

New EU legislation Animal Health and Official Controls

Reg. EU 2016/429

Reg. EU 625/2017

innovazioni

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Implementing acts

Primary responsibility for implementing EU law lies with EU countries. However, in areas where uniform conditions for implementation are needed (taxation, agriculture, the internal market, health and food safety, etc.), the Commission (or exceptionally the Council) adopts an implementing act.

Delegated acts

The Commission adopts them on the basis of a delegation granted in the text of an EU law, in this case a legislative act.

The Commission's power to adopt delegated acts is subject to strict limits:

the delegated act cannot change the essential elements of the law

the legislative act must define the objectives, content, scope and duration of the delegation of power

Parliament and Council may revoke the delegation or express objections to the delegated act



**Tertiary legislation published at
Nov 2019 Reg.2016/429**

- **Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)**
- **Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases**
- **Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')**

Tertiary legislation checked by FVE WG at Nov
2019

- **COMMISSION IMPLEMENTING REGULATION (EU) .../... laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established**
- **COMMISSION DELEGATED REGULATION (EU) .../... as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs – FVE019/doc/026**
- **COMMISSION DELEGATED REGULATION (EU) .../...as regards rules for the entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin – FVE 019/doc/025**
- **COMMISSION DELEGATED REGULATION (EU) .../... as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases**
- **COMMISSION IMPLEMENTING REGULATION (EU) .../... on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases**

- **COMMISSION IMPLEMENTING REGULATION (EU) .../... laying down implementing measures for the Rapid alert system for food and feed, and rules as regards the computerised information system for notifying and reporting on listed animal diseases, the notification of the presence of, and protective measures taken against, plant pests, administrative assistance and cooperation between Member States' authorities, and the functioning of the information management system for official controls ('the IMSOC Regulation')**
- **COMMISSION DELEGATED REGULATION (EU) .../... as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs**
- **COMMISSION DELEGATED REGULATION (EU) .../... as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals**
- **COMMISSION IMPLEMENTING REGULATION (EU) .../... on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases**
- **COMMISSION DELEGATED REGULATION (EU) .../... amending the list of diseases set out in Annex II to Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')**

PREVENTION
IS BETTER
THAN CURE

TERMINOLOGIA COMUNE

PREVENZIONE

PROFILASSI

ANALISI del RISCHIO

SICUREZZA

GESTIONE DATI

PRIORITIZZAZIONE (RATING/CATEGORIZZAZIONE)



RISK BASED APPROACH IN AHL LAW

RISK BASED DISEASES CATEGORISATION AND CONTROL MEASURES

RISK BASED ANIMAL HEALTH FBO'S MEASURES & BIOSECURITY; ANIMAL
HEALTH VISITS

RISK BASED COMMUNICATION

COMP. AUTHORITIES RISK BASED SURVEILLANCE (OTHER OFFICIAL
ACTIVITIES REG. 2017/625)

DATA MANAGEMENT

RISK BASED HOLDINGS RATING

COMPARTIMENTALIZATION

Prioritisation of EU intervention

The new Animal Health strategy must be seen as an integrated **risk assessment** and **risk management strategy** focusing on risks of EU relevance.

- **Categorisation** of biological and chemical risks according to level of relevance for the EU;
- Agreement on the **acceptable** level of risk;
- Setting of **priorities**, quantifiable targets and performance indicators;
- Setting of the amount of **resources** to be committed to identified threats.

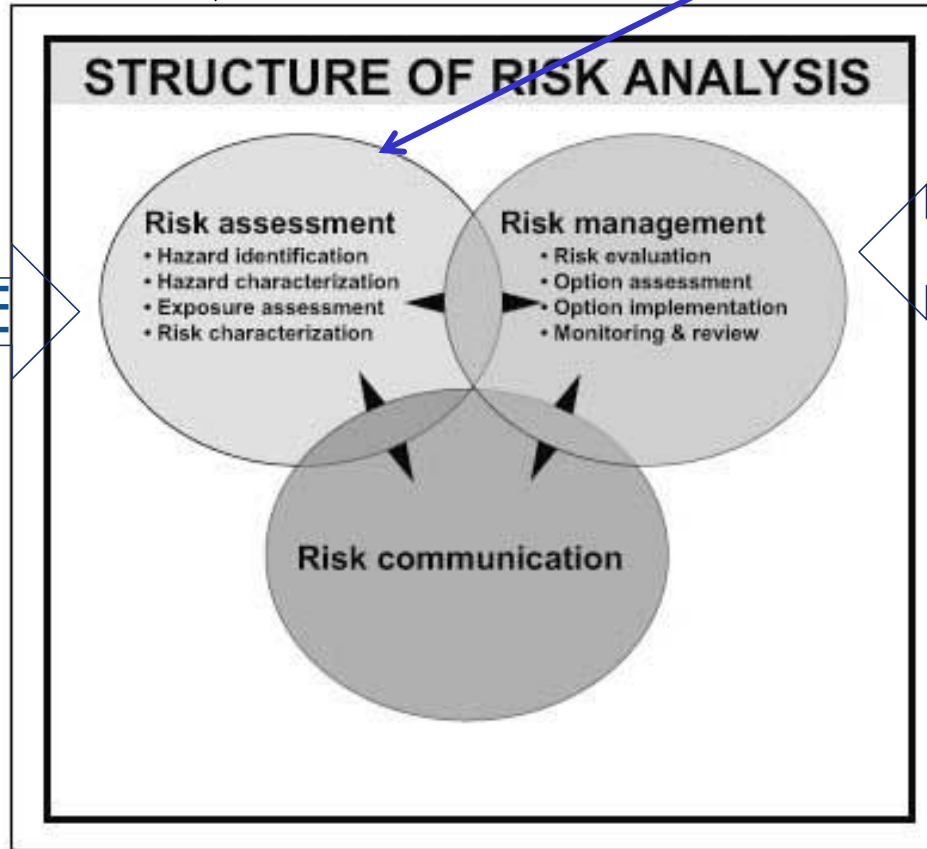
ANALISI DEL RISCHIO

(Reg. 178/2002)



EFSA

SCIENCE



POLICY

Decide ALOP*
Measures to
reduce and
mantain it

Quantification
of risk

* ALOP: Appropriate Level of Protection



European
Commission

Risk vs Hazard



RISK = HAZARD x EXPOSURE

Risk & hazard

HAZARD: any agent (biological, chemical or physical) or condition, with the potential to cause an adverse effect to health

RISK: likelihood of identified hazards causing harm in exposed population in a specified time frame, including the severity of consequences

EXPOSURE: the extent to which the recipient is subjected or exposed to a hazard

hazards: EXAMPLES

FOOD SAFETY

Salmonella
(e.g. Reg.852/04 and Reg.2074/05)

Dioxin

Radionuclides

Foreign bodies

LADDER

WATER

ASBESTOS

SMOKING

Concetti integrativi

Quantitative vs Qualitative Risk Assessment

Risk–benefit analysis

Cost benefit analysis

Impact assessment

Risk based categorisation

Evidence based decision

Precautionary principle

RISK MANAGEMENT - GESTIONE

Reg. 178/2002

SCELTE POLITICHE

MISURE DI SANITA'
PUBBLICA

ANALISI
COSTO/BENEFICIO

RIMODULAZIONE
PERIODICA

Reg. 882/2004 ora
625/2017

Categorizzazione
sulla base del
RISCHIO
(QUALITATIVO)

REGIMI
AUTORIZZATIVI
REGOLAMENTARI