

Акредитација и безбедност хране данас и сутра у Републици Србији

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Акредитација

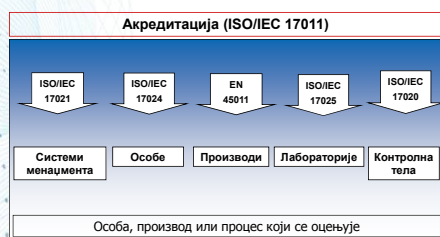
Акредитација – званично утврђивање компетенције организација за оцењивање усаглашености

- Организације за оцењивање усаглашености оцењују усаглашеност производа, услуга и испоручилаца са спецификацијама и/или захтевима
- **Крајњи циљ – Обезбеђивање усклађености са релевантним стандардом**
- **Заштита јавног интереса**
 - Опште здравље и безбедност
 - Безбедност и здравље на раду
 - Заштита потрошача
- **Заштита животне средине**



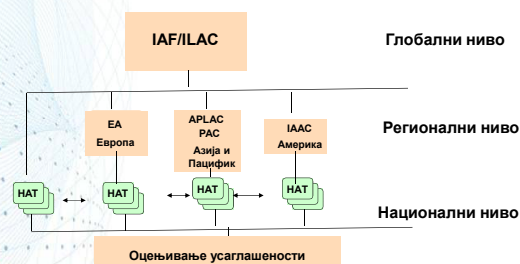
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Међународни стандарди који се примењују код потврђивања компетенције



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Јединствена светска мрежа акредитације



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СТО ТБТ споразум – члан 6.1.1 Примена акредитације – компетенција и поверење

Члан 6.1.1

Акредитација обезбеђује верификацију техничке компетенције тела за оцењивање усаглашености

Акредитација примењивана у складу са релевантним међународним стандардом представља поуздан начин успостављање поверења



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WORLD TRADE ORGANIZATION



СТО споразуми

Споразум о техничким препрекама трговини - ТБТ споразум

- Осигурава да технички прописи и стандарди укључујући и поступке оцењивања усаглашености не представљају непотребну препреку у међународној трговини.
- Могуће предузети мере за осигурање квалитета, заштиту здравља и живота људи, животиња и биљака, заштите животне средине и спречавање превара.
- **Споразум о примени санитарних и фитосанитарних мера – СПС споразум**
 - Хармонизовани међународни стандарди, упутства и препоруке the Codex Alimentarius Commission, OIE, IPPC



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Међународни стандарди, упутства и препоруке

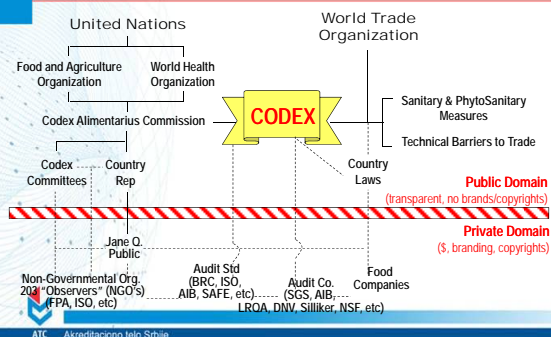
- **Codex Alimentarius Commission** – безбедност хране – адитиви, резидуе ветеринарских лекова и пестицида и контаминената, методе анализа и узорковања, добра хигијенска праксе
- **OIE** – здравље животиња, зоонозе
- **IPPC** – здравље биљака



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Codex: Food Code

174 signatory countries = 98% of the world population



Закон о безбедности хране

Службени гласник Републике Србије 41/2009

- Обавезе и одговорности субјекта у пословању храном и храном за животиње
 - Члан 31-34 - одговорност, следљивост
 - Члан 45-54 - услови хигијене, успостављање система за осигурање безбедности хране у складу са принципима добре произвођачке и хигијенске праксе и анализе опасности и критичних контролних тачака - HACCP
 - Члан 47 и 52 Министар прописује услове за оцену поступака самоконтроле



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Закон о безбедности хране

Службени гласник Републике Србије 41/2009

- Члан 69-70- планови службене контроле и мониторинг безбедности хране и хране за животиње, узорковање, анализе
- Члан 72-73 инспекцијски надзор
 - Контролише да ли је субјект испунио прописане услове у вези са хигијеном, да ли је успостављен систем осигурања безбедности хране у складу са принципима добре произвођачке и хигијенске праксе и HACCP



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Закон о ветеринарству

Службени гласник Републике Србије 91/2005

- Члан 82 - систем за осигурања безбедности производа који је уведен и одржаван на принципима добре произвођачке и хигијенске праксе и анализе опасности и критичних контролних тачака – HACCP програм
- Члан 146 – надзор – да ли има HACCP програм



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Обавезна акредитација лабораторија за испитивање хране и хране за животиње

- Акредитација - Закон о безбедности хране
 - Члан 18 – Дирекција за националне референтне лабораторије
 - Члан 20 – Лабораторије
- Акредитација - Закон о ветеринарству
 - Члан 21, 26, 28,30 - Лабораторије



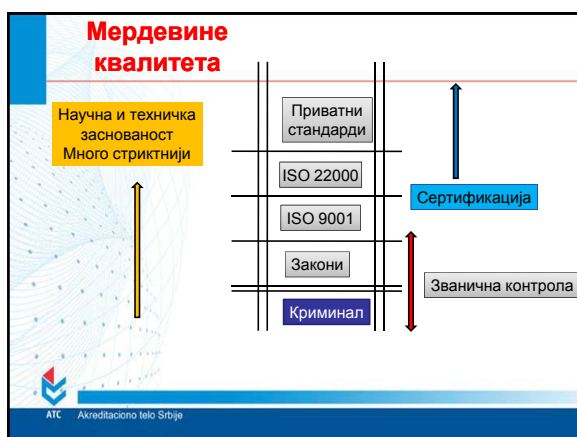
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Regulation EC 882 2004 – званична контрола

- **члан 5** – делегирање одређених задатака
the control body works and is accredited in accordance with European Standard EN 45004 'General criteria for the operation of various types of bodies performing inspection' and/or another standard if more relevant to the delegated tasks in question;
- **члан 12** – званичне лабораторије
2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:
 (a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
 (b) EN 45002 on 'General criteria for the assessment of testing laboratories';

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Доброволни и приватни стандарди

BRC GLOBAL STANDARDS THE WORLDWIDE STANDARDS OF CHOICE

International standards IFS

GRMS

FS HACCP SYSTEM

Food Safety System Certification 22000

SQF INSTITUTE

GLOBALG.A.P. The Global Partnership for Clean, Safe and Fair Food

primusGFS™

Synergy 22000

FORUM

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Неке од компанија које прихватају GSFI признате шеме

Wegmans DAYMON WORLDWIDE McDonald's

Honnet AEON The Coca-Cola Company coles

Walmart ASDA ShopRite Campbell's groupe carrefour kroger

Carrefour KRAFT ConAgra Foods FOOD LION MIGROS

DELHAIZE GROUP Group Strength, Local Expertise Iyson H-E-B ICA

sodexo Ahold DANONE TESCO Click n Pay

ATC Akreditaciono Loblaw Publix METRO Group MADE TO TRADE.

SRPS EN ISO 22000 – Системи менаџмента безбедношћу хране

- **Захтеви за сваку организацију у ланцу хране**
- **SRPS EN ISO 9001 + HACCP**
 - Систем менаџмента безбедношћу хране
 - Одговорност руководства
 - Менаџмент ресурсима – људски ресурси, инфраструктура, радна средина
 - Планирање и реализација безбедних производа – претходно потребни програми, анализа опасности, успостављање HACCP плана, систем следљивости
 - Валидација, верификација и побољшавање система менаџмента безбедношћу хране

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Системи менаџмента безбедношћу хране

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Defining day-one competencies for veterinarians working for State Veterinary Services in Europe

Workshop participants: H Batho, K Jörger, U Kihm, D Krnjaic, J Risi, U Sperling, K Stärk, W Winding, H. Wyss

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Accreditation of official food/feed safety and animal health laboratories

Alexander Rogge
DG SANCO.E5- Enforcement

EA General Assembly
23-24 May 2012
Madrid

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Legal requirements

- Article 12 of Regulation (EC) No 882/2004 on food, feed, animal health and animal welfare official controls:
 - The competent authority of the Member State **designates the laboratories** that carry out analysis of samples taken during official controls
 - To be designated, a **laboratory has to be accredited in accordance with EN ISO/IEC 17025**
 - The accreditation « may relate to individual tests or groups of tests »

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Background

- Recurrent findings of DG SANCO (Food and Veterinary Office (FVO)) during audits in the Member States: **lack of accreditation** of some official laboratories
- **Specific situations** (e.g. emerging risks, *Trichinella*)
- **Different understandings** of Article 12 of Regulation (EC) 882/2004 or ISO/IEC 17025 requirements
- **Current review of Regulation (EC) No 882/2004** (proposal: end of 3rd quarter 2012)


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Consultations and discussions

- **Who:** Competent Authorities (CA) of the Member States (MS):
 - Official controls (Regulation (EC) No 882/2004)
 - Animal health
 - Plant health
 - Seeds and plant propagating material
- As well as:
 - European co-operation for Accreditation (EA)
 - DG Enterprise and Industry - European Commission
- **When and how:** several meetings in 2010, 2011 and 2012 and discussion paper (January 2011) and answers


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State of discussions and ideas for change on following issues

1. Article 12 of Regulation (EC) No 882/2004 (« groups of test »)
2. Use of a method recently required in Union legislation
3. Changes of a method already in use
4. Emergency situations and emerging risks
5. *Trichinella* laboratories
6. Accreditation of animal health laboratories
7. Accreditation of plant health laboratories
8. Participation in proficiency tests/comparative tests
9. Validation of methods
10. Flexible scope and fixed scope accreditations

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Issue 1: Article 12 of Regulation (EC) No 882/2004

- **Issue:** Article 12: the accreditation "may relate to individual tests or groups of tests"
- **Comments:** sentence needs to be clarified

↳ **Clarification of Article 12 to ensure that:**

- ↳ **The scope of accreditation includes all methods used by the laboratory as official laboratory**
- ↳ *The scope can comprise one or several methods (flexible scope possible)*


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Issue 2: use of a method recently required in Union legislation

- **Issue:** use of a method is a recent/new requirement in Union legislation and requires validation of the new method and (in general) a new accreditation or an extension of accreditation of the laboratory
- **Comments:**
 - Time needed for validation of the method and accreditation of the laboratory
 - Use of a validated but « not (yet) accredited » method by an already ISO/IEC 17025 accredited laboratory should be possible

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Issue 2: use of a method recently required in legislation

↳ **Modification of Article 12: possibility for the CA to temporarily designate a laboratory if alternative guarantees:**

- ↳ **Laboratory already accredited ISO/IEC 17025 for the use of a similar method**
- ↳ **Analysis/diagnosis under supervision of CA or relevant national reference laboratory (NRL)**
- ↳ **Temporary designation (for the time needed to be accredited)**

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Issue 3: changes of a method already in use

- **Issue:** changes of a method already in use require a new accreditation or an extension of the accreditation already obtained by the laboratory
- **Comments:** same as for issue 2

↳ **Modification of Article 12: possibility for the CA to temporarily designate a laboratory if alternative guarantees (same as for issue 2)**

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Issue 4: emergency situations and emerging risks

- **Issue:** emergency situations or cases of emerging risks where a **sudden increase of analytical needs** requires the use by official laboratories of a (standardised/validated) method which is not included in their scope of accreditation
- **Comments:**
 - Swift and efficient management of the situation/risk is priority
 - Use of a validated but « not (yet) accredited » method by an already ISO/IEC 17025 accredited laboratory should be possible
- ↳ **Modification of Article 12:** possibility for the CA to **temporarily designate a laboratory** if alternative guarantees (same as for issues 2 and 3)

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Issue 5: *Trichinella* laboratories

- **Issue:** mandatory accreditation ISO/IEC 17025 of small sized ***Trichinella* laboratories** attached to slaughterhouses or game handling establishments
- **Comments:** huge difficulties
 - ↳ **Solutions are being studied for laboratories:**
 - ↳ **Attached to slaughterhouses or game handling establishments**
 - ↳ **Which use only the *Trichinella* reference method or equivalent methods** in accordance with Regulation (EC) No 2075/2005
 - ↳ **Under the supervision of the competent authority or of an official laboratory accredited ISO/IEC 17025 for the use of these methods**


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Issue 6: accreditation of animal health laboratories

- **Issue:** mandatory accreditation ISO/IEC 17025 of animal health laboratories
- **Comments:** accreditation difficult:
 - for **all methods used in diagnosis of viral diseases** (because of important resources needed)
 - For **all methods used in diagnosis of parasitic diseases** (because of multitude of diseases and broad spectrum of diagnostic tests)
- ↳ **Commission empowered to consider solutions if necessary**


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Issue 7: accreditation of plant health laboratories

- **Issue:**
 - **Currently no mandatory ISO/IEC 17025 accreditation** of plant health laboratories
 - Need to improve reliability, soundness and uniformity of their results
 - Weaknesses and problems as regards performance of these laboratories identified during DG SANCO (FVO) audits
- **Comments:**
 - Move towards accreditation broadly supported
 - Many laboratories already accredited, worldwide development towards accreditation of laboratories
 - But under certain conditions


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Issue 7: accreditation of plant health laboratories

- ↳ **Modification of Regulation (EC) N° 882/2004:**
 - ↳ **Extension of the mandatory ISO/IEC 17025 accreditation to official plant health laboratories**
 - ↳ **Transitional period of 5 years**
 - ↳ **Commission empowered to consider solutions (accreditation not for all the methods they use as official laboratory if accreditation already obtained for the use of certain significant and representative methods?)**


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Issue 8: participation at proficiency tests (PTs) or comparative tests (CTs)

- **Issue:**
 - ISO 17025 recommends the participation at PTs/CTs
 - In some areas, like **residues of veterinary medicines and pesticides**, legislation provides for **mandatory participation**
 - Sometimes:
 - **lack of participation** of laboratories at PTs/CTs,
 - **lack of PTs/CTs** organised
 - **different interpretations** of ISO 17025
 - different mandatory **minimum frequencies of participation** at PTs/CTs


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Issue 8: participation at proficiency tests (PTs) or comparative tests (CTs)

- Comments:
 - **Frequent/regular participation at PTs/CTs** relevant to scope of accreditation of laboratory and satisfactory performance at these PTs/CTs are **absolutely necessary/mandatory**
 - To ensure higher participation at PTs/CTs:
 - participation at EURL PTs to be made possible for routine laboratories
 - possibility to participate at PTs/CTs from NRLs from other MS
 - organisation of PTs/CTs in a more coordinated manner


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Issue 8: participation at proficiency tests (PTs) or comparative tests (CTs)

- ↳ **Modification of Article 12: upon request by the relevant EURL or the NRL, participation of official (routine) laboratories at PTs/CTs organised in their scope of accreditation ISO/IEC 17025**
- ↳ **More harmonised interpretation of ISO/IEC 17025 by the Abs (role of EA)**


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Issue 9: validation of methods

- Issue: ISO/IEC 17025:
 - The **laboratory has to use standardised methods or validated methods**
 - Which methods are / have equivalent status to « standardised methods »?
- Comments: methods validated by EURLs/NRLs to be given equivalent status to « standardised methods »


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Issue 9: validation of methods

- ↳ **Modification of Article 11: methods validated by EURLs and those validated by NRLs mentioned in cascade of methods of sampling, analysis and diagnosis. Aim is:**
 - For methods validated by EURLs:
 - **All EU ABs to deliver accreditation for the use within intended scope of these methods without requesting supplementary internal full validation by the laboratory (only verification by laboratory)**
 - For methods validated by the NRL in a MS:
 - **AB of this MS to deliver accreditation for the use within intended scope of these methods without requesting supplementary internal full validation by a laboratory in the MS (only verification by laboratory)**


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Issue 10: flexible scope / fixed scope accreditation

- Issue: **very different/diverging requirements in particular for flexible scope accreditation** (but also for fixed scope accreditation) **from one AB to another**
- Comments:
 - EA Guide on accreditation of flexible scopes too general
 - Harmonised interpretation of accreditation of flexible scopes needed across the EU (if not, huge differences in levels of difficulty, time needed and costs for laboratories)
 - Accreditation of flexible scope in particular useful if no specific assessment by AB prior to the addition of the matrix/analyte/method to the scope (e.g. in case of emergency situations and emerging risks)


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Issue 10: flexible scope / fixed scope accreditation


- Comments: examples of diverging interpretation between ABs:
 - Fixed scope accreditation: only specific combination matrix/analyte/specific method to be followed precisely/closely in some MS, broader combinations in other MS
 - New version of method without fundamental change and same matrix/analyte: only possible with flexible scope accreditation in some MS, possible with fixed scope accreditation in other MS
 - When a new method is already covered by a flexible scope accreditation, then in some MS the AB includes it in the scope without carrying out a specific assessment, in others the AB first carries out a specific assessment
 - For some ABs but not for others, a flexible scope can include all methods using a same analytical technique (e.g. ELISA, LC-MS/MS)

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Issue 10: flexible scope / fixed scope accreditation

- ⚙ *Additional EA guidance:*
- ⚙ *on what a flexible scope could cover and corresponding detailed requirements*
- ⚙ *on different degrees of flexibility of flexible scopes accreditations*
- ⚙ *on flexible scope accreditation assessments by ABs*
- ⚙ *on pros and cons of flexible and fixed scopes accreditations (for the laboratories to be able to chose according to their situation)*
- ⚙ *with concrete examples*
- ⚙ *...*



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