

NEWSLETTER

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NEW SCOPE OF ACCREDITATION

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We are pleased to inform you that on September 1, 2022, the Accreditation Body of Serbia announced the SP Laboratorija's new scope of accreditation. Now, the accredited test methods include:

-Determining mustard as allergen in meat and meat products, oil, mayonnaise, vegetable products, cheese, bakery products, soups and sauces. The analyse is performed using ELISA technique with a quantification limit of 0.5 mg/kg. The presence of allergens in food as well as their labeling is extremely important nowadays. Considering that neither the legislation of Serbia nor the EU does not have a defined limit for the maximum allowed amount of celery as an allergen in food, it is crucial to prove its absence. Though, the list of allergens that SP Laboratorija examines under the sign of accreditation is extremely wide and includes:

- gluten
- peanuts
- hazelnut
- soy
- milk
- eggs
- mustard

SP Laboratorija outside the scope of accreditation examines the presence of the following allergens:

- celery
- walnut
- sesame

-Detection of Salmonella spp. using PCR technique in food, animal feed and samples from the surface, which enables faster determination compared to standard determination of pathogenic microorganisms.

The detection and determination of the number of Salmonella SP Laboratorija has been performing for many years by the standard classical accredited method according to various standards in food, animal feed, surface samples and pharmaceutical preparations.

Since 2020, SP Laboratorija has been accredited for Salmonella serotyping using the method SRPS CEN ISO TR 6579-3.

The application of the PCR method allows to our customers to obtain test results much faster. The first results are available even after 24 hours, which is a significantly shorter time compared to the classic

method for Salmonella spp, where the results in the case of a positive finding are obtained only on the seventh or eighth day from the start of the test.

-Detection of Listeria monocytogenes and Listeria spp using ELFA technique in food and surface samples.

For many years, SP Laboratorija has also been accredited for classical methods of detection and determination of the number of Listeria monocytogenes and Listeria spp in food, feed and surface samples. Applying the ELFA technique allows to our customers to get results much faster. The results are available already after 48-72 hours, while the classic method, in case of doubt and the need for confirmation, gives results on the tenth to fourteenth day, depending on the confirmation procedures.



-Evaluation of the antimicrobial protection of cosmetic products (Challenge test) - is carried out during the production stages of cosmetic products in order to ensure microbiological stability and preservation during storage and use during the shelf life. The application of this test is recognized in the Regulation on cosmetic products, with the provisions of which producers, importers, and distributors of cosmetic products should comply by April 10, 2023. More details in the article: „Test of the efficiency of preserving cosmetic products - „Challenge test“

The most significant **changes** implemented in the new scope of accreditation are:

-significant reduction of the **LOQ for vitamin D** in food to a minimum of 0.75 µg/100g.

15% of the nutritional reference value is considered as significant amount of vitamin D in accordance with the legislation. In the past few years, the importance of vitamin D in protecting and strengthening

immunity has been additionally recognized, so the need to emphasize its content on the product declaration has increased. With this limit of quantification, SP Laboratorija can confirm the vitamin D content at the level of a significant amount.

- **increasing of the area of application of the method for the determination of perchlorate** to medicinal herbs and tea, in addition to the accredited test subjects - fruits, vegetables, cereals and legumes.

It was recognized the illegal use of perchlorate for food disinfection, which resulted in a change in EU and Serbian legislation. In 2021 there were several notifications to the RASFF system related to the unauthorized use of perchlorate in food including herbs and spices.

The detailed scope of accreditation is available on the website of Accreditation Body of Serbia: <http://www.registar.ats.rs/> under accreditation number 01-018.

The flexible scope of accreditation is permanently changes in the part of the introduction of new pesticide residue testing. In the period January-August 2022, SP Laboratorija has been introduced testing of 28 pesticide residues in order to make the offer to our customers as complete as possible.

When introducing new pesticide residues, SP Laboratorija is guided by the changes and trends of EU regulations, the requirements of exporters and the requirements of the prestigious QS certification dictated by the demanding German market, and increasingly by the market of most of the EU. SP Laboratorija is the only QS certified laboratory in Serbia.

Lists of accredited residues of pesticides, GMO modifications, mycotoxins, plant toxins and metals and metalloids are subject to permanent changes in accordance with the needs of customers, and are available on the website of SP Laboratorija via the link: <https://splaboratorija.rs/sr/o-nama/certificates-and-scope-of-accreditation>



ANALYSES OF ITEMS OF GENERAL USE IN SP LABORATORIJA AND THE LABORATORY OF J.S. HAMILTON

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Following the requests of the market, SP Laboratorija, as part of the Hamilton Group headquartered in Poland, enables manufacturers and users, importers and sellers of packaging, toys, products for children and other items of general use to carry out tests of compliance with requirements and product safety in accordance with EU requirements and specific requirements, using accredited methods, with unbiased assessment of quality.

In the EU, there are general and specific guidelines for materials that come into contact with food (food contact materials - FCM), based on which member countries adopt their own regulations. Changes to Commission Regulation (EU) 10/2011, for plastic materials and Commission Regulation (EU) 2020/1245 and Council Directive 84/500/EEC, for ceramics, have been announced, and we will provide information about them when they will be published.

For parameters in accordance with EU regulations, as well as special requirements, SP Laboratorija organizes transport and analyses in the laboratory of J.S.Hamilton in Poland:

Testing of plastic materials intended for contact with food and cosmetic products:

- Total migration in all food simulants (including simulant E - Tenax);
- Specific migration:
Metals (Li, Na, Mg, Al, K, Ca, Cr, Mn, Fe, Co, Ni, Cu, Zn, As, Cd, Sb, Ba, La, Eu, Gd, Tb, Hg, Pb, and sum lanthanides: La, Eu, Gd, Tb)
PAA (Primary Aromatic Amines - > 40 individual compounds);
NIAS screening (unintentionally added substances) with toxicological assessment;

PFAS (polyfluoroalkyl compounds - > 50 individual compounds);

VOC (volatile organic compounds -> 50 individual compounds)

Mineral oils (MOSH/POSH AND MOAH - individually and collectively);

Acetaldehyde, terephthalic and isophthalic acids,

- Content of bisphenol A, B, F and S, and derivatives of BADGE, BFDGE and NOGE epoxy resins in coatings, plastic materials and adhesives;

- Plasticizers, antioxidants, monomers and additives according to EU 10/11 Annex I, and Swiss regulations;

- Oligomer;

- Isocyanate content and migration (laminates with adhesives, printed materials);

- Influence of printing inks and specific migration of UV inhibitors, acrylates, BHT, PAA,...;

- Sensory tests;

- Color fastness;

- Permeability of O₂, water vapor, CO₂, N₂.

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Examination of paper and cardboard as FCM:

- Grammage and moisture content;

- Dry matter in aqueous extract

- Heavy metals according to EU 94/62, metals in aqueous extract;

- Methanal (formaldehyde), PCB, glyoxal, anthraquinone;

- PAA (Primary aromatic amines - > 40 individual compounds);

- NIAS screening;

- PFAS (polyfluoroalkyl compounds);

- Content and specific migration of mineral oils (MOSH AND MOAH);

- PCB;

- Bisphenol A, S and other bisphenols;

- Aromatic ketones;

- Phthalates;

- PAH;

- Transfer of antimicrobial ingredients;

- Characteristics of bleached paper and cardboard according to EN 648;

- Color fastness according to EN 646;

- Specific migration of printing inks (UV inhibitors and acrylates);

- Extraction test according to FDA Sec. 176.170;

- According to Toy Directive EN71 and RoHS.

Packaging for pharmaceutical products, according to GMP:

- Appearance of the solution, absorbance;

- Acidity and alkalinity;

- Reducing the content of substances;

- Extractable metals - Al, Ti, Zn;

- Extractable heavy metals;

- Sulfate ash;

- Additives in plastic materials;

- Amides and stearates;

- Phenolic and non-phenolic antioxidants;

- Penetration ability.

Child-resistant packaging (CRC) according to EN ISO 8317 (resealable packaging for pharmaceutical and chemical products, such as detergents, disinfectants, washing capsules and other substances and chemicals);

Toys and goods for children;

FCM testing of metals, alloys, glass, ceramics, textiles, rubber, silicone, cork, wood;

Testing of general use items and recycled materials (short-, medium- and long-chain chlorinated paraffins -SCCP, MCCP, LCCP; BPA and other bisphenols, azo dyes, toxic substances and substances whose use is restricted).

SP Laboratorija performs part of the testing in the laboratory in Bečej, in accordance with the requirements of the applicable regulations in Serbia, but also in the EU:

Total migration: in model solutions (simulants): ultrapure H₂O, 3% CH₃COOH (B), 10% C₂H₅OH (A), 50% C₂H₅OH (D1), 95% C₂H₅OH (substitute for D2) at 20±2°C and 40 ±2°C; 24h, 5 and 10 days;

Specific migration of metals: Pb, Cd, Hg, As, Cr, Ba, Zn, Mo, Co, Cu, Fe, Mn, Sn and Se, in model solutions (simulants): ultrapure H₂O, 3% CH₃COOH (B), 10 % C₂H₅OH (A), 50% C₂H₅OH (D1), 95% C₂H₅OH (substitute for D2) at 20±2°C and 40±2°C; 24h, 5 and 10 days;

Content of metals in packaging: Pb, Cd, Hg and total Cr;

Microbiological testing of surfaces

Sensory tests (color, smell and texture).



In the area of testing of items of general use, SP laboratorija also cooperate with the Institute for Occupational Safety in Novi Sad, also a member of the Hamilton Group, accredited for determining the content of PCBs, formaldehyde and Cr⁶⁺.

Besides analyses, J.S. Hamilton offers consultations regarding the scope and conditions of testing, application and optimization of packaging materials and aids, as well as certification services - voluntary certification: Food safe, Useful for recycling and Biodegradable and compostable.

More about FCM testing possibilities in J.S Hamilton can be found on the SP Laboratorija' website, in the brochure:

<https://hamilton.com.pl/wp-content/uploads/2022/05/BROSZURA-EN-2.pdf> And ambipak magazine:

<https://www.ambalazaipakovanje.com/lider/sp-laboratorija-a-d-clan-hamilton-grupe/>

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TEST OF THE EFFICIENCY OF PRESERVING COSMETIC PRODUCTS - "CHALLENGE TEST"

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Chemical mixtures in cosmetic products pose a potential risk to the health of consumers. In order to prevent chemical degradation of the product, and therefore the growth of microorganisms, chemical substances known as preservatives are added to cosmetic products. Added preservatives must be compatible with other ingredients of the product and must not have toxic, allergic or any other irritating effects on the skin. The efficacy of preservation should be experimentally evaluated during the development of the cosmetic product, in order to ensure the microbiological stability of the product during storage and application. Basically, the Challenge test checks the effectiveness of the cosmetic product's preservatives and whether it is able to withstand various types of (challenges) contamination during production, from the environment and from direct contact with the human body to which the cosmetic product is exposed.

According to EU Regulation 1223/2009, every cosmetic manufacturer must ensure that the product is microbiologically stable during the declared shelf life. With the entry into force of the Refulation on cosmetic products (Official Gazette RS 60/2019, 47/2022), subjects in the business of cosmetic products are obliged to harmonize their operations with the provisions of this rulebook no later than April 10, 2023, in accordance with Article 117 of the Law on items of general use (Official Gazette RS 25/2019). The rulebook clearly defines that the report on the safety of the cosmetic product must, among other things, contain the results of the "Challenge test".

As part of cosmetic product testing services, SP Laboratorija performs the mentioned testing in accordance with SRPS EN ISO 11930 - Evaluation of antimicrobial protection of cosmetic products. This

standard provides a comprehensive approach to testing the antimicrobial protection of a cosmetic product and is mainly used by laboratories as a reference test. It is very important to point out that the preservation efficiency test is not required for those cosmetic products that have been determined to be low-risk in terms of microbiological contamination, which is defined in the standard SRPS EN ISO 29621 - Guidelines for risk assessment and identification of products with low microbiological risks. This document provides guidance to cosmetic manufacturers in defining those finished products which, based on a risk assessment, present a low risk of microbial contamination during manufacture and/or intended use, and therefore do not require the application of the *Challenge test*.

In the table, as an aid, the characteristics and types of products whose formulation is considered low-risk in terms of microbiological contamination are given:

Physico-chemical factor	Limit	Example of a product
pH value	≤3,0	Skin peels (glycolic acid)
pH value	≥10,0	Hair straightening preparations (relaxers)
Ethanol or other alcohol	≥20,0	Hairsprays, tonics, perfumes
Charging temperature	≥65°C	Lip balms and lipsticks, blushes with a creamy consistency
Water activity (aw)	≤0,75	Solvent-based products, nail polishes
Oxidation products	-	Hair colors
Aluminium chlorhydrate	≥25 %	Antiperspirants

Certain packaging components provide physical protection against contamination from consumer use (eg, pump dispenser, single-dose units) and contribute to the protection and preservation of the formulation. Other factors, such as the small volume of the product that limits the number of uses or the short duration of the indication also contribute to the protection of the formulation. If a product is microbiologically acceptable when placed on the market, it will remain so throughout its use. In this case, the microbiological risk during use is low, based on the high level of protection provided by the packaging.

How is the *Challenge test* performed?

The product is first tested to verify that it is not already contaminated. It is then artificially contaminated with a calibrated inoculum, which is prepared from certain reference strains of microorganisms, and then the ability of the preservative to destroy/reduce them is monitored.

The test microorganisms used for the analysis are:

- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Candida albicans*
- *Aspergillus brasiliensis*

The level of microorganisms in the product is checked at specified time intervals, after 7 (T7) days, then after 14 (T14) and after 28 (T28) days. For each time and for each strain, the value of the reduction in the number of microorganisms (in log units) is calculated and compared with the minimum values required under criteria "A" and "B", which are given in the reference document. The number of test microorganisms determined in intervals T14 and T28 must be lower than the number of microorganisms determined in interval T7. So, it is necessary to reduce the number of microorganisms.

Interpretation of *Challenge test* results:

-If the formulation complies with criterion "A", the microbiological risk is considered acceptable (the cosmetic product is protected from microbiological proliferation that poses a potential risk to the user) and the cosmetic product is considered to comply with the requirements of this standard without additional explanation.



- If the formulation complies with criterion "B", from the aspect of microbiological risk, the presence of control factors that are independent of the formulation is necessary, e.g. protective packaging with a pump that provides a higher level of protection than a box (Annex D, ISO 11930).

The duration of the *Challenge test* by testing stages:

- 7 days initial trial
- 28 days of test challenges
- 5 days of processing the results

Check the effectiveness of your preservative to ensure that your products are resistant to the growth and development of potentially harmful microorganisms!

CHANGES IN SERBIAN LEGISLATION IN THE PERIOD FROM 01.06.2022-31.08.2022

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GENERAL

- Official Gazette of RS 91/2022 - Regulation on maximum allowable residues of pesticides in food and animal feed
- Official Gazette of RS 37/2021, 84/2022 Regulation on types

of measuring instruments subject to legal control

PLANT PROTECTION PRODUCTS

- Official Gazette of RS 89/2022 - Regulation on establishing the annual program for post-registration control of plant protection products for 2022

CHANGES IN EUROPEAN FOOD LEGISLATION

(Contaminants, pesticide residues)

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Contaminants

Commission Regulation (EU) 2022/1364 of 4 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of hydrocyanic acid in certain foodstuffs (Text with EEA relevance)

Commission Regulation (EU) 2022/1370 of 5 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of ochratoxin A in certain foodstuffs (Text with EEA relevance)

Commission Regulation (EU) 2022/1393 of 11 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ 9-THC) in hemp seeds and products derived therefrom (Text with EEA relevance)

Pesticide residues

Commission Regulation (EU) 2022/1264 of 20 July 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fludioxonil in or on certain products

Commission Regulation (EU) 2022/1290 of 22 July 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlormequat, dodine, nicotine, profenofos and Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in

or on certain products

Commission Regulation (EU) 2022/1321 of 25 July 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluoride ion, oxyfluorfen, pyroxsulam, quinmerac and sulfuryl fluoride in or on certain products

Commission Regulation (EU) 2022/1324 of 28 July 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products

Commission Regulation (EU) 2022/1343 of 29 July 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, chlorantraniliprole and emamectin in or on certain products

Commission Regulation (EU) 2022/1346 of 1 August 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate in or on certain products

Commission Regulation (EU) 2022/1363 of 3 August 2022 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb and silthiofam in or on certain products

Commission Regulation (EU) 2022/1406 of 3 August 2022 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of

the Council as regards maximum residue levels for methoxyfenozide, propoxur, spinosad and thiram in or on certain products

Commission Regulation (EU) 2022/1435 of 26 August 2022 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for calcium carbonate, carbon dioxide, cyprodinil and potassium hydrogen carbonate in or on certain products

