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BASIC PRINCIPLES OF PLANNING

ANIMAL PRODUCT NATIONAL VETERINARY MONITORING

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SUMMARY
The paper presents the results of basic parameter selection and optimization of sample quantity calculation method for chemical (banned and harmful substance residues), microbiological and radiological tests carried out annually within the Plan of National Veterinary Laboratory Monitoring of Banned and Harmful Substances and Residues Thereof in Live Animals, Animal Products and Feeds in the RF by the Federal Centre for Animal Health (FGBI «ARRIAH»).

Key words: monitoring, chemical, microbiological, radiological parameters, food products, contaminants.

INTRODUCTION

In the contest of Russia's accession to the World Trade Organization (WTO) the RF reports to the appropriate international organizations on national quality and safety control of domestic food products, primary animal products, and animal and plant products [4, 14].

One of the major elements in the system of food safety national control is the National Veterinary Laboratory Monitoring of Banned and Harmful Substances and Residues Thereof in Live Animals, Animal Products and Feeds in the RF. Monitoring of animal product and feed safety in the RF as well as in the European Union countries is planned in accordance with the provisions of Council Directive 96/23/EC of April 29, 1996 on measures to monitor banned and harmful substances and residues thereof in live animals and animal products [2, 10], and is based on the Concept of National Veterinary Laboratory Monitoring of Banned and Harmful Substances and Residues Thereof in Live Animals, Animal Products and Feeds in the RF for 2008 and onwards, approved by Head of the Federal Service for Veterinary and Phytosanitary Surveillance S.A. Dankvert on May 5, 2008 and taking into account national peculiarities and traditions, obligatory control of drugs and xenobiotics as well as transition period and harmonization of the RF legislation with the EU's one [11, 12].

Notwithstanding the fact that the list of product safety parameters subject to laboratory testing is determined by the appropriate regulatory acts, there are a lot of factors facilitating the probability of banned and harmful substance presence in controlled objects [3, 4]. Such factors include national peculiarities and traditions, epidemic situation in individual regions and probable use of different drugs and xenobiotics, including those which are banned in the RF. [9]. In this context the differentiated approach to testing of the most informative safety parameters in different RF regions is needed as well as the improvement of the method recommended by the EU Commission for the calculation of minimum sample quantity needed for monitoring tests [13].

The target of this study was to determine the basic principles used for the selection of animal product safety parameters (chemical, radiological and microbiological), to optimize the method used for calculation of test number and needed for the development of the Plan of National Veterinary Laboratory Monitoring of Banned and Harmful Substances and Residues Thereof in Live Animals, Animal Products and Feeds in the RF (Monitoring Plan).

MATERIALS AND METHODS

Tested objects. The monitored objects are farmed and wild animals, animal products and feeds produced in the Russian Federation (RF), Customs Union (CU) and imported products.

Table 1
Residue or substance group to be detected by type of animal, their feedingstuffs, including drinking water, and primary animal products

No	Substance Group \ Type of animal, animal products, feeds	Bovine, ovine, caprine, porcine, equine animals	Poultry	Aquaculture animals	Milk and dairy products	Eggs	Rabbit meat and the meat of wild game and farmed game	Honey	Feeds and feed additives
1	A1	X	X	X			X		X
2	A2	X	X				X		X
3	A3	X	X	X			X		
4	A4	X	X				X		
5	A5	X	X				X		X
6	A6	X	X	X	X	X	X		X
7	B1	X	X	X	X	X	X	X	X
8	B2a	X	X	X	X		X		X
9	B2b	X	X			X	X		X
10	B2c	X	X				X	X	X
11	B2d	X							
12	B2e	X	X		X		X		
13	B2f								X
14	B3a	X	X	X	X	X	X	X	X
15	B3b	X			X			X	X
16	B3c	X	X	X	X		X	X	X
17	B3d	X	X	X	X				X
18	B3e			X					
19	B3f								X
20	Adulteration*				X				

* Adulteration of products is adding certain foreign matters into food products (honey, meat, milk and etc.) thus changing their quality and value. Adulterated products are not allowed to be used. Adulterated products are subject to constant control in the RF within meat inspection and special monitoring programs (phosphates, soy presence and etc.) [6]. Currently special attention is given to testing of food products for preservatives, fish for histamine and milk products for adulteration with plant oils (fatty acid content) [5].

Parameter groups. Based on the accepted classification and the provisions of Council Directive 96/23/EC the controlled contaminants are divided into several groups [2].

GROUP «A» – Substances having anabolic effect and unauthorized substances

(**A1**) Stilbenes, stilbene derivatives, and their salts and esters
(**A2**) Antithyroid agents
(**A3**) Steroids
(**A4**) Resorcylic acid lactones including zeranol
(**A5**) Beta-agonists
(**A6**) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990 (chloramphenicol, nitrofurans and metabolites thereof, nitroimidazoles) [10]

GROUP «B» – Veterinary drugs and contaminants

(**B1**) Antibacterial substances, including sulphonomides, quinolones
(**B2**) Other veterinary drugs:
(a) Anthelmintics
(b) Anticoccidials
(c) Carbamates and pyrethroids
(d) Sedatives
(e) Non-steroidal anti-inflammatory drugs (NSAIDs)
(f) Other pharmacologically active substances
(**B3**) Other substances and environmental contaminants
(a) Organochlorine compounds including PCBs, dioxins;
(b) Organophosphorus compounds
(c) Chemical elements: mercury, lead, cadmium, arsenic (for primary products); mercury, lead, cadmium, arsenic,

copper, zinc, ferrum, stibium, nickel, selenium, chrome, fluorine, molybdenum, cobalt (for feeds and feed additives);

(d) Mycotoxins

(e) Dyes

(f) Other substances including unpatented drugs, pesticides, biotoxins and radionuclides (sum of PAHs including benz(a)pyren, nitrosamines, phycotoxins (ASP, DSP, PSP), 2,4-D acid, salts and esters thereof, histamine, hydroxymethylfurfural (Table 1).

Microbiological parameters include pathogenic and opportunistic microorganisms:

(1) number of mesophilic aerobic and facultatively anaerobic microorganisms / total viable count (TVC);

(2) *Coliforms*/ enteropathogenic types of *E. coli*/ toxin producing bacteria;

(3) *Salmonella;*

(4) *Listeria monocytogenes;*

(5) *Vibrio parahaemolyticus;*

(6) *Clostridium* (sulphite reducing clostridia);

(7) *Staphylococcus* (*S. aureus*);

(8) *Proteus*.

Methods for calculating minimum required sample quantity. Minimum sample quantity required for monitoring is determined using the EU programme published on website: http://ec.europa.eu/food/safety/chemical_safety/pesticide_residues/index_en.htm [13]. Entering data on the number of animals and manufactured products this programme automatically calculates minimum required sample/test quantity for each type of tested products and safety parameters. The programme gives proportion per each group of parameters for calculating the test quantity.

RESULTS AND DISCUSSION

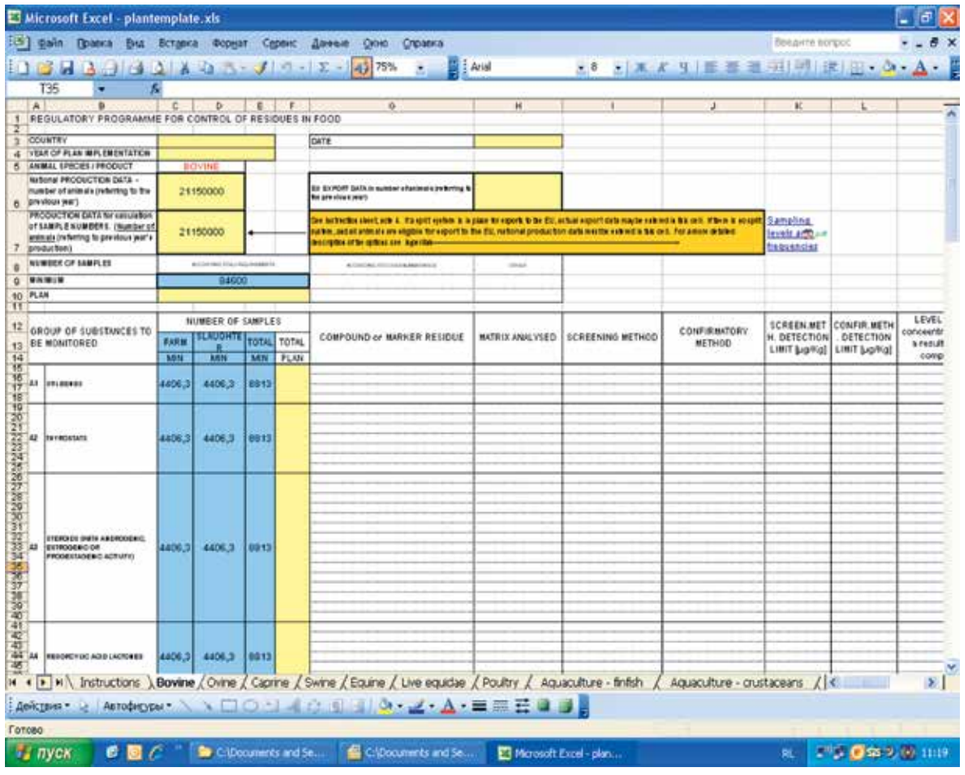
1. General provisions for planning and arranging food safety monitoring activities. Territorial Administrations of the Federal Service for Veterinary and Phytosanitary Surveillance, to whom the FGBI «ARRIAH» renders services, are in charge of product safety control and sampling in the regions for the purpose of Monitoring Plan implementation. The Rosselkhoznadzor Order On Laboratory Tests within the Rosselkhoznadzor Measures Taken to Comply with WTO SPS Agreement at the RF Accession to the WTO assigns the following RF Subjects to the FGBI «ARRIAH»:

- Rosselkhoznadzor Territorial Administration for Vladimir Oblast;
- Rosselkhoznadzor Territorial Administration for Kostroma amd Ivanovo Oblasts;
- entire Russian Federation, when necessary.

Laboratory tests compliant with the Food Safety Monitoring Plan are performed in the RF using federal funds.

For each subsequent year the FGBI «ARRIAH» Department for Research Coordination develops the Monitoring Plan in November of the current year using previous year monitoring results for calculations. To perform this task the Department for Research Coordination requests the assigned Rosselkhoznadzor Territorial Administrations to submit the following information by November 1 of the current year: number of farms, number of kept and slaughtered animals for the previous year, (for all productive animal species), number of fish hatcheries and fish harvesting ponds, apiaries, rabbit farms, poultry farms and processing plants, as well as the amount of animal product and feed manufacture (including number of establishments producing animal products by types of products and feeds), a list of veterinary drugs used for prevention of animal diseases, and a list of used pesticides.

Table 2
Programme for calculating minimum required test quantity for Food Monitoring Plan implementation



The Monitoring Plan for the next year including data on the required test quantity for each product type and each RF Subject as well as the amount of money required for implementing the Monitoring Plan are submitted to the Rosselkhoznadzor in December each year for consideration and approval in due order. The project is also published in FGIS «ASSOL» in «Monitoring Plan» section. In January next year the Rosselkhoznadzor Central Office informs the FGBI «ARRIAH» about the fact that the Monitoring Plan was approved.

The Research Coordination Department, not later than the 1st of March current year, makes a tripartite Agreement on Cooperation (FGBI «ARRIAH», Rosselkhoznadzor Territorial Administration, Veterinary Authority of the RF subject) in which the Monitoring Plan criteria for the next year are indicated. Reports on the Monitoring Plan results for the previous year are sent to the FGBI «Central Scientific and Methodological Veterinary Laboratory» by the 1st of February of the year following the reporting period.

The Monitoring Plan can be amended throughout a year due to detected veterinary risks as well as force majeure events [1].

2. Optimization of test quantity calculation methods for the Monitoring Plan development. Minimum required sample quantity for monitoring tests is calculated using the EU programme published on the web site: http://ec.europa.eu/food/safety/chemical_safety/pesticide_residues/index_en.htm [13].

On entering data on the number of animals and manufactured products this programme automatically calculates minimum required sample/test quantity for each type of tested products and safety parameters (Table 2). The programme gives proportion per each group of parameters for calculating test quantity.

2.1. Calculating quantity of chemical and radiological product tests. Quantity of chemical and radiological tests of biomaterials as well as products of animal origin and feeds is calculated using the EU programme *plantemplate.xls* [13], where numeric values of the number of slaughtered animals and manufactured products a year are entered. On entering the required information the programme automatically calculates the minimum sample quantity to be collected for each type of test by Groups «A» and «B».

2.2. Calculating quantity of microbiological tests of biomaterials and products of animal origin. The main criteria indicated in the documents is absence of microorganisms, their toxins or metabolites in primary food products in quantities, posing risk to human health. Calculation methods are based on recommendation of Codex Alimentarius Commission «Principles and Guidelines for the Conduct of Microbiological Risk Assessment» CAC/GL-30 (1999) and the EU Directives (Annex II) [4, 8].

Criteria for product monitoring plan calculation by microbiological parameters. Development of annual Monitoring Plans by microbiological parameters envisages assessment of risks of biological contamination.

Risk assessment is planned in compliance with regulatory documents. The following criteria are determined for each RF Subject for the previous year:

- number of animals by species;
- rate of *Salmonella* and *Listeria* infected animals detected previous year;
- number of positives obtained previous year by each type of tested microorganisms in each product type.

Calculation example. There are 10 million animals in the region. Last year there were detected 0.1 million of *Salmonella* infected animals, i.e. prevalence (p) is 1%:

$$p = \frac{number\ of\ diseased\ animals}{number\ of\ susceptible\ animals} \times 100\% = 1\%$$

Required sample quantity is calculated basing on the following criteria: 1% prevalence and 95% confirmation level. Sample quantity calculation for disease detection is performed according to the formula:

$$n = \frac{\log\ (1-c)}{\log\ (1-p)}$$

c = 95% = 0,95, p = 1% = 0,01, then:

$$n = \frac{\log(1-0{,}95)}{\log(1-0{,}01)} = \frac{\log 0{,}05}{\log 0{,}99} = \frac{-1{,}301029}{-0{,}004364} = 300\ samples$$

So, 300 product samples shall be collected from an establishment with 1% prevalence for *Salmonella* tests. Similar calculations were performed for each establishment.

Microorganism detection rate in a controlled animal product can be calculated basing on veterinary and sanitary inspection results and on annual report data for each RF subject according to 4-vet form (annual).

For instance, there are 100 food producing establishments in the controlled subject. Previous year monitoring revealed TVC in beef in 1.5% cases. It is necessary to collect 5 samples a year (100×5) from each establishment i.e. 500 samples for testing microorganisms belonging to this group.

For calculations by microbiological parameters related to imported product monitoring plan it is necessary to take into account the following data on each foreign country:

- number of beef exporting establishments;
- number of pork exporting establishments;
- number of establishments, exporting sheep and goat meat;
- number of establishments, exporting horse meat;
- number of establishments exporting rabbit meat;
- number of establishments exporting aquaculture products;
- number of establishments exporting non-fin fish products;
- number of establishments exporting milk and dairy products;
- number of establishments exporting honey and apicultural products;
- number of establishments exporting table eggs.

When establishing the Monitoring plan 5 samples shall be collected once at each supplying establishment not violating the RF veterinary and sanitary requirements and the samples shall be tested for the microbiological parameters required for this type of product. In case of the establishments exporting their products to the Russian Federation

Table 3
Number of samples required for the detection of at least one nonconformity with 90, 95 and 99% confidence level in products (feed) with known nonconformity

Prevalence of nonconformity (% in population, product)	Minimal number of samples required for nonconformity detection		
	90%	95%	99%
35	6	7	11
30	7	9	13
25	9	11	17
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	230	299	459
0,5	460	598	919
0,1	2302	2995	4603

with violations a doubled number of product samples is required (10 samples per establishment).

Example: last year Russia imported products from 12 German establishments, 2 of them violated the requirements during export.

Example 1. Germany. Calculation for the establishments, exporting their products without violations. For example, last year beef was exported from 10 establishments without any violations. The next year monitoring plan suggests that 5 samples shall be collected from each of the 10 establishments and tested for *Salmonella*, *Listeria*, TVC and Coliforms (10 establishments×5 samples×4 microorganisms) – that is 200 tests in total.

Example 2. Germany. Calculation for the establishments exporting their products with violations. Beef from 2 establishments was exported with violations. Excess in TVC was detected in the products exported from the first establishment and in Coliforms from the other one. For the next year the Monitoring plan suggests a doubled number of samples from these two establishments (10 samples per establishment): for TVC – 10 tests (10 samples from the corresponding establishment); Coliforms – 10 tests (10 samples from the corresponding establishment).

In case TVC is above the admissible level the establishment is subject to enhanced monitoring at the expense of the product owner. In case the safety parameter of concern is detected during the enhanced laboratory control temporary restrictions may be imposed on products exported from this establishment.

In case the last year prevalence data by each country and each product type exported to the Russian Federation is available, calculations should be made taking into account risk assessment in regards to the detected nonconformity levels.

2.3. Calculation of the number of feed samples to be tested for chemical, radiological and microbiological parameters. Feeds must meet approved safety and quality standards. To detect harmful substances in feed the establishment performs GMP implementation control by analyzing hazardous factors, including potential sources of contamination [7].

Feed monitoring tests are performed to ensure safe production, transportation and storage of feeds, as well as safe feeding of all animal species, including of those used in the production of food products intended for human consumption (productive animals) [9].

Feed ingredient monitoring includes random checking and testing for banned and harmful substances based on the risk analysis. Feed ingredients must meet standards limiting the levels of pathogens, mycotoxins and pesticides posing a potential threat to animal health and, via the food products, to humans.

Calculation criteria for feed monitoring tests. The number of feeds and feed additive tests by each safety parameter is calculated using the Codex Alimentarius Commission Guidelines for the design and implementation of National regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals CAC/GL 71-2009 [3].

In this case to calculate the Monitoring plan one shall have the following data on the previous year:

1. List and volume of all types of feeds subject to monitoring, produced in the Subject of the Russian Federation.
2. Prevalence of nonconformities by each feed type detected during the previous year.

In case the abovementioned data is available, the sample size is calculated using data from Table 3.

Calculation example. 95% confidence level. Mixed feed for poultry. In case 5% of nonconformities were detected in this type of product during the previous year (5% prevalence), at least 59 samples of mixed feed shall be taken and tested for the reliable detection of nonconformities. 50% of this number (29 samples) shall be tested for group «A» safety parameters, another 50% - for group «B» parameters. Calculations for other types of products are made in the same way.

The table should also be used when calculating the justified number of samples from slaughter poultry at feed-

processing rooms, on farms, in case the last year data on the prevalence of feed nonconformities on this farm is available.

When making a calculation, every establishment producing feeds, including feed-processing rooms on farms, and farms of all forms of ownership, shall be taken into account. At least 10 feed samples shall be collected at each establishment and tested for safety parameters in accordance with the previously determined risk level. Vegetable feeds produced on farms shall be tested for the residues of agricultural fertilizers, pesticides, chemical elements, mycotoxins, plant toxins, etc.

Microorganisms are spread in feeds unevenly, thus, raising concerns that the pooled sample could be representative of the whole batch. That is why to tests the batch for microbiological parameters random samples (n) shall be used rather than the pooled ones. Normally at least 5 samples are taken and each sample is tested for each safety parameter.

When developing a feed microbiology monitoring plan at least 5 samples shall be taken once from all the feed types and at every establishment.

CONCLUSION

Based on the analysis of the RF and EU regulatory documents, scientific literature on food and primary product safety assessment and data provided in this paper, «Regulation on the development of the Plan of National Veterinary Laboratory Monitoring of Banned and Harmful Substances and Residues Thereof in Live Animals, Animal Products and Feeds in the RF» was worked out and approved. The basic principles of this document are harmonized with the system adopted in the EU and are based on the considerable national experience in veterinary control of food and feed safety. The Monitoring plan is designed taking into account national peculiarities of veterinary drug, pesticide and agrochemical use in the Russian Federation, as well as positive results obtained in previous years.

As for the enhanced food safety monitoring, there is an antibiotic monitoring subprogram within the Monitoring plan. The subprogram is performed using reference methods for antibiotic control and for the confirmation of positive screening test results obtained in other laboratories (risk identification).

REFERENCES

1. Barannikov V.D., Kirillov N.K. Ecological safety of agricultural products. – M.: Kolos, 2005. – 352 p.
2. Council Directive 96/23/EC of 29 April 1996. – URL: http:/www.fsvps.ru/fsvps-docs/ru/laws/eu/96-23.pdf.
3. Codex Alimentarius. General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995). – URL:http://dokipedia.ru/document/5197124.
4. Codex Alimentarius. Animal food production : transl. from Eng./ FAO/WHO. – M.: Ves Mir, 2007. – 230 p.
5. Dairy product quality control by fatty acid composition / S.A. Dunin, U.V. Pivovarov, V.A. Zenin, O.V. Vjunovskaya // Product Quality Control. – 2012. – № 5. – P. 18–23.
6. Microbiological testing of meat, poultry meat and egg products: transl. from eng. / ed. J.K. Mid. – SPb.: Professiya, 2008. – 384 p.
7. Rules for bacteriological testing of feeds: approved by the Main Veterinary Department of the Ministry of Agriculture of the USSR on 10.06.1975. – M., 1976. – 12 p.
8. Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30 (1999)). – 15 p.
9. Food safety in Russia and other leading countries: analytical review / E.L. Aronov, T.P. Nino, T.A. Surkova [et al.]; Ministry of Agriculture of the Russian Federation, Federal Agriculture Agency. – M.: Posinformagrotech, 2005. – 124 p.
10. Regulation (EC) № 470/2009 of the European Parliament and of the Council of 6 May 2009 – 19 p.
11. SanPin 2.3.2.1078-01. The Hygienic Requirements for Foodstuff Safety and Nutritional Value. – M.: Gosstandart Rossiyi, 2002. – 246 p.
12. TR CU 024/2011. Technical regulation on oil and fat products: approved by the CU Commission on 09.12.2011 № 883 – 37 p.
13. Pesticide Residues. – URL: http://ec.europa.eu/food/safety/chemical_safety/pesticide_residues/index_en.htm.
14. WHO/FAO. Report of a Joint WHO/FAO Consultation N 61: Biotechnology and food safety. – WHO/FAO, 1996. – 29 p.