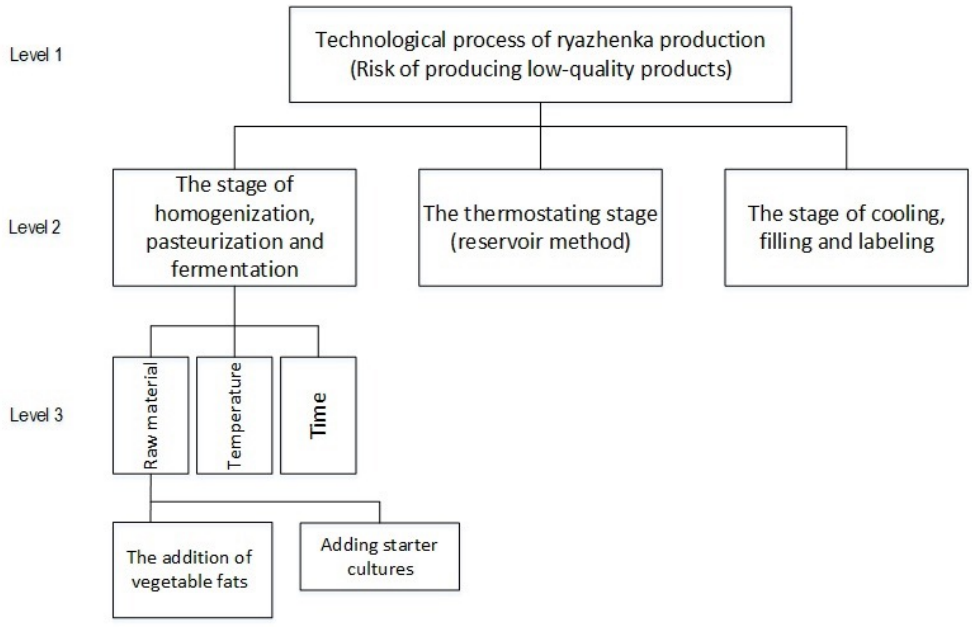

Figure 2. An event tree to investigate the risk of producing low-quality products
Source: Akramova & Moroz, 2016; Gorlenko, Mozhaeva & Vavili, 2016

However, the statistical reproducibility of the production process was assessed by means of one-factor analysis of variance. As an independent variable x was taken the indicator of fatty acid composition of the

fat phase – mass fraction of palmitic acid, as an indicator parameter of the quality of manufactured products. During the experiment, the factor x was varied at u = 5 levels. As a response function y, characterising the content of vegetable fats in ryazhenka, the data of test protocols were used. Therefore, m = 3 parallel experiments were conducted at each level of variation of the factor. The values of mass fraction of palmitic acid in three parallel experiments (m = 3) at all levels (u = 5) of variation of factors are presented. Table 2 presents the data.

Hereinafter, the following designations are used: the ordinal number of the level of variation of the factor – j (j = 1, 2, u); the ordinal number of the parallel experiment in the series at each j-th level – l (l = 1, 2, m).

Further, statistical processing of the experimental results was performed using one-factor analysis of variance. As a result of calculations it was established the influence of palmitic acid on the addition of plant raw materials. It should be recognised as significant one.

A process stability study showed a possibility of adding vegetable fats to the ryazhenka, and an event tree evaluation of reproducibility identified a key parameter in production control.

Table 2 – Results processing of one-factor analysis of variance

No. of product protocol	Variation level of factor j	Response function value in parallel experiments			Arithmetic mean of the response function in parallel experiments	Sum of observations by series Y_j	Square of observations in parallel experiments Y_{jl}^2			$\frac{Y_j^2}{m}$
		1	2	3			1	2	3	
Protocol 1	1	21	33.11	33	29.04	87.11	441	1096.3	1089	2529.38
Protocol 2	2	21	27.05	33	27.02	81.05	441	731.7	1089	2189.7
Protocol 3	3	21	31.36	33	28.45	85.36	441	983.45	1089	2428.78
Protocol 4	4	21	31.19	33	28.40	85.19	441	972.82	1089	2419.11
Protocol 5	5	21	29.37	33	27.79	83.37	441	862.6	1089	2316.85
Amount	—	422.08	2205	4646.8	5445	11883.8				

Source: composed by the authors

Hence, there is of adding of vegetable fats in the raw material at the stage of homogenisation, pasteurisation, and squashing. The study of fatty acid composition indicators of the fat phase allowed ones to identify the product adulteration more objective, even in the conditions of the technological process. It is certainly valuable in the conditions of product certification. Analysing the data on the statistical stability and reproducibility assessment, we can conclude that in order to implement the principles of compliance-certification in the State Budget Institution of YaO YaGIKSPP it is necessary to create prerequisites for the development and implementation of software and statistical complexes for monitoring of production processes.

Conclusion

Thus, compliance certification will become increasingly relevant for companies, including not only large businesses, but also small and medium-sized ones. It is also an issue of gradual development of anti-corruption legislation, changes in other areas, sanctions, requirements, and restrictions in a rapidly changing world.

Therefore, in order to maintain the status of consumer confidence and full transparency of activities, organisations in the field of conformity assessment also have to implement a compliance system in their work. The implementation of compliance certification will allow consumers to be sure of high quality, competitiveness, and safety of the products.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

Sofya A. Tsareva – conceptualization, project administration, writing – original draft.
Yana V. Denisova – validation, writing – review & editing.
Alexandra I. Semenova – data curation
Varvara A. Selezneva – formal analysis

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