WHIRDEC
Saumur – October 2019
AGENDA

1 – EU REGULATION
2- ANIMAL HEALTH LAW – UPDATES
   • Different DA
   • Upcoming IA
3 - REGULATION ON VETERINARY MEDICINAL PRODUCTS (2019/6)
4 – PROPOSITION TO THE COMMISSION
5- ZOOTECHNICAL CERTIFICATE FOR SEMEN, OOCYTES AND EMBRYOS
6- HORSES IMPORTED FROM THIRD COUNTRIES (ABR 2016/1012)
7 - FOAL’S SB REGISTRATION WITOUT A CERTIFICATE OF COVERING
8- DATA EXCHANGES
   • Pilot project – Horselink
9 - EQUIS
REGULATION (EU) 2015/262
on
the methods for the identification of equidae (Equine Passport Regulation)
1 – EU REGULATION

Regulation (EU) 2016/429 (AHL) 04/2021

Regulation (EU) 2016/1012 (ABR) 09/2018

Regulation (EU) 2019/6 (VM) 01/2022

Horse ID

DA on establishments and animal ID

IA on equine animal ID

DA on Movements of terrestrial animals within the union 2019/7072

DA on Germinal products 2018/7073

IA on Germinal products 2018/7073?

Delegated Regulation (EU) 2017/1940 (Zootechnical certificate)

IA (EU) 2017/717 (Zootechnical certificate)

IA (EU) 2017/716 (Recognised breed societies)

Delegated Regulation on information to be included in SLID Article 109(1)

and rules for the application of veterinary medicinal products to food-producing animals Articles 8(4), 112(4), 115(5)

Others DA & IA

DA on surveillance 2019/7066

DA on disease control 2019/7070

DA on entry into EU 2019/7068

Delegated Regulation (EU) 2018/1629 (list of animal disease)
2 - ANIMAL HEALTH LAW (n°2016/429)

Rules for the prevention and control of animal diseases:

Key points:

- Disease categorisation
- Responsibilities for animal health
- Disease Surveillance
- Disease control
- Emergency measures
- Identification
- SLID
- Computer Database
- Establishments keeping equidae
- Traceability of animals
- Traceability of germinal products
- Transporters
- Movements
- Entry into EU
- Into a MS
- Within the Union
## 2- ANIMAL HEALTH LAW (n°2016/429)

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<th>Key points</th>
<th>AHL Articles</th>
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<td>the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health</td>
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<td>the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease–free status</td>
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<td>the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union</td>
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<td>the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union</td>
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<td>non–commercial movements of pet animals into a Member State from another Member State or from a third country or territory</td>
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<td>the emergency measures to be taken in the event of a disease emergency situation</td>
<td>Part VII: Articles 257 to 262</td>
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2-ANIMAL HEALTH LAW (n°2016/429)

DA on surveillance 2019/7066

Disease Surveillance

Regulation (EU) 2016/429 (AHL)
04/2021
2-ANIMAL HEALTH LAW (n°2016/429)

DA on surveillance 2019/7066

Draft 21 April 2021

Key points:

- rules and conditions for surveillance
- rules setting up the requirements for the Union surveillance programmes
- rules for the implementation eradication programmes
- measures to be implemented the eradication programmes
- rules for granting disease-free status to MS
- rules for surveillance and biosecurity measures for maintaining disease-free status of MS
- supplementary rules for the suspension, withdrawal and restoration of disease-free

Main issues: No main changes

Linked to:

- Regulation (EU) 2016/429
- Regulation (EU) 2017/625
- Implementing Regulation (EU) 2018/1882 (bovin)
- Regulation (EC) 1069/2009
- Regulation (EC) No 1255/970
- Regulation (EU) 2017/625 (art 34)
2-ANIMAL HEALTH LAW (n°2016/429)

DA on disease control 2019/7070

Disease control

Regulation (EU) 2016/429 (AHL)
04/2021
Key points:

- the rules on disease awareness, preparedness and control to be applied with regard to the listed diseases

Main issues

No main changes

Linked to:

- Regulation (EU) 2016/429
- DA on Surveillance 2019/7066
- Regulation (EC) 1069/2009
- Regulation (EU) 2017/625 (art 37)
- Regulation (EU) 2018/1882
- Annex I to Regulation (EC) 853/20041
- DA on Movements of terrestrial animals within the union 2019/7072
- Regulation (EC) No 852/2004
2-ANIMAL HEALTH LAW (n°2016/429)

DA on entry into EU 2019/7068

Regulation (EU) 2016/429 (AHL) 04/2021

- Identification
- Computer Database
- Movements
- Entry into EU
- Export from the Union

- Traceability of animals
- Traceability of germinal products
Key points:

the rules for entry into the Union, and movement and handling after the entry into the Union from third countries and territories of consignments of:

- kept ungulates & germinal products & meat of ungulates
- general rules and derogations for transit through the Union and the re-entry into the Union of consignments of animals, germinal products and products of animal origin;
- transitional measures

Main Issues

No more temporary admission

Linked to:

- Regulation (EU) 2016/429
- Regulation (EC) 853/2004
- Commission Implementing Regulation (EU) 2018/1882
- DA on Surveillance 2019/7066
- Regulation (EU) No 2017/625 (art136)
- DA on conditions for monitoring the transport 2018/7146
- Regulation (EU) 2017/425 (art47)
- DA on Germinal products 2018/7073
- DA on Movements of terrestrial animals within the union 2019/7072
- DA on establishments and animal ID
2-ANIMAL HEALTH LAW (n°2016/429)

Regulation (EU) 2016/429 (AHL)
04/2021

- Identification
- SLID
- Computer Database
- Transporters
- Movements
- Traceability of animals
- Within the Union
DA on Movements of terrestrial animals within the union 2019/7072

Key points:

- Biosecurity rules for the means of transport and containers transporting terrestrial animals
- Timeframe within which kept ungulates should be slaughtered after their arrival to a slaughterhouse in another MS
- Animal health requirements for movements between MS
- Specific rules for assembly operations
- Animal health certification and notification requirements for movements between MS

Main Issues

- Threat of existing agreements (derogation only applicable to “registered equine animals”)
- Difficulties in implementing the derogations from the duration of validity of the animal health certificate
- No definition of health status
- Licence and validation mark not registered in DB

Linked to:

- Regulation (EU) 2016/429
- Delegated Regulation (EU) 2018/1629
- Commission Implementing Regulation (EU) 2018/1882
- DA on Surveillance 2019/7066
- DA on establishments and animal ID
- Regulation (EU) 2017/625 (art 131 – IMSOC instead of TRACES)
2-ANIMAL HEALTH LAW (n°2016/429)

Regulation (EU) 2016/429 (AHL) 04/2021

- Identification
- Traceability of germinal products
- Computer Database
- Movements
- Entry into EU
- Within the Union
Key points:

- requirements for registered and approved germinal product establishments
- traceability and animal health requirements for movements with the Union of germinal products
- informations to be declared to the competent authority
- rules for the record-keeping obligations on operators of approved germinal product establishments
- animal health requirements, including derogations, for movements between MS of germinal products
- health certification

Main Issues

No main changes

Linked to:

- Regulation (EU) 2016/429
- IA on Germlinal products 2018/7072
- Regulation (EU) 2016/1012
- Regulation (EU) No 1069/2009
- DA on entry into EU 2019/7068
- DA on Surveillance 2019/7066
- DA on movement 2019/7072
- DA on establishments and animal ID
2-ANIMAL HEALTH LAW (n°2016/429)

Regulation (EU) 2016/429 (AHL) 04/2021

Identification

SLID

Computer Database

Transporters

 Movements

Establishments keeping equidae

Traceability of animals

Into a MS
DA on establishments and animal ID

Key points:

- Requirements for the approval of establishments keeping equidae;
- Information to be included in the registers of establishments and transporters to be kept by the CA;
- Additional record-keeping obligations for operators and transporters;
- Traceability requirements for equine;
- Transitional measures.

Main Issues

- Less mandatory information in the SLID (Name..);
- No description of markings (pictorial and verbal) mandatory for non registered equidae microchipped;
- The establishments where equine animals are habitually kept is not defined and derogation are broad and difficult to regulate;
- No mention of unique life number (UELN), « Unique code » must be specified;
- Rules to classify the equidae as not intended for slaughter for human consumption are missing.

Linked to:

- Regulation (EU) 2016/429
- Implementing act adopted in accordance with Article 120(2) of Regulation (EU) 2016/429
- Implementing Regulation (EU) 2018/1882
- Regulation (EU) 2019/6 (VM)
- Regulation (EU) 2016/1012 (ABR)
- Implementing acts laying down model forms for the single lifetime identification document
- Regulation (EC) No 1069/2009
- Regulation (EU) No 952/2013
- Regulation (EU) 2015/262
- Regulation (EU) 2017/1940
Focus on DA on establishments and animal ID (Art 86)

Transitional measures related to the repeal of Regulation (EU) 2015/262:

• the deadlines for the identification of equidae born in the Union provided (Article 12 Regulation (EU) 2015/262) shall remain applicable until a date to be determined in an **IA adopted in accordance with Article 120(2) of Regulation (EU) 2016/429**

• the rules on the format and content of identification documents issued for equidae born in the shall remain applicable until a date to be determined in an **IA adopted in accordance with Article 120(2) of Regulation (EU) 2016/429**.

• the rules on equidae intended for slaughter for human consumption and medication records (Art37 of Regulation (EU) 2015/262) shall remain applicable until a date to be determined in a **DA adopted in accordance with Article 109(1) of Regulation (EU) 2019/6**

Articles 18 to 21 of this Regulation for existing establishments and operators ➔ **by 21 of April 2021.**

The other articles shall also apply from 21 April 2021.
Key points:

- Uniform access to data in, and technical specifications and operational rules of the computer database
- Technical specifications, procedures, formats, design and operational rules for the means and methods of identification,
  - Time for the application, methods of identification
  - Conditions and deadlines for removal, modification or replacement of the means of identification
  - Configuration of the identification code
- Configuration of animal ID deadlines, obligations and procedures for the transmission of information and registration of equidae in the database
- Technical specifications, formats and operational rules for the identification documents for equidae
- Guidelines and procedures for e-identification
- Exemptions from the ID and registration requirements
1. Canadian Warmblood: Is the location of the microchip given in the EU regulation? In Canada, Thoroughbreds were microchipped in the lips and it works well, the microchip didn’t migrate.

→ In the regulation EU 2015/262, the microchip should be implanted in the neck, the location is precisely defined (article 18).
→ For the thoroughbred the international rule is to put the microchip in the neck
→ Horses can live 30 years. If rules change, many horses might have more than one microchip because the first one will not be found.
→ Studbooks don’t want this rule to be changed.
MINUTES ON ANIMAL HEALTH LAW (n°2016/429)

2. Irish Sport horses: Microchipped could be altered. More discussion with the Commission should be made. Traceability will not be ensured with only a microchip. Ireland has suggest to keep an hair sample of each horse when the horse is identified, to be able to check it’s identity at anytime with a DNA test.

→ The draft of the DA on movements and animal ID is going in the opposite direction, as the description of markings is not mandatory anymore for non registered microchipped equidaes.

→ The position of the Commission is probably that if the microchip is unreadable, a replacement document will be issued and the horse will be excluded from the food chain.

Irish Sport Horse: If the horse is not intendent to be slaughter, his microchip number could be given to another horse. The traceability is then disrupted.
3 – REGULATION ON VETERINARY MEDICINAL PRODUCTS (2019/6)

Rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of veterinary medicinal products:

**Key points:**

- Procedures for marketing authorisations
- Marketing authorisations
- Clinical trials
- Post-Marketing authorisation measures
- Union Database on VMP
- Homeopathic VMP
- Manufacturing
- Import & Export
- Advertising of veterinary medicinal products
- Specific rules for the administration of veterinary medicinal products to food-producing animals
- Regulatory network
- Inspections and controls
- Restrictions and penalties
- Supply and use of medicinal products

**Regulation (EU) 2019/6 (VM) 01/2022**
Key points:

- Derogations for equine animals declared as not intended for slaughter for human consumption in SLID
- IA -> list of essential substances for the treatment of equine species (withdrawal period: six months)

**SLID**

- contains the medication record as a separate section
- The medication record and the identification details are protected from fraudulent alterations
- the permanent exclusion of the animal from slaughter for human consumption is recorded in Part II of the medication record and in the database

**Duplicates and New identification document (an identified equine -> registered equine animal New)**
- Administrative withdrawal period of at least 6 months if the horse is not excluded from slaughter for human consumption

**Replacement document**
- the animal is permanently excluded from slaughter for human consumption
MINUTES ON ANIMAL HEALTH LAW (n°2016/429)

Swedish trotting Association: Foals will need to be microchipped before receiving any medical treatment

→ Some of the treatment are given just after birth
→ Foals will be microchipped very young
3 – REGULATION ON VETERINARY MEDICINAL PRODUCTS (2019/6)

DA on information to be included in SLID Article 109(1) and rules for the application of veterinary medicinal products to food-producing animals Articles 8(4), 112(4), 115(5)

Under discussion

Main Issues

• The operator may request the CA to enter the permanent exclusion in the SLID (art 3a) -> exclusion before issuing the passport on grounds other than the administration of a veterinary medicinal product?
• The operator shall notify the permanent exclusion from slaughter for human consumption to CA without delay after the entry was made in the part II of the SLID by the vet (art 3b) -> Why not the vet directly in the database?
• If the equidae is too young, he should be identified by implanting an injectable transponder before the administration of a VMP and excluded from the food chain on the identification form (art 4)
• No information on the operational rules of the updates in the database

Linked to:

• Regulation (EU) 2016/429
• IA on Germinal products 2018/7072
• Regulation (EC) No 1950/2006 + IA?
• DA on Surveillance 2019/7066

• DA on entry into EU 2019/7068
• DA on movement 2019/7072
• DA on establishments and animal ID
Regarding the main issues and the expected IA on Equine animal ID, here are the main positions to make a feedback to the Commission:

**POSITION 1 :**

- Model of identification document
- Time limit for identification
- Rules for the exclusion from the food chain

*Do not modify these rules, which would have a significant impact on the equine sector. Due to the lifetime and the important mobility of equidea, stability of rules is essential.*
POSITION 2:

- Pictorial description of markings should be an obligation for all equine animals (not only for registered animals).

In the absence of description of markings for non-registered equine animals, what elements can be used by the competent authority to allow the replacement of the mean of identification, in case of unreadable transponder, while ensuring an uninterrupted traceability? Due to the sanitary objective of this regulation, the difference in management of equine animals does not seem relevant.
POSITION 3:

UELN should be maintained and mentioned with the same definition as in the 2015/262 regulation. Indeed, UELN has been validated by many international organizations and has been widely used for many years. It enables us to identify the issuing body and its country.

The definition of the 2015/262 regulation, which precises number of digits, the obligation to indicate the country code of the issuing body, and which mentioned the compliance with the UELN system should be included. « [...] a unique 15-digit alpha-numeric code compiling information on the individual equine animal and the database and country where such information is first recorded in accordance with the coding system of the Universal Equine Life Number (UELN) and comprising: (i) a six-digit UELN-compatible identification code for the database referred to in Article 39; followed by (ii) a nine-digit individual identification number assigned to the equine animal ; »
POSITION 4:

“Establishment where the animal of equine species is habitually kept” Enlarge the period from 30 days to 90 days would be easier to implement the horse’s movement follow up.

POSITION 5:

For horses born in foreign countries, agreements should be kept to enable studbooks to issue passport for horses of their breed, with a validation by the competent authority of the country of birth.
DISCUSSION WITHOUT CONSENSUS:

“Establishment where the animal of equine species is habitually kept”

AES: Stallions/mare can move for the breeding season for more than 30 days. In some cases, these horses can have several places. It would be easier if a horse could have more than one place where he is habitually kept, these horses could move more freely into these different places. BWP doesn’t agree and prefers to have national rules. German FN: It would be easier to manage one place by horse regarding FEI facilities for high health status horses. It would be preferable to request 90 days instead of 30.
Questions after the meeting on the establishments:

• Would it be possible to have more than one person responsible (=> more than one establishment ?) with the same adress (ex : different trainers on the same place)
• Will an implemented act be published on the registration of these establishments and the registration of the horses in these establishments?
• Would it be possible to register an establishment through the studbook or should the operator give the information directly to the central database?
Zootechnical certificates for semen, oocytes and embryos

Number of replies: 41
Including 32 not applicable, 9 complete

7/9 Issue zootechnical certificate (ZC) for germinal products
6/7 complete only part A - 1/7 Part A and B
6/7 Issue ZC to breeders and 4/7 to stallion holders, EU station and Semen collection center

5/7 fullfil the owner’s information
Breeder’s information:

1 the owner of the donor at birth
1 The owner of the donor when the ZC is issued
3 the breeder (not precised)
2 not fullfiled
Zootechnical certificates for semen, oocytes and embryos

For which horse:

3/7 All the horses registered in your database whatever the breed
2 Only the horses for which you have issued their identification document
2 For the horses that produces foals who will be registered at birth in your studbook

4/9 request CZ for foal registration when the foal is registered
5 - ANIMAL BREEDING REGULATION (N°2016/1012)

Zootechnical certificates for semen, oocytes and embryos

- The zootechnical certificate should accompanied the semen, but at that time, we don't know in which breeding book the offspring produced from those germinal products will be entered. Many stallions produces foals that could be registered in many different studbooks. In this case, which studbook should issue the zootechnical certificate for the semen?

- How the Breeder should be completed? Is it the owner of the donor at birth? Is it the owner of the semen? Or the owner of the foal to be born?

- 2 signatures may be needed: one for Part A completed by the studbook, another for part B completed by the EU station.

-> Evocated in the last working group -> complex issue
- > a whole new set of certificates will be prepared for November
6 - HORSES IMPORTED FROM THIRD COUNTRIES (ABR 2016/1012)

Zootechnical certificate and customs rate

**Article 37:**
Where the operator responsible for a consignment of purebred breeding animals requests the application of the conventional rate of duty for purebred breeding animals on the animals of that consignment:
(a) those animals shall be accompanied by:
   (i) the zootechnical certificate;
   (ii) a document indicating that they are to be entered in a breeding book maintained by a breed society or registered in a breeding register maintained by a breeding operation;

→ How do you manage these requests?
→ Who should issue the document (ii)? Could this document be issued by the breeding book of origin?
→ Nobody has heard of this procedure
Mail exchange with Dr Fussel: “For imports from third countries a model zootechnical certificate is laid down since we cannot rely on the existence of a passport.

This zootechnical certificate may be requested by the importer of the animal or a subsequent owner when he/she intends to have the animal entered in an EU studbook.

However, when the importing individual wants to avail of the conventional rate of customs duties which is zero for purebred breeding animals, the individual has to present the proof to the customs in the context of the claim of the conventional rate of duties, this may be at the time of entry into the Union, but as any other customs procedure may be at a later time”.
Number of replies: 41
Including 32 not applicable, 9 complete

Documents needed to register a foal in your studbook:
9/9 Covering certificate
5/9 Parentage control based on DNA analysis
1/9 semen’s invoice or sales contract
EU Regulation 2016/1012

**Annex I – Part 3**: “In addition to identification rules, purebred breeding animals of the equine species shall only be entered in a breeding book if they are identified by a covering certificate and, where required by the breeding programme, as ‘foal at foot’”

By way of derogation, a **Member State** or its **competent authority** may authorise a breed society to enter purebred breeding animals in the breeding book if those animals “are identified by any other appropriate method that provides at least the same degree of certainty as a covering certificate such as parentage control based on DNA analysis or analysis of their blood groups” (Annex I – part 3).

- **No definition** of the covering certificate
- **No rules** of use of the covering certificate
Project developed by Delta Horses

Organisations who initiated the project
- Netherlands, Studbooks working with Delta Horses
- Luxembourg Government and Luxembourg Studbooks
- France, Ifce

Romania and BWP (Belgium) join soon, others showed interest

Context
• Replace the Hub project,
• Data exchange only → NO DATA TRANSFERED OR STORED
• Access rights by owning organisation as well as the content of the dataset
• Search and access to horse data by microchip number or UELN

→ If the horse is registred in more than one database, the information from each database is displayed
Perspectives

- Anyone who wants to join the project only need to develop webservices to plug on the Horselink Interface.
- Primarily used for data exchange between National Data Bases and Studbooks and only for I&R issues.
- First phase of the pilot -> only providing data on the interface.
- Real data exchange can be done in a second phase.
- This tool could also be used for other purposes: like listing the foals of a stallion registered in different studbooks, or cleaning the data in a database to avoid horse duplicates...
Project developed by Delta Horses

- Joining the project is free up to 1 July 2020
- If you want to join the project, contact us:
  - whirdec@ifce.fr or Emilie.goulas@ifce.fr
  - max@deltahorses.nl
• Tool useful for identification purposes
• Tool useful to clean our databases

In Finland, Trotters breeders association has a similar project
Horselink is an exchange platform like Google. You search a horse and you can
compare this horse’s information provided by the different databases.
German NF : the current data exchanges with central database are very manual.
Would it be possible to make a recommendation to use this tool in the EU
regulation?
BWP : Present to the Commission the tool established : Horselink and ask them
to enforced this system.
Ifce : This tool could be at least cited in the preliminary remarks
German NF encourage all the stubooks to make a feedback to their MS to tell
them what they expect about data exchanges,
UK: The EU regulation should at least recommend digital exchanges, with an agreed format of exchanges. Each studbook should be able to make a tender and choose the provider they want.

Ifce: If the EU regulation gives only the format, the feature to request and import horse data with its UELN or Microchip won’t be available. The agreed format will just allow each MS to send data in the same format.

POSITION 6:
The EU regulation should at least ask for online data exchange and give a common format; the existing hub could be recommended even if it’s not mandatory.
Cf. Presentation

Currently, the tool is in English and Dutch. More languages could be added.