

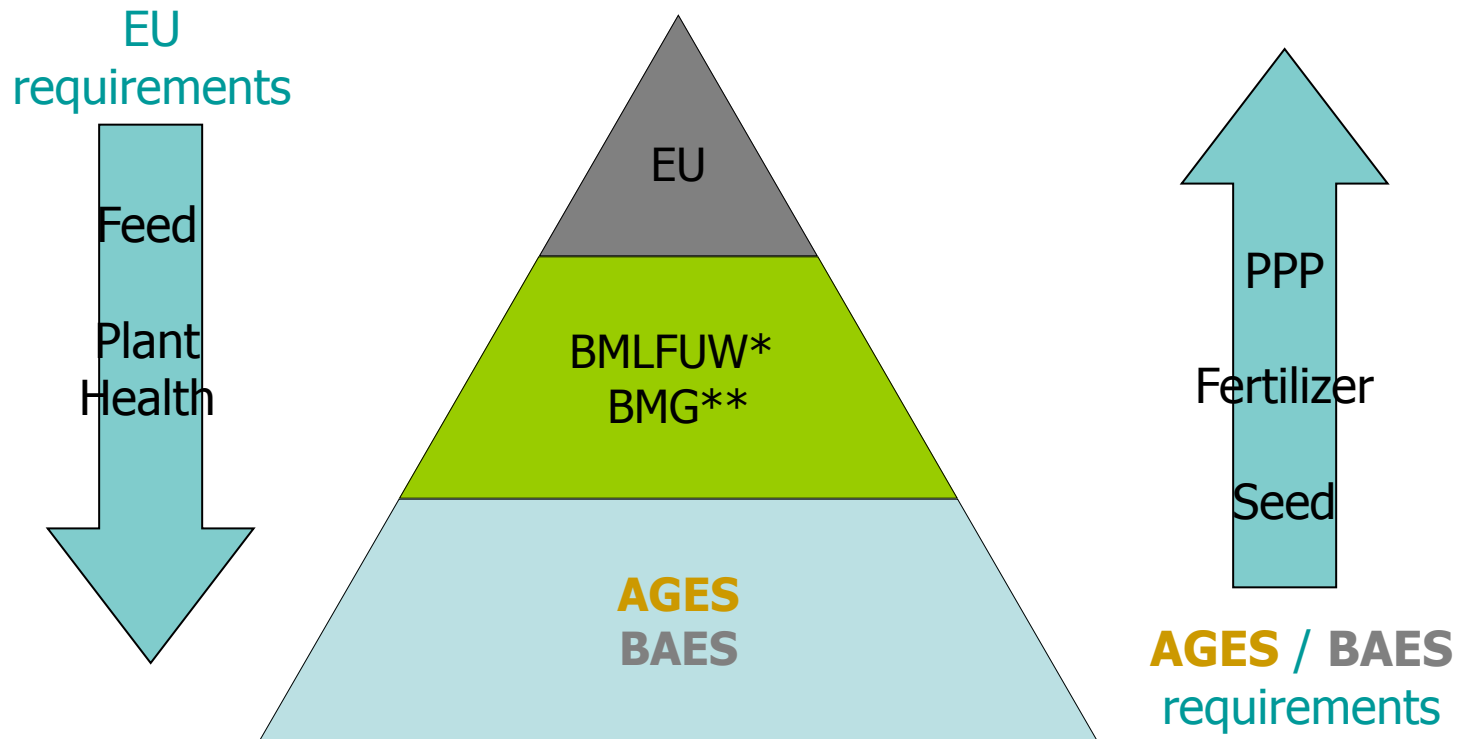
# Risk based control planning: General & specific features

Angelika Pauer

CEUREG Forum XVI., Vienna  
15<sup>th</sup> & 16<sup>th</sup> October 2012

# Regulation (EC) No 882/2004

... on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules



\* Federal Ministry of Agriculture, Forestry, Environment and Water Management

\*\* Federal Ministry of Health

Definition: **'control plan'** means a description established by the competent authority (CA) containing general information on the structure and **organisation** of its official control systems.

## **Article 3 – General obligations with regard to the **organisation** of official controls**

- ⇒ Member states shall ensure that official controls are carried out
  - ⇒ regularly,
  - ⇒ on a risk basis and
  - ⇒ with appropriate frequency,
- ⇒ so as to achieve the **objectives** taking account of
  - ⇒ identified risks associated with;
  - ⇒ business operators' past record as regards compliance with law or rules;
  - ⇒ the reliability of any own checks that have already been carried out; and
  - ⇒ any information that might indicate non-compliance.

# Objectives of control on marketing of PPP(⇒ EU & national legal acts)

- ⇒ feed and food safety
- ⇒ health protection
- ⇒ user protection
- ⇒ protection of the environment and resources
- ⇒ food and nutrition security
- ⇒ quality and fraud protection



# Regulation (EC) No 882/2004



## ⇒ **Risk-based approach**

- frequency of official controls should be regular and **proportionate to the risk**, taking into account the results of the checks carried out by business operators

## → **Risk based control planning ensures effectiveness of controls**

- ad-hoc controls should be carried out in case of suspicion of non-compliance

# Risk based annual plan

multi-annual plan				
controls			risk-based annual plan	basis
testing plan	sampling plan	operating control plan		
number of tests and/or assessments of conformity (AC)	number of tests and/or assessments of conformity (AC)	number of operating controls	randomised sampling plan	<b>statistical calculation + risk management</b>
+ number of tests and/or AC	+ number of tests and/or AC	+ number of operating controls	+ follow-up activities	<b>catalogue of follow-up activities and measures</b>
+ number of tests and/or AC	+ number of tests and/or AC	+ number of operating controls	+ resources for ad-hoc measures	<b>presumptions</b>
$\Sigma$ number of tests and/or AC	$\Sigma$ number of samples	$\Sigma$ number of operating controls	$\Sigma$	

# On-the-spot inspection (1)



**Control on marketing of PPP is an accredited procedure** within EN ISO/IEC 17020 (Conformity assessment - Requirements for the operation of various types of bodies performing inspection)

At the inspection, **thematic focuses are:**

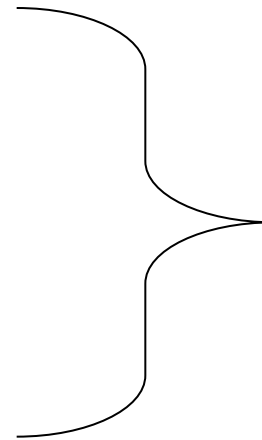
- **Checking distributor** (business documents, source of supply, distribution channel, etc.)
- **Checking PPP**, which are placed at distributors:  
**Assessment of Conformity (AC):**

# On-the-spot inspection (2)

## Assessment of Conformity (AC):

Most important criteria of PPP are checked:

- Authorisation status
- Labelling
  - registration number
  - trade name
  - chemical classification
  - field of use
  - ...



**Checkpoints**

→ Non-conformities at every checkpoint are documented in MOBI

→ AC provides data for statistical calculation of **testing plan**



# On-the-spot inspection (3)

## MOBI - AC

**Pflanzenschutzmittel - Konformitätsüberprüfung**

Fertig  Abbrechen  neue Probe  Speichern  Löschen  Hilfe

Pauer Angelika, Dipl.Ing. ( PMKK / HOHE / ANGEL16 / TPZ ) BAES-Nr.: PMK11001854KK01  
Auftrag Amtshandlung: 11001854 11001856-001

Betrieb: [REDACTED]  
Verantwortliche(r): [REDACTED] Prüfungsdatum: 21.11.2011 Probenart: Stichprobe  
Leiter der Amtshandlung: Pauer Angelika, Dipl.Ing. [REDACTED]  
anw. Betriebsvertreter: [REDACTED]  verfügbareberechtigt  
sonst. Anwesende: [REDACTED]  
Handelsbezeichnung: [REDACTED]  ok  
Charge: [REDACTED]  Chargenr. vorhanden  
Register- / Anmelde-nr.: [REDACTED]  Bezeichnung als 'Pflanzenschutzmittel'  
Wirkungstyp: [REDACTED]  PSM Registernummer vorhanden  
Art der Zubereitung: [REDACTED]  Wirkungstyp ok  
Chemikalienrechtl. Einstufung: [REDACTED]  Zubereitung ok  
 Einstufung ok  
 Verpackung in Ordnung

Bemerkung: [REDACTED]  
Hinweis: [REDACTED]

Lisa-Nr. ▾	Datum	Handelsbezeichnung	Register-Nr.
[REDACTED]			

# On-the-spot inspection (4)

## MOBI - AC



**Pflanzenschutzmittel - Konformitätsüberprüfung**

Pauer Angelika, Dipl.Ing. ( PMKK / HOHE / ANGEL16 / TPZ )

BAES-Nr.: PMK11001854KK01

Auftrag Amtshandlung: 11001854 11001856-001

Betrieb: [REDACTED]

Verantwortliche(r): [REDACTED] Prüfungsdatum: 21.11.2011 Probenart: Stichprobe

Leiter der Amtshandlung: Pauer Angelika, Dipl.Ing. anw. Betriebsvertreter: [REDACTED]  verfügbungsberechtigt

sonst. Anwesende: [REDACTED]

Handelsbezeichnung: Principal Charge: [REDACTED]  Chargennr. vorhanden  Bezeichnung als 'Pflanzenschutzmittel'  PSM Registernummer vorhanden  Wirkungstyp ok  Zubereitung ok  Einstufung ok  Verpackung in Ordnung

Register- / Anmeldenr.: 3131 Wirkungstyp: HB Art der Zubereitung: WG Chemikalienrechtl. Einstufung: N

Registernr.: 3131 Handelsbez.: null Ern.-Antrag: Zul.Ende: Zeitablauf: 31.07.2021 Abverkauf: Anmelder: DPD MGS: Reg.Nr.-MGS: Hand.Bez.MGS: Wirkstoff: Nicosulfuron, Rimsulfuron Organismus: Wirkungstyp: HB Zubereitung: WG Einstufung: N Änderungsdat.:

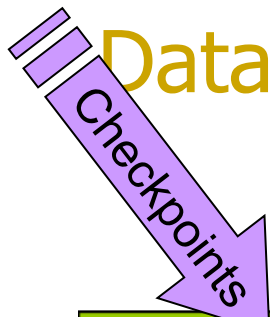
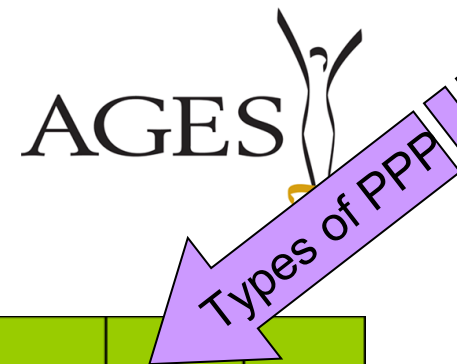
Bemerkung: [REDACTED]

Hinweis: [REDACTED] vorläufige Beschlagnahme  
Maßnahme(n) zur Mängelbehebung

Lisa-Nr. ▾	Datum	Handelsbezeichnung	Register-Nr.

# Risk based testing plan (1)

## Database for statistical calculation



		AC	FU	HB	IN	L	MO	PG	RE	RO
Differentiated checkpoints	safety-relevant quality-relevant									
Amount of AC per type (01.10.2010 - 30.09.2011; total: 1862 AC)		163	394	581	428	59	86	32	102	17
Permission1	QF	0,6%	0,0%	0,0%	0,2%	0,0%	0,0%	0,0%	0,0%	0,0%
Permission2	QF	0,0%	0,0%	0,3%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Permission3	S	0,0%	0,0%	0,7%	0,5%	1,7%	0,0%	0,0%	0,0%	0,0%
Permission4	S	0,0%	0,3%	0,5%	0,0%	1,7%	0,0%	0,0%	2,9%	0,0%
Labelling1	QF	9,2%	0,3%	0,5%	4,2%	6,8%	3,5%	6,3%	1,0%	0,0%
Labelling2	S	<b>15,3%</b>	3,0%	1,7%	<b>8,9%</b>	<b>42,4%</b>	<b>5,8%</b>	<b>12,5%</b>	<b>47,1%</b>	0,0%
Packaging1	S	0,6%	2,0%	1,5%	0,2%	1,7%	2,3%	0,0%	2,0%	0,0%
Authorisation1	S	0,0%	1,8%	0,5%	0,7%	0,0%	0,0%	3,7%	2,0%	0,0%
Authorisation2	S	1,2%	<b>3,6%</b>	<b>3,8%</b>	3,7%	0,0%	0,0%	3,7%	0,0%	0,0%
Authorisation3	S	0,0%	0,3%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%	0,0%
Data for finite population correction (fpc): 10 times the amount of autorisation per type		1220	4350	6390	3640	190	400	540	310	270

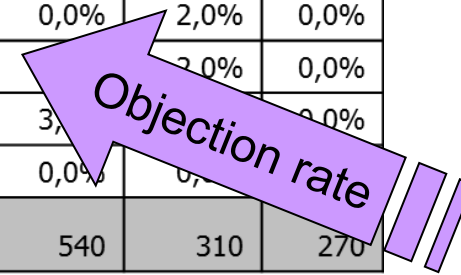


Table 1: Objection rate resulting from AC during period under review

# Risk based testing plan (2)

## Statistical calculation: result



- **Checkpoints** are differentiated according to the gravity of the infringement (e.g. permission1-permission4)
- **Weighted calculation** of each checkpoint for RTP

Checkpoint	S/QF	AC	FU	HB	IN	L	MO	PG	RE	RO	total
Permission	S	30	13	39	30	44	36	60	54	61	
Labelling	S	235	56	38	182	128	105	172	176	61	
Packaging	S	30	38	41	13	34	45	60	35	61	
Autorisation	S	38	129	112	124	39	36	53	54	61	
<b>RTP</b>		235	129	112	182	128	105	172	176	61	<b>1300</b>

Table 2: RTP 2012

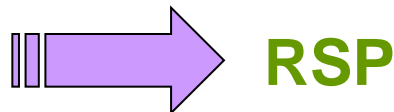
- **Parametric approach:** AC, FU, HB, IN, L, MO, PG, RE
- **Non-parametric approach:** RO (17 AC-samples in period under review, objection rate 0% → 78 samples → finite population correction → **61 samples**)

# Risk based sampling plan RSP (1)

## Risk management – Regulation (EC) No 178/2002

means the process, distinct from **risk assessment**, of weighing policy alternatives in consultation with interested parties, considering **risk assessment** and other legitimate factors, and, if need be, selecting appropriate prevention and control options

- **Risk management:** increase, reduction, etc. of AC-samples in a certain field of use
- further **calculation-methods** (freedom from disease, observation of market) etc.
- **Key actions:** e.g. increase of AC-samples of HB, IN, FU, sampling of PI-products, etc. possible

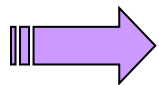


# Risk based sampling plan RSP (2) Example

	AC	FU	HB	IN	L	MO	PG	RE	RO	AT, BA, NE, VI	total
<b>RBTP</b>	235	129	112	182	128	105	172	176	61	-	<b>1300</b>
<b>+ key action</b>	0	100	100	100	0	0	0	0	0	-	
<b>RBTP + key action = RBSP</b>	235	229	212	282	128	105	172	176	61	n	<b>1600</b>
<b>follow up control</b>											<b>200</b>
<b>ad hoc control</b>											<b>100</b>
<b>planned AC 2012</b>											<b>1900</b>

## Example:

- Key action: + 100 AC for HB, FU & IN
- resources for follow up controls and ad hoc controls



**1900 AC-samples in total**

# Risk based sampling plan (RSP) sampling



- 30-50 samples each year
- Kind of chemical and physical formulation-analyses are determined as key actions; e.g.:
  - Identity of parallel traded products
  - Contamination with active substances
  - Contamination with substances which are harmful for bees
  - ...

# Operating control plan OPC (1)

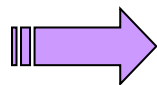
## Primary factor

For the creation of the operating control plan, it is necessary to describe **risks of business operators, which depends on type of business activity:**

**Step 1:** Definition of types of operator categories, processes and products

**Step 2:** Identification and evaluation of hazard regarding to objectives (feed and food safety, health protection, user protection, protection of the environment and resources, quality and fraud protection)

**Step 3:** Definition of the probability regarding to every hazard and every objective



**statistical calculation of primary factor**

The primary factors are under review when necessary (e.g. because of changes in legislation).



# Operating control plan OPC (2)

## Primary factor



<b>Operator category</b>	<b>Primary factor</b>	<b>Registered companies</b>
Authorisation holder and approval holder with or without trade	42	243
Sales locations of PPP for professional user (use in agriculture); includes wholesale and retail trade	34	1670
Sales locations of PPP for non-professional user (use in allotment); mainly gardening shops and chain stores	30	4325

# Operating control plan OPC (3)

## Secondary factor

**Secondary factor (SF)** gives detailed information on operator's risk;  
 **differentiation within the operator category**

Secondary factor	Authorisation holder and approval holder with or without trade
<b>Annual tonnage turnover:</b>	
0,1 - 1	2
1 - 10	4
10 - 50	6
50 - 200	8
> 200	10
<b>Product range</b>	
1 - 5	2
6 - 10	4
11 - 20	6
21 - 50	8
> 50	10
<b>Parallel traded PPP</b>	<b>0/5</b>
<b>Repackaging</b>	<b>0/5</b>
<b>Only PPP for non-professional use</b>	<b>0/- 4</b>

**Primary factor**  
 +  
**Secondary factor**  
 =  
**company specific risk**

# Operating control plan OPC (4)



## **Data collection:**

Primary and secondary data are collected in the registration process (business owner are obliged to register)

## **Statistical calculation of frequency model:**

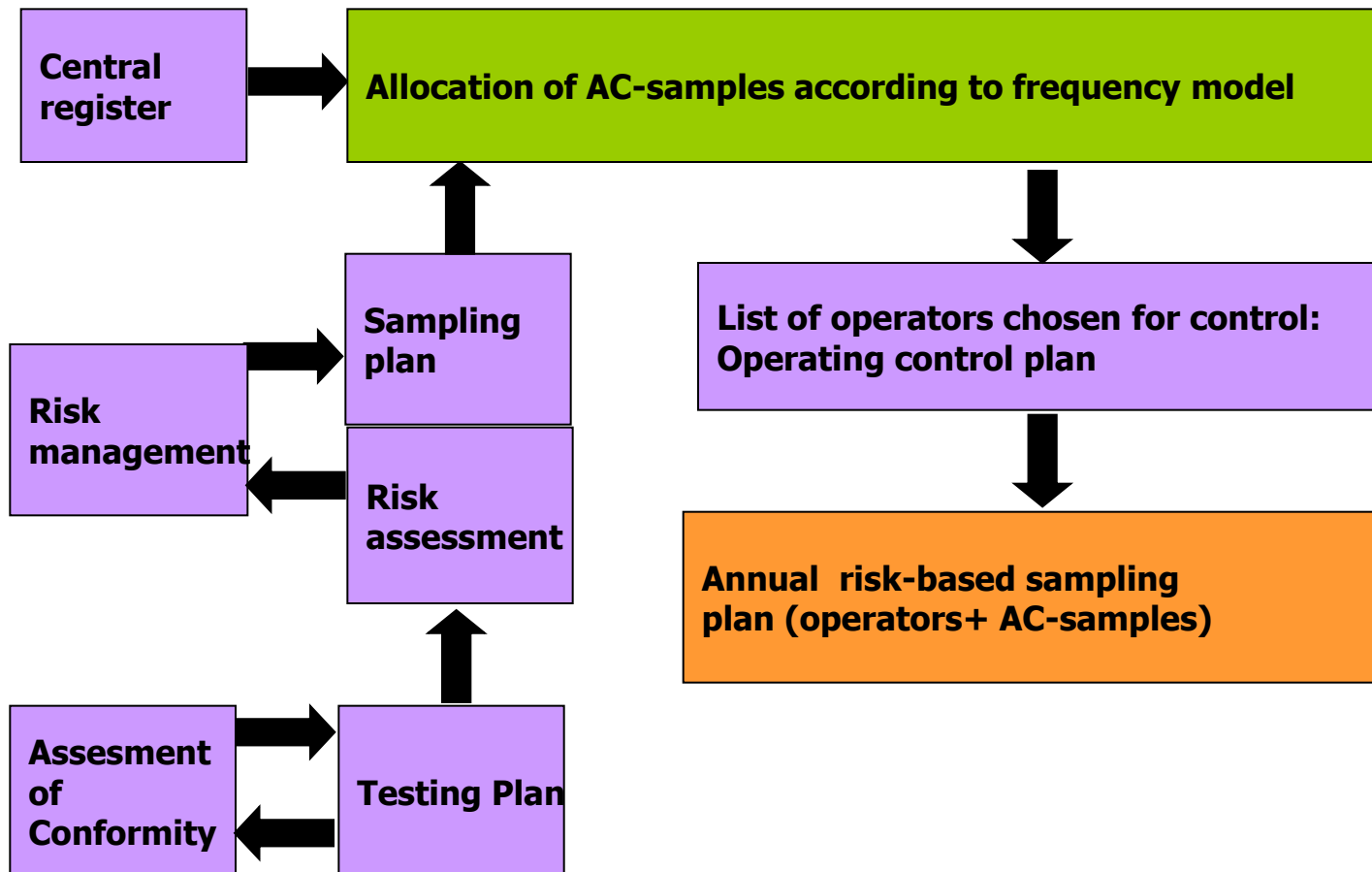
**Proportionate to the risk level**, all sales locations are controlled **once to five times in five years**.

(Chain Stores are viewed as one sales location)

## **Key actions**

e.g. networking of companies, obligation of registration, etc.

# Risk-based randomised sampling plan



# Follow-up activities (1)

## List of criteria\*

Category	Measures	Follow-up activity	Measures in case of recurrence	Follow-up activity in case of recurrence
<b>Compliance</b>				
<b>Non-Compliance Remediable</b>	corrective action, remediation of infringement	documented evidence of conformity	corrective action, official letter of non-compliance	documented evidence of conformity
<b>Non-Compliance Irremediable</b>				
<b>QF minor</b>	corrective action, official letter of non-compliance	documented evidence of conformity	corrective action, report to DAA	follow-up control, 25-100%
<b>QF major</b>	corrective action, official letter of non-compliance	follow-up control, 25-100%	corrective action, report to DAA	follow-up control, 50-100%
<b>S minor</b>	corrective action, report to DAA	follow-up control, 50-100%	preliminary confiscation, report to DAA	follow-up control, 100%
<b>S major</b>	corrective action, report to DAA	follow-up control, 100%	preliminary confiscation, report to DAA	follow-up control, 100%
<b>SQF severe</b>	preliminary confiscation, report to DAA	follow-up control, 100%	preliminary confiscation, report to DAA	follow-up control, 100%

\* examples – measures and activities are depending on legal acts and are taken in light of the results

# Resources for ad-hoc measures



## Resources for ad-hoc measures

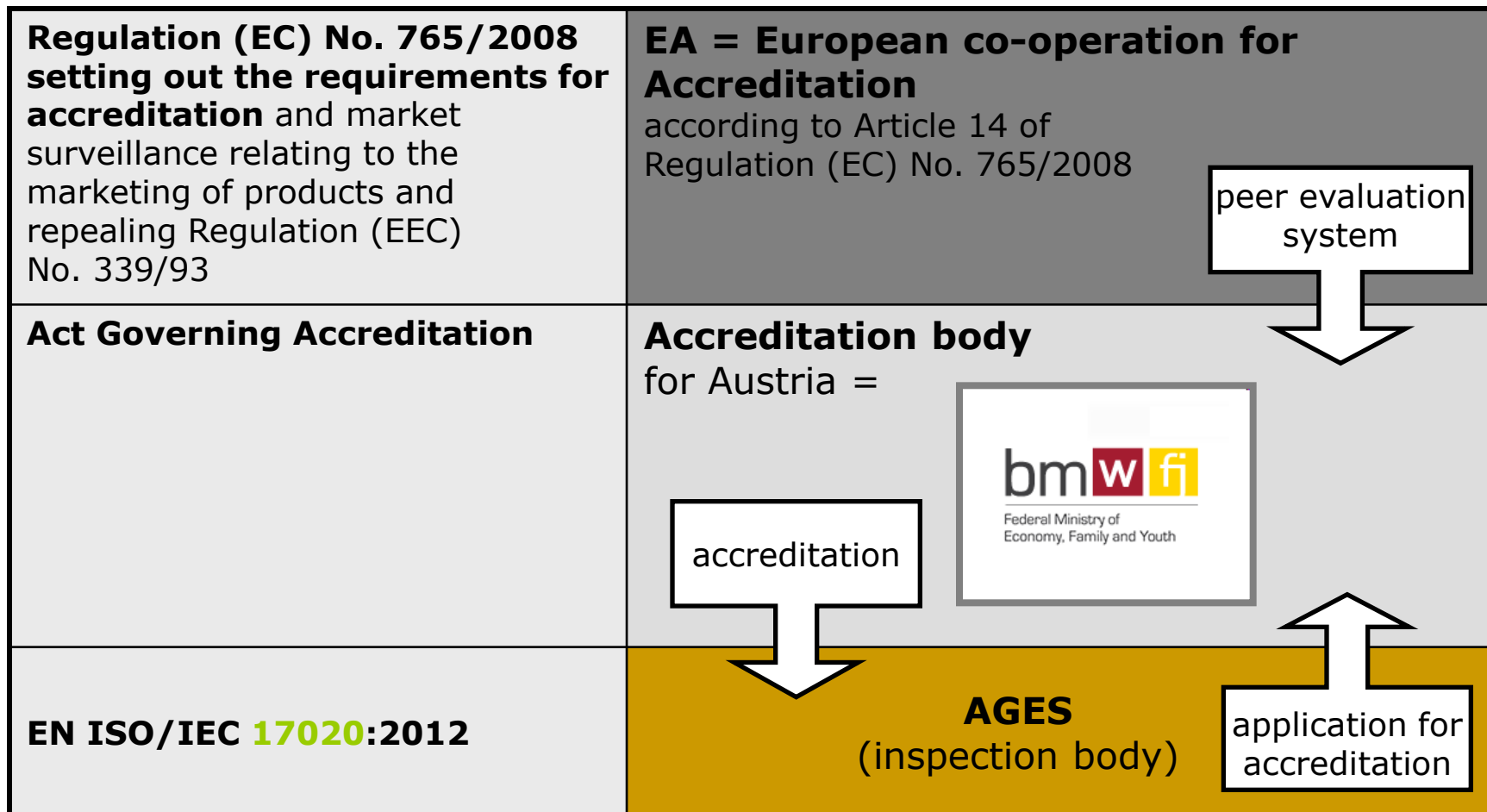
Approximately 10% of the resources are **presumed** to be subject to ad-hoc measures and activities. Ad-hoc activities (e.g. controls) are carried out in particular in case of suspicion of non-compliance.

# QM and Audit

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CEUREG Forum XVI., Vienna  
15<sup>th</sup> & 16<sup>th</sup> October 2012

# EN ISO/IEC 17020:2012 – Conformity assessment -- Requirements for the operation of various types of bodies performing inspection





# EN ISO/IEC 17020:2012 – Conformity assessment -- Requirements for the operation of various types of bodies performing inspection



- ⇒ specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities;
- ⇒ requirements
  - ⇒ General requirements
  - ⇒ Structural requirements
  - ⇒ Resource requirements
  - ⇒ Process requirements
  - ⇒ Management system requirements
- ⇒ “Inspection” regarding PPP = controls on marketing of PPP

## ⇒ Types of specifications

### ⇒ Standard Operating Procedures

They describe the workflow and frame conditions of activities (with the exception of testing activities ⇒ test specifications).

- **Planing, documentation and performance of PPP control regarding to relevant national acts and EU requirements**

### ⇒ Standard Working Procedures

They contain detailed rules for standard operating procedures and test specifications.

- **Sampling of PPPs**

## ⇒ Types of specifications

### ⇒ Forms

They are used to record results or data (forms become records or tracing documents after they have been filled out).

- **All reports created at the on-the-spot-inspection**
- **Notification of registration**

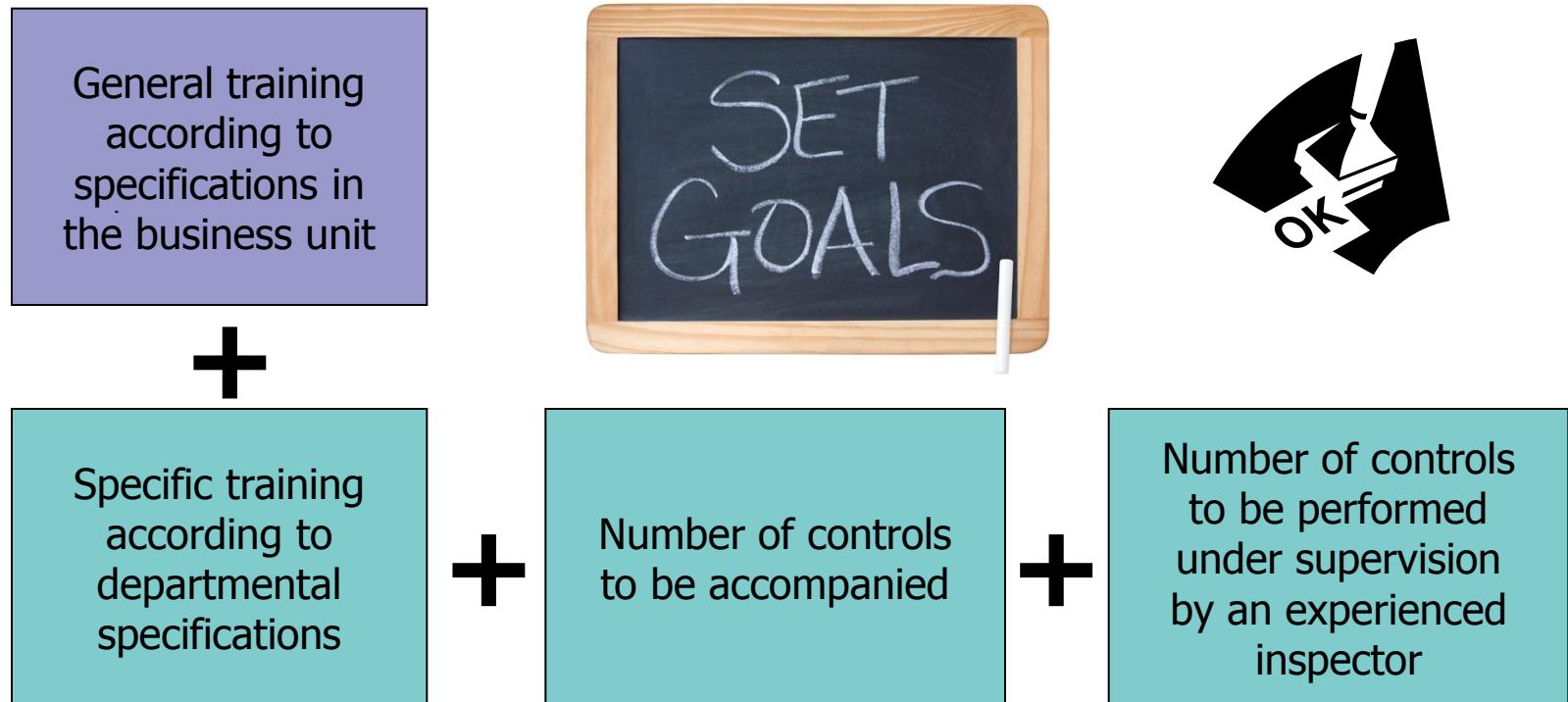
### ⇒ Lists

Lists enumerate characteristics, circumstances, materials, etc. as supplemental information for a procedure.

- **List of criteria (regarding to corrective actions, preliminary confiscation and follow up activities)**
- **Specific requirements on education and further trainings of inspectors in field of control of marketing of PPPs**

# Exemplary excerpts of implementation regarding to training of inspectors

## ⇒ Training of inspectors

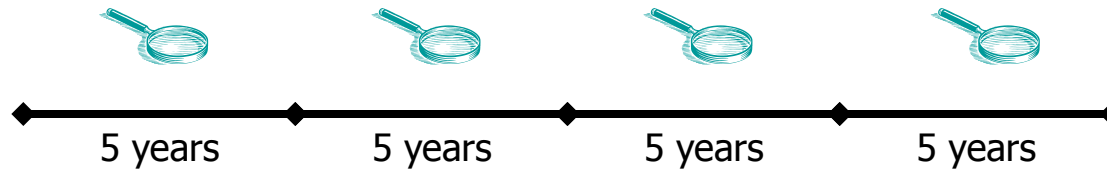


## Exemplary excerpts of implementation regarding to training of inspectors

Category*		Type of training	Training	
C	B	A	General	<ul style="list-style-type: none"> <li>- Quality Management</li> <li>- General Administrative Procedure Act</li> </ul>
			Specific	Basics of <ul style="list-style-type: none"> <li>- PPP Act 2011</li> <li>- Record taking</li> <li>- Sampling</li> </ul>
General		<ul style="list-style-type: none"> <li>- Communication and conflict management</li> <li>- Integrated Management Systems</li> <li>- Business documents and accompanying papers</li> </ul>		
Specific		<ul style="list-style-type: none"> <li>- PPP Act 2011</li> <li>- Related EU-Acts</li> <li>- PPP decree 2011</li> </ul>		
General		<ul style="list-style-type: none"> <li>- Hazard Analysis and Critical Control Points</li> <li>- Better Training for Safer Food</li> </ul>		
Specific		further departmental specifications		

## Exemplary excerpts of implementation

### ⇒ Supervision of inspectors



### ⇒ On-site supervision by supervisors





**Thank you for your attention!**