



**ORGANIC  
TRADE FOR  
DEVELOPMENT**

# Organic Trade for Development

The goal of OT4D is to foster organic business development in export and domestic trade to create and expand job opportunities in rural areas, particularly for youth and women, and to bring the multiple positive effects of investing in organic agriculture in terms of economic growth, sector capacity development, innovation and natural environment to Albania, Serbia and Ukraine.

# New Organic EU Regulations

## An introduction for stakeholders from Ukraine, Albania and Serbia



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,  
Education and Research EAER  
**State Secretariat for Economic Affairs SECO**



# New Organic Regulations



**Tom Nizet**

Managing Director Authent Ltd

[tn@authent.bio](mailto:tn@authent.bio)

[www.authent.bio](http://www.authent.bio)



**Toralf Richter**

FiBL

[Toralf.richter@fibl.org](mailto:Toralf.richter@fibl.org)



# Program



Timing	Topic
10:00 – 10:15	Reception, welcome and introduction
10:15 – 12:00	From equivalence to compliance: the main challenges
	Lunch break
13:00 – 14:30	Introduction to the new production rules (compliance)
	Coffee break
14:40 – 15:50	Introduction to the new requirements for controls and certification (compliance)

# Introduction (Topic)

## Co-existing systems:

- National organic rules
- EU Regulations:
  - Equivalent standards
  - Compliance with EU Regulation

Equivalence of CB Standard

Compliance of CB

Equivalence for  
production rules and  
control measures  
compared to  
requirements in  
834/2007

Compliance with  
Objectives and  
principles  
Production rules  
And Labelling rules

Control rules => Reg 2021/1698



Equivalence of  
CB Standard



Compliance of CB

Compliance with  
Objectives and  
principles =  
Production rules  
And Labelling rules

Relevant EU Regulations for third countries:  
-2018/848 + amendments by

2020/1794

2020/715

2021/1691

2021/1697

+2020/464 (not referred to in the slides)

+2021/279

+2021/771

+2021/1165

+2021/1342

+2021/1378

+2021/1698

Transition period

01/01/2022

31/12/2024



Compliance EU

?

Equivalence of CB Standard

Compliance of CB

Differences?

Ukraine Organic Legislation



Transition period

01/01/2022

31/12/2024



Compliance EU

Equivalence CB Standard 2

Compliance CB



Equivalence CB Standard 1

Compliance CB

Serbian Organic Legislation



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# **Part 1: From equivalence to compliance: the main challenges for operators and control bodies**

# Part 1: From equivalence to compliance: the main challenges for operators and control bodies



- a) Certificate
- b) Non compliances and measures
- c) Traceability
- d) Mass balance
- e) Subcontractors
- f) Precautionary measures
- g) Products and substances
- h) Records

# Part 1: main challenges



- a) Certificate (Reg 2021/1378)
  - 1. Mandatory model
  - 2. Issued in TRACES
  - 3. List with CBs authorized to issue certificates for compliance

# Part 1: main challenges



## a) Certificate

### 1. Mandatory model (1378.I)

- i. Product categories – product names and CN codes
- ii. No date of control(s) and no maximum validity
- iii. List with names of members of a group of operators
- iv. General information on organic / in-conversion / non-organic

# Part 1: main challenges



## a) Certificate

### 3. List with CBs authorized to issue certificates for compliance

(1378.II)

- i. Name and code number
- ii. Product categories (a – g)
- iii. Third countries (not covered by agreement on trade or equivalence recognition 834/2007)
- iv. For organic and “in-conversion” products

# Part 1: main challenges



## b) Non compliances (NC) and measures:

### 1. examples from the new rules:

- i. A new conversion period in the case of treatment with a product/substance not authorized for use in organic production (848.II.I.1.7.3§1)
- ii. A new conversion period in the case of treatment of livestock more often than allowed per year/lifecycle (848.II.II.1.5.2.4)
- iii. A conversion period of 12 months in case of treatment of beehives with chemically synthesized allopathic products (848.II.II.1.9.6.3f)
- iv. Mandatory withdrawal of the certificate for the whole group where deficiencies in the set-up or functioning of the ICS affect integrity of products (848.36.2)
- v. A new conversion period for the land after use of treated seeds (848.II.I.1.8.5.3§2)

# Part 1: main challenges



b) Non compliances (NC) and measures:

2. Requirements for CBs: (1698)

- i. Catalogue of measures as requirement for recognition (1.2h)
- ii. Mandatory information on NC and measures in the database (18)
- iii. Mandatory exchange of information on any suspicion of NC that affects integrity of products (21.2)
- iv. Mandatory investigation and blocking in the event of suspicion of NC (22)

# Part 1: main challenges



b) Non compliances (NC) and measures:

3. Catalogue of measures for CBs (1698.22.3 & Ann IV)

- i. List of NC with reference to specific rules of 2018/848
- ii. Mandatory NCs
- iii. Classification of NC as minor, major and critical based on 4 criteria (application of PCM, impact on integrity of products, traceability of affected products and operator's response to previous NC)
- iv. Measure(s) to be applied for each NC

# Part 1: main challenges



b) Non compliances (NC) and measures:

4. Measures in the event of NC affecting the integrity (1698.23)

- i. E.g. as result of the use of unauthorized substances, products or techniques, or commingling
- ii. No reference to organic production
- iii. Where the NC is established, determine origin and extend of the NC and establish responsibilities of the operator/GG and take measures to ensure that the operator/GG remedies NC and prevents further occurrences of such NC
- iv. Apply the catalogue of measures and increase frequencies of controls
- v. In the event of serious/repetitive/continued NC, suspend or withdraw the certificate

# Part 1: main challenges



b) Non compliances (NC) and measures:

5. Three types of NC (characterized by one or more of the following): (1698.IV)

	minor	Major	Critical
PCM in place, proportionate and appropriate and operator's own controls are efficient?	Yes	No	No
NC affects the integrity of products?	No	Yes	Yes
Did operator correct minor NC in a timely manner?	-	No	No
Products can be traced and prevented from being imported?	Yes	Yes	No

# Part 1: main challenges



b) Non compliances (NC) and measures:

6. Measures related to each type of NC (2021/1698.IV)

	minor	Major	Critical
Submission of action plan (incl deadline to correct)	X		
No reference to organic production on products		X	X
Prohibition of import		X	X
New conversion period		X	X
Limitation of certificate's scope		X	X
Improvement of PCM		X	
Suspension of the certificate			X
Withdrawal of the certificate			X

# Part 1: main challenges



## b) Non compliances (NC) and measures:

### 7. Minimum content of the catalogue of measures (2021/1698.IV)

	Major	Critical
Significant deviation between input and output calculation (mass balance)	X	
Absence of records and financial records showing the compliance with Regulation (EU) 2018/848		X
Intentional omission of information leading to incomplete records		X
Falsification of documents connected with the certification of organic products		X
Intentional re-labelling of downgraded products as organic		X
Intentional mixing organic with in-conversion or non-organic products		X
Intentional use of non-authorized substances or products within the scope of the Regulation (EU) 2018/848		X
Intentional use of GMOs		X
The operator refuses the control authority or the control body access to premises subject to controls, or to its book keepings, including financial records, or refuses to allow the control authority or control body to take sample		X

# Part 1: main challenges



## c) Traceability

=: ability to trace and follow products through all stages of production, preparation and distribution (848.3.48)

-operators in third countries are able at any time to provide information ensuring traceability (848.45.1c)

-detailed requirements for traceability records for groups (279.5g)

-traceability checks by the Commission (Supervision) (1698.6)

-mandatory method/technique for controls (1698.11)

-mandatory documentary check in verification of consignment (1698.16)

-cfr catalog of measures

-mandatory part of witness audit report (1698.II.A.2.2f)

# Part 1: main challenges



## d) Mass balance

- =: balance between incoming and outgoing products
- Mandatory part of annual controls (1698.11.2)
- Selection of operators/GG shall be based on a risk assessment (1698.11.3)
- Taking into account delivered products, products in storage, products that have left the unit, yield (N-1 and N), losses and amounts sold as non-organic (1698.11.5)
- Included in documentary check during verification of consignment (1698.16.3)
- Subject to witness audit report (1698.II.A.2.2f)
- Catalogue of measures ! (1698.IV)

# Part 1: main challenges



- e) Subcontracting and subcontractors (1698)
  - To be included in CB risk assessment (Art 9.2)
  - To be included in contract (exchange of information) (Art 10.1d)
  - Transfer of responsibilities – subject to controls (Art 10.2)
  - To be included in the CB database (Art 18e)

# Part 1: main challenges



f) Precautionary measures (PCM) (848.28 + 29)

to avoid the presence of non authorized products and substances

- i. Identify risks of contamination, put in place measures to avoid risks of contamination of organic production and products and regularly review and adjust
- ii. Substantiate, block products and inform CB in case of suspicion of non-compliance because of presence of certain products/substances
- iii. CB shall start official investigation while products remain blocked. Products cannot remain organic in case of
  - i. Use of unauthorized substances
  - ii. Absence of PCM
  - iii. Insufficient response to previous NC

# Part 1: main challenges



## g) Products and substances

- Products and substances for EU based operators also apply in third countries (compliance) (related to 848.24)
- In addition: lists with products/subs for third countries (2021/1165.10 + VI)
- List with products/subs for cleaning/disinfection for all organic activities (NEW) (2021/1165.5 and 1165.IV)

# Part 1: main challenges



## h) Records (2021/1691)

- Activity specific requirements

- Demonstrate compliance via records of PCM, derogations, external inputs used, movement (in/storage/out), cleaning

OPERATORS' main challenges	Plant production	Processing	Storage	Groups	CONTROLS	NT
Seeds	X				X	
Non organic ingredients		X			X	
Natural flavouring s/p		X				
Soil management	X				X	
Preparation	X	X			X	
Products and substances	X	X	X		X	
Records	X	X	X		X	
Traceability	X	X	X	X	X	
Mass balance	X	X	X	X	X	
Precautionary measures	X	X	X		X	
Subcontractors	X	X	X	X		
Composition & size				X	X	
Established and legal personality				X		
Joint marketing system				X		
Adjust ICS				X	X	
Non-compliances and measures	X	X	X	X	X	
Certificate	X	X	X	X	X	

**Thank you for your attention**

**End of part 1**

**Any Questions ?**

# Part 2: The new production rules: the main challenges for operators

13:00 – 14:30

## Part 2: The new production rules: the main challenges for operators

- 2.1 For a certified producer of organic cereals
- 2.2 For a certified processor
- 2.3 For a certified operator involved in storage
- 2.4 For a certified group of operators

## Part 2: From equivalence to compliance: the main challenges for operators

### 2.1 For a certified producer of organic cereals

- a) Seeds
- b) Soil management
- c) Preparation operations other than processing on the plants
- d) Products and substances
- e) Records
- f) Traceability
- g) Mass balance
- h) Precautionary measures to avoid presence of non-authorized products and substances

# Part 2: From equivalence to compliance: the main challenges

## 2.1 For a certified producer of organic cereals

### a) Seeds

- i. “Organic heterogeneous material” in the EU (848.3.18, 13 and II.I.1.10.1)
- ii. “Organic Varieties suitable for organic production” in the EU (848.II.I.1.8.4)
- iii. Authorised use of own in-conversion and organic seed (848.II.I.1.8.5.2 §2)
- iv. Authorised use of in-conversion seed without derogation (848.II.I.1.8.5.2§1)
- v. Use of treated seeds results in a new conversion period of the land (848.II.I.1.8.5.3§2)
- vi. Production of organic seeds and “in-conversion” seeds (848.II.I.1.8.2 & 848.10.4)

## Part 2: From equivalence to compliance: the main challenges

### 2.1 For a certified producer of organic cereals

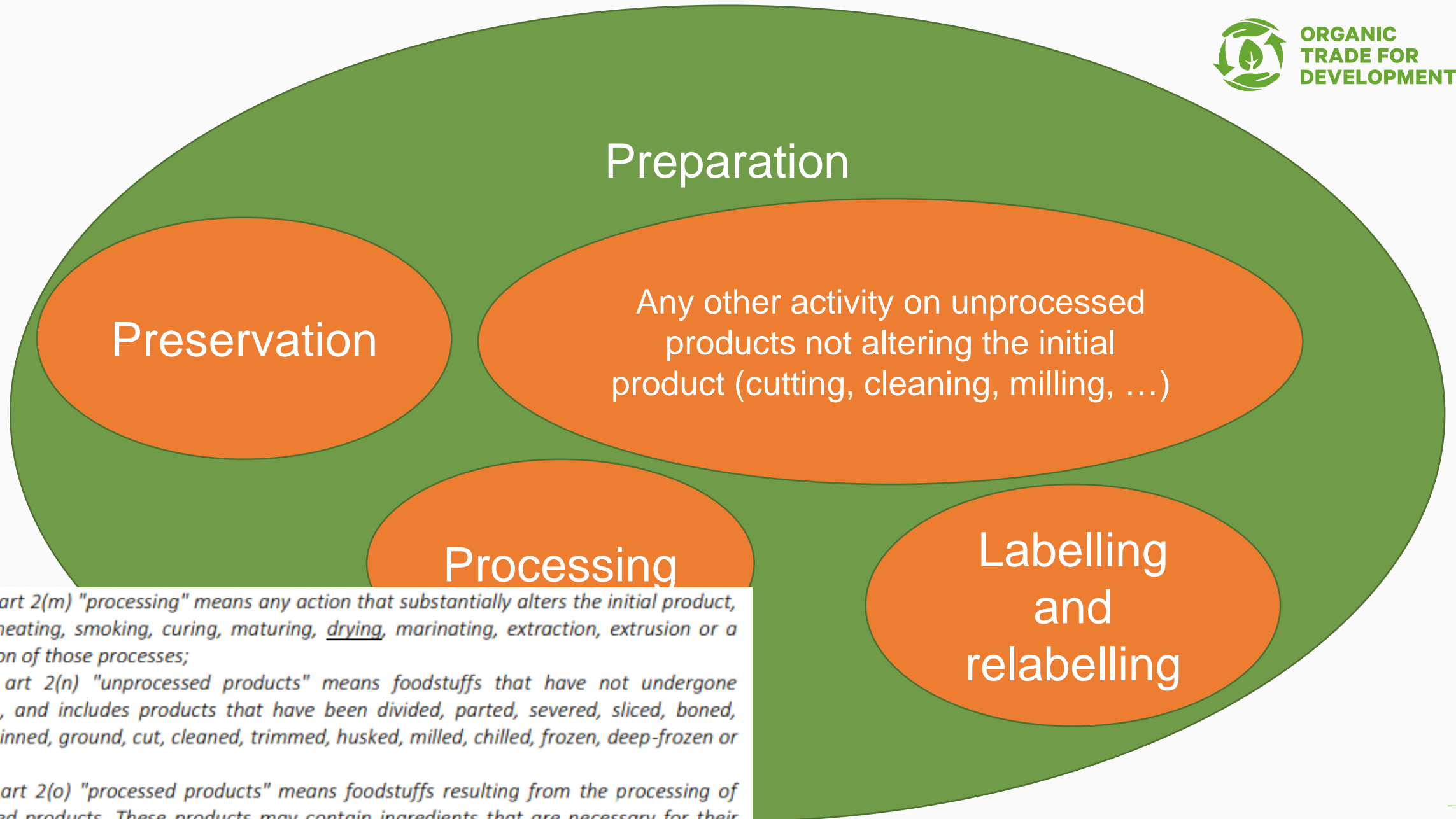
#### b) Soil management

- i. Tillage and cultivation practices (848.II.I.1.9.1)
- ii. Fertility of the soil shall be maintained and increased by the use of multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops and by the application of livestock manure or organic matter, both preferably composted, from organic production (848.II.I.1.9.2)

## Part 2: From equivalence to compliance: the main challenges

### 2.1 For a certified producer of organic cereals

- c) Preparation operations other than processing: “cleaning”, sorting, (drying is a processing activity)
  - i. Requirements for processing of food apply (848.II.I.1.13)
    - Identification of critical steps
    - Take precautionary measures and keep records of those measures
    - Guarantee separation
    - Only use authorized products/substances for the purpose of cleaning and disinfection



852/2004 art 2(m) "processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;

852/2004 art 2(n) "unprocessed products" means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;

852/2004 art 2(o) "processed products" means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

# Part 2: From equivalence to compliance: the main challenges



## 2.1 For a certified producer of organic cereals

### d) Products and substances

- i. A new conversion period in the case of treatment with a product/substance not authorized for use in organic
- ii. An extension of the conversion period in the case of contamination of the land or one or more parcels
- iii. Fertilizers, soil amendments and nutrients: (2021/1165.II + VI: 16/07/2022: new limits for contaminants in EU: 2019/1009)
- iv. Plant protection products: 2021/1165.I + VI (new category of products: basic substances and new conditions for ethylene)
- v. Products/substances for the purpose of cleaning and disinfection: 2021/1165.IV + VI

## Part 2: From equivalence to compliance: the main challenges

### 2.1 For a certified producer of organic cereals

#### e) Records

- i. Any external input used on each parcel (farmyard manure from factory farming = forbidden) (1165.II)
- ii. Detailed records on the amount of the harvest (per parcel) (848.1.12§1)
- iii. Documentary evidence on any derogation (NONT seeds) (848.1.12§1)
- iv. Detailed records on the use of fertilizers and soil conditioners (848.1.12§1)
- v. Detailed records on the use of plant protection products (848.1.12§1)
- vi. Products used for cleaning and disinfection (848.1.11)

## Part 2: From equivalence to compliance: the main challenges

### 2.1 For a certified producer of organic cereals

#### f) Traceability

- i. The buyers
- ii. The quantities in stock and their location

## Part 2: From equivalence to compliance: the main challenges

### 2.1 For a certified producer of organic cereals

#### g) Mass balance

- i. Records to allow the mass balance check shall cover at least the following elements: products delivered, in storage, products that left, yields (N-1 & N), losses, and the sales as non-organic
- ii. Mass balance (estimation) can also be a “N” balance of 1 parcel over a period of 3 years.
- iii. Mass balance can be comparison of kg of seeds purchased and compared against kg of harvest for one field.

# Part 2: From equivalence to compliance: the main challenges



## 2.1 For a certified producer of organic cereals

### h) Precautionary measures to avoid the presence of non authorized products and substances

- i. Identify risks: fungi attacks, insects, harvesting conditions, post harvest contamination and commingling (silo, cleaning, transport, ...)
- ii. PCM: soil analysis, crop rotation, legumes, associations, organic matter input, separate inputs for non-organic PU from in-conversion & organic PU (848.III.7.2)
- iii. In case of suspicion of non-compliance because of presence of certain products/substances
  1. Isolate; 2. Substantiate (check inputs used / storage unit's history / transport means / subcontractor's PCM); 3. Block and inform CB; 4. Cooperate

## Part 2: From equivalence to compliance: the main challenges

2.2 For a certified processor of organic products

- a) Precautionary measures and records
- b) Non organic ingredients and records
- c) Products and substances
- d) Records of any input used
- e) Recipe
- f) Subcontractors
- g) Natural flavouring substances & - preparations

## Part 2: From equivalence to compliance: the main challenges

2.2 For a certified processor of organic products

- a) Precautionary measures and records
- b) Non organic ingredients and records
- c) **Products and substances**
- d) Records of any input used
- e) **Recipe**
- f) Subcontractors
- g) **Natural flavouring substances & - preparations** (= agric ingredients)

## Part 2: From equivalence to compliance: the main challenges

### 2.2 For a certified processor of organic products

#### c) Products and substances

1. Food additives: no more separation “plant / animal origin” & minor changes (e.g. conditions for use of E 903 - carnauba wax) (1165.V.A1)
2. Processing aids: status quo (1165.V.A2)
3. Authorised non-organic ingredients  
(EU level): strongly reduced and 2 new (1165.V.B)
4. TC - CB level: Procedure via Comm and MS (1165.10 & VI)

## Part 2: From equivalence to compliance: the main challenges

### 2.2 For a certified processor of organic products

#### e) **Recipe (848.II.IV.2.3)**

- Mono-ingredient products (ex honey, wild garlic, raspberries, ...)
  - # kg of sub-batches which may vary per batch of end product)
- Multi-ingredient products (ex jam:
  - 50 kg fruits + 50 kg sugar + ...
  - 75 kg jam

## Part 2: From equivalence to compliance: the main challenges

2.2 For a certified processor of organic products

g) **Flavouring substances and – preparations**

-889.27.2b: “shall not be calculated as ingredients of agricultural origin” covering also flavourings changed into “shall not be calculated as ingredients of agricultural origin” no longer referring to flavourings (848.II.IV.2.2.4)

-All of the flavouring components and carriers of flavouring components in the flavouring concerned are organic (848.30.5c(iii))

## Part 2: From equivalence to compliance: the main challenges

2.3 For a certified operation involved in storage (848.III.5 & 7)

- a) Precautionary measures and records (reception, identification, coherence of information, separation, registration of movement, ...)
- b) Products and substances for cleaning and disinfection (2021/1665.IV)
- c) Records (848.III.7.4c)

## Part 2: From equivalence to compliance: the main challenges

### 2.4 For a certified group of operators

- a) Composition and size (848.36.1 and 279.4 + 10)
- b) Established and legal personality
- c) Joint marketing system
- d) Adjust ICS to the new requirements (848.36.1, 279.5+6)
- e) Internal traceability (279.5g)
- f) **Be aware of “deficiencies of the ICS”**

# Part 2: From equivalence to compliance: the main challenges



## 2.4 For a certified group of operators

- f) Be aware of “deficiencies of the ICS”

### **Suspend/withdraw the certificate in case of deficiencies of ICS affecting integrity of products (848.36.2)**

- a) Producing, preparing or selling products from suspended/withdrawn members or production units
- b) Selling products for which the ICS manager has decided to sell them as conventional
- c) Adding new members/PU without prior approval of the ICS manager
- d) Not carrying out annual physical on-the-spot inspection of a member in a given year
- e) Failing to indicate the members which have been suspended/withdrawn
- f) Serious deviations in findings between ICS inspections and CB inspections
- g) Serious deviations in imposing measures and carrying out the follow up
- h) Inadequate number of ICS inspectors or inadequate competences of ICS inspectors

**Thank you for your attention**

**End of part 2**

**Any Questions ?**



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# Part 3: Introduction to the new requirements for control bodies

14:40 – 15:50

Transition period

01/01/2022

31/12/2024



Equivalence CB Standard 2

Compliance CB



Equivalence CB Standard 1

Balance?

Differences?

Changing National Organic Legislation

Compliance EU

## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. Switch from equivalence to compliance in practice
4. Controls
5. Other Actions

## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. Switch from equivalence to compliance in practice
4. Controls under the compliance regime
5. Other actions under the compliance regime

# Part 3: Introduction to the new requirements for control bodies



## 1. Continue under the equivalence regime (2021/1342.2)

-Under (risk based) supervision of the Commission (based on the annual reports and other information received)

-by 28/3 each year, send the annual report (update of the Technical Dossier) containing at least:

- a) Overview of activities (# op/GG sorted by categories and grouped by tariff codes)
- b) Updates on the production standards (incl assessment of equivalence)
- c) Updates of the control measures applied (incl assessment of equivalence)
- d) Description of controls carried out and the results (NC – corrective actions)
- e) Other updates of information
- f) Copy of the latest assessment report
- g) Internet website (list of operators)
- h) Any other information

# Part 3: Introduction to the new requirements for control bodies



## 1. Continue under the equivalence regime (2021/1342.4)

- Commission may amend specifications
- Commission may suspend (based on info received or where CB has not supplied sufficient info where required or has not agreed to on-site inspection)
- Commission shall suspend (based on failure to take time remedial action)
- Commission shall withdraw based on
  - not sending Annual report in time
  - send incomplete Annual report
  - CB does not keep available or does not communicate (TD or investigations)
  - failure to take corrective measures
  - not agree with on-the-spot inspection
  - when there is a risk for the consumer to be misled about true nature of products

## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. Switch from equivalence to compliance in practice
4. Controls under the compliance regime
5. Other actions under the compliance regime

## Part 3: Introduction to the new requirements for control bodies

### 2. Introduce request for recognition for the compliance regime

A) Prepare the technical dossier referred to in 848.46.4

(2021/1698.1.2) containing among others:

e) Translations of production rules and control measures

g) **Procedures** describing in detail the controls

h) Catalog of measures

j) Proof of notification of authorities of third countries

k) Website address (list of operators)

## Part 3: Introduction to the new requirements for control bodies

### 2. Introduce request for recognition for the compliance regime

A) Prepare the technical dossier :

g) **Procedures** describing in detail the controls (2021/1698.13)

c) sampling strategy, procedures and methodology, control methods and techniques, including lab analysis, testing and interpretation and evaluation of results and consequent decisions

e) a procedure for assessing the risk linked to operators/GG for carrying out the inspections and sampling

f) verification of the appropriateness of methods (sampling & testing)

h) for groups, effectiveness of ICS

## Part 3: Introduction to the new requirements for control bodies

### 2. Introduce request for recognition for the compliance regime

B) Prepare the assessment (Minimum content of Assessment report:  
2021/1698.I)

1. Document and record review report
2. On-site assessment report
  1. Office assessment report
  2. Witness audit report

## Part 3: Introduction to the new requirements for control bodies

### 2. Introduce request for recognition for the compliance regime

#### C) Complete the Technical Dossier by inclusion of

- copy of accreditation certificate (2021/1698.1.2f)
- copy of the most recent assessment report (carried out within two years preceding the request) (2021/1698.1.2i)

## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. **Switch from equivalence to compliance in practice**
4. Controls under the compliance regime
5. Other actions under the compliance regime

## Part 3: Introduction to the new requirements for control bodies

### 3. Switch from equivalence to compliance in practice

Organise simulations according to the new rules

- checklists
- derogations
- database (linked with website – list of operators) (1698.II.2)
- letters of NC
- certificate
- catalog of measures
- inspection of groups of operators

And switch all on 1 day in agreement with AB.



## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. Switch from equivalence to compliance in practice
4. **Controls under the compliance regime**
5. Other actions under the compliance regime

# Part 3: Introduction to the new requirements for control bodies

## 4. **Controls** (2021/1698 Art 9 – 16)

(9) General provisions

(10) Checks for the certification of operators or groups of operators

(11) Methods and techniques for controls

(12) Sampling, methods used for sampling and selection of laboratories for sample analysis

(13) Documented control procedures

(14) Written records of controls

(16) Verification of consignments intended for import into the Union

# Part 3: Introduction to the new requirements for control bodies



## 4. **Controls** (2021/1698 Art 9 – 16)

### (9) General provisions

1. Mandatory elements to control (PCM and separation)
2. Determination of likelihood of NC taking into account 14 parameters
3. Official controls of groups (2021/771.2)
4. 1 Verification of compliance for all operators/GG each year, including a physical on-the-spot inspection
5. At least 10 % additional controls. At least 10% of all physical on-the-spot inspections shall be unannounced. 5% of members of GG
9. All units (incl those used for non-organic products) shall be subject to annual controls

# Part 3: Introduction to the new requirements for control bodies



## 4. Controls (2021/1698 Art 9 – 16)

(10) Checks for the certification of operators or groups of operators

1. Requirements related to accepting to control an operator/GG
  - a) Description of the Production Units + activities
  - b) Confirmation by the members that they have not been certified on individual basis
  - c) Confirmation by the members that they have not been certified on individual basis
2. Requirements related to certifying an operator/GG
  - a) Compliance with Ch II, III and IV of 2018/848 + Art 36
  - b) Subcontractors under control
4. Not certify operators that have been withdrawn by previous CB in the last two years

# Part 3: Introduction to the new requirements for control bodies



## 4. **Controls** (2021/1698 Art 9 – 16)

(11) Methods and techniques for controls

1. Control methods and techniques (check maps, inspection, ...)
2. Traceability (T) check and mass balance (MB)
3. Risk based selection of products and period for T and MB
4. Elements to be included for T
5. Elements to be included for MB

# Part 3: Introduction to the new requirements for control bodies



## 4. **Controls** (2021/1698 Art 9 – 16)

(12) Sampling, methods used for sampling and selection of laboratories for sample analysis

1. Purposes of sampling (use, production techniques and contamination)
2. At least 5% (2% of members of each group)
3. Risk based selection of operators/GG
4. Mandatory sampling when “use” is suspected
6. Requirements for the labs
7. Delegation of sampling to other recognised bodies or to ISO 17025 accredited bodies

# Part 3: Introduction to the new requirements for control bodies

## 4. **Controls** (2021/1698 Art 9 – 16)

### (13) Documented control procedures

#### 1. Documented procedures

b) Tasks, responsibilities and duties of staff

c) Sampling strategy, procedures, methodology, control methods including lab analysis, testing and interpretation and evaluation of results and consequent decisions

d) Procedure for assessing risk

...

#### 2. Obligation to correct and update the procedures

## Part 3: Introduction to the new requirements for control bodies

### 4. **Controls** (2021/1698 Art 9 – 16)

#### (14) Written records of controls

1. Mandatory written records of each control. On paper or in electronic form. Keep for 5 years. Minimum content.
2. Countersigned by the operator or the inspected member of the GG as confirmation of receipt.

# Part 3: Introduction to the new requirements for control bodies

## 4. **Controls** (2021/1698 Art 9 – 16)

(16) Verification of consignments intended for import into the Union

1. Systematic documentary check and, according to a risk (cfr 4) assessment, a physical check before the consignment leaves
2. By CB of producer or processor or CB of operator who did the last operation for the purpose of preparation.
3. Aim of documentary checks (traceability, mass balance, transport and equivalence or conformity of ingredients if processed product)
5. Travel plan for bulk products
7. In case of suspicion, MS may request list of all operator/GG of which the consignment is part and their CBs

## Part 3: Introduction to the new requirements for control bodies

1. Continue under the equivalence regime
2. Introduce request for recognition for the compliance regime
3. Switch from equivalence to compliance in practice
4. Controls
5. Other actions under the compliance regime

# Part 3: Introduction to the new requirements for control bodies

## 5. **Other actions** (2021/1698 Art 17 - 29)

(17) List of operators and groups

(18) Database

(22) Actions in case of NC

(23) Measures in case of NC affecting integrity of products

(24) Checks for the purpose of retroactive recognition of a previous period

(25) Authorisations for the use of non-organic PRM

## Part 3: Introduction to the new requirements for control bodies

### 5. **Other actions** (2021/1698 Art 17 - 29)

#### (22) Actions in case of NC

1. CB suspects or receives substantiated information
  - a) Investigate with a view to verifying compliance
  - b) Prohibit import
2. In the event that the result of the investigation do not show any non-compliance affecting integrity, those products shall be allowed to be used and labelled as organic/in-conversion

# Part 3: Introduction to the new requirements for control bodies

## 5. **Other actions** (2021/1698 Art 17 - 29)

(23) Measures in case of NC affecting integrity of products

1. NC affecting integrity => “downgrading”
2. CB shall take any action necessary to determine origin and extent of the NC to establish responsibilities AND take measures to ensure that operator/GG remedies the NC and prevents further occurrences
3. Apply catalog of measures
4. Suspend or withdraw the certificate

## Part 3: Introduction to the new requirements for control bodies

### 5. **Other actions** (2021/1698 Art 17 - 29)

(24) Checks for the purpose of retroactive recognition of a previous period

1. Operator submits a 'dossier'
2. CB shall carry out detailed risk analysis, shall take samples and shall draw up an inspection report
3. CB informs immediately AB and Comm
4. CB informs immediately AB and Comm

## Part 3: Introduction to the new requirements for control bodies

### 5. **Other actions** (2021/1698 Art 17 - 29)

(25) Authorisations for the use of non-organic PRM

1. Elements to be verified
2. Inclusion of derogations granted in the annual report

# Part 3: Introduction to the new requirements for control bodies



## 6. High risk products: special approach (2021/1698)

-Comm may identify high-risk products (IA not published yet)

-at least two physical on-the-spot inspections per year and one shall be without prior notice (9.8)

-1 field sample/year taken at the most appropriate moment to detect potential use of non-authorized substances. (post harvest operations involved: 1 sample of incoming products) (12.5)

-During verification of consignment: systematical physical check + at least 1 representative sample of each consignment + complete documentation of traceability (16.6)

-special chapter on high risk products in the annual report (II.6)

-need for additional witness audit every 2<sup>nd</sup> year ( - AR) (3.4c(i))

**End of part 3**

**Thank you for your attention**

**Any questions?**

**Thank you**