



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants
Animal health

**SUBMISSION OF ERADICATION PROGRAMMES FOR CATEGORY B AND C
DISEASES OF TERRESTRIAL ANIMALS BASED ON GRANTING DISEASE-FREE
STATUS AT ESTABLISHMENT LEVEL**

**Template in accordance with Article 10 of
Commission Implementing Regulation (EU)
2020/2002**

1. Date of submission

31 May 2021

2. Member State :

Croatia

3. Name of the disease¹

Infection with *Mycobacterium tuberculosis* complex (MTBC) in bovine population

4. Contact details

5. Territorial scope with a description and demarcation of the geographical and administrative areas covered by the eradication programme and the names of the zones and regions, if more than one region is included in the territorial scope of the programme.

The eradication programme will be implemented on the whole territory of Croatia. Croatia has 21 regional administrative units (counties – “županije”). Map with 21 administrative counties is attached to this document (Attachment 1).

Final goal of the eradication programme in Croatia is to fulfil requirements of Annex IV, Part II, Chapter 2, Section 1 for the whole territory of Croatia in the time period set in the point 10 of this eradication programme.

6. A description of the epidemiological situation for each zone or region, if more than one region is included in the territorial scope of the programme:

(a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishments falling under the derogation referred to in point (6)(f) at 31 December;

¹ This template is to be used for the submission of the following eradication programmes for the following listed diseases:

Category B-diseases

a) Infection with *Brucella abortus*, *B. melitensis* and *B. suis*

b) Infection with *Mycobacterium tuberculosis* complex

Category C-diseases

a) Enzootic bovine leukosis

c) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

d) Infection with Aujeszky's disease virus

e) Bovine viral diarrhoea

Targeted animal population are kept bovine animals. Number of establishments keeping animals of the targeted animal population by health status is presented in the table in the Attachment 2.

(b) the number of animals of the targeted animal population kept in the establishments referred to in point (a) by health status;

Detail information on targeted animal population are presented in the Attachment 2.

(c) maps indicating the density of the targeted animal population referred to in point (b) by health status;

Maps indicating the density of establishments keeping the targeted animal population are presented in the Attachment 3.

(d) timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years; and

Systematic control and eradication of bovine tuberculosis in Croatia started in 1946. Due to comprehensive measures, herd disease incidence was rapidly reduced from 28% in 1946 to less than 1.4% in 1953. In the following 10 years herd disease incidence decreased to less than 1% of infected herds, and during the period of 1965 - 1990 it stayed constantly at the level between 0.5 - 1%. Designation of bovine establishments as officially free from bovine tuberculosis aligned with Directive 64/432/EEZ started in 2010. Definition of the confirmed case in Croatia has been isolation and identification of bacteria from *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae*, *M. tuberculosis* and *M. africanum*). Annual routine testing to maintain disease-free status of establishments was performed each year until 2016 when interval between tests has been increased to 36 months. Official post-mortem examination for all slaughtered animals is mandatory.

Prevalence of bovine tuberculosis in the period 2010 – 2020 is presented in Figure 1 below.

Figure 1 – prevalence of infection with *M. tuberculosis* complex in the time period 2010-2020

Year	Number of establishments on 31 December	Establishments with confirmed infection	% infected establishments
2010	40872	24	0,059
2011	40086	10	0,025
2012	37681	5	0,013
2013	35707	6	0,017
2014	34399	8	0,023
2015	32753	6	0,018
2016	27904	2	0,007
2017	25754	1	0,004
2018	23220	3	0,013
2019	21178	8	0,038
2020	19875	4	0,020

Figure 2 – number of establishments and animals with confirmed infection with *M. tuberculosis* complex 2010-2020

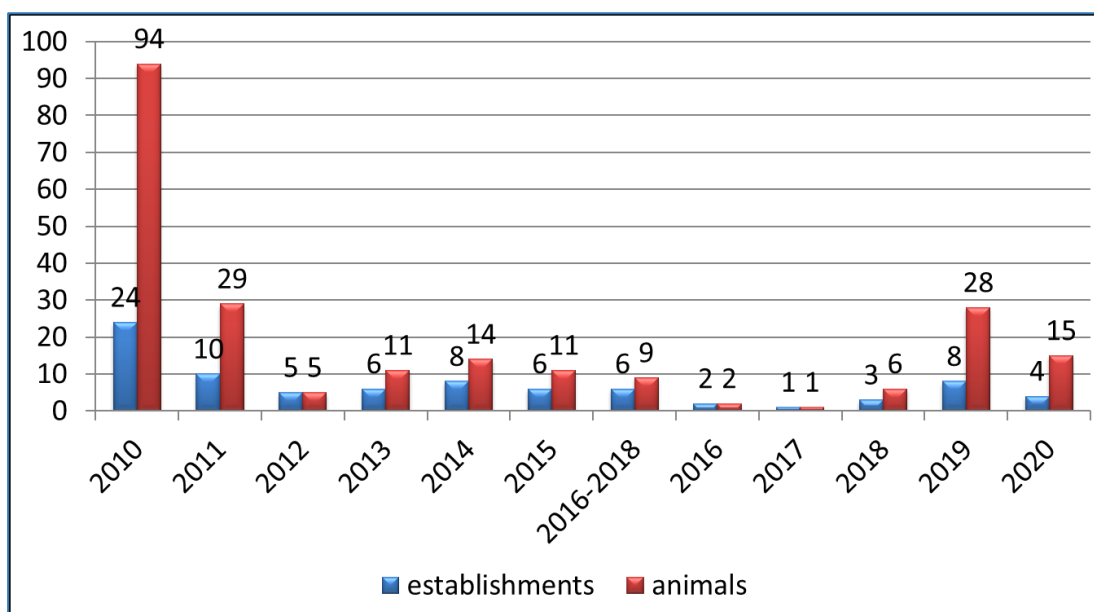


Figure 3 – Number of animals with lesions suspect to tuberculosis submitted to bacteriological examinations 2014-2020

Year	Number of animals with lesions suspect to tuberculosis submitted to bacteriological examinations	Number of animals with lesions suspect to tuberculosis submitted to bacteriological examinations - Mycobacterium tuberculosis complex confirmed
2014	29	7
2015	13	6
2016	2	2
2017	10	1
2018	4	4
2019	25	10
2020	3	3

(e) information as regards the epidemiological situation in additional animal populations, where relevant.

Analysis of the eradication programme results during previous years and epidemiological investigations of the outbreaks does not indicate additional animal population was involved or could be involved in spreading of the disease or could be a reservoir. During 2013 - 2015 surveillance of wildlife was conducted in three counties with the most MTBC outbreaks. Detailed information is presented below.

2013 wildlife surveillance

Monitoring was performed in Sisak – moslavina and Zagreb county. Wild boars in seven hunting grounds were sampled for bacteriological investigation by authorised veterinarians. In total 115 wild boars were sampled. *Mycobacterium tuberculosis* complex was not isolated. 73 samples were bacteriologically negative. In other samples, other nonspecific mycobacteria were detected.

2014 & 2015 wildlife surveillance

Monitoring of roe deer population was performed in several hunting associations in Bjelovar-bilogora county. In 2014 108 animals were sampled, while in 2015, 110 animals were sampled by authorized veterinary organizations. All samples were negative on *Mycobacterium tuberculosis* complex.

- A description of the disease control strategy of the eradication programme in accordance with Article 16 of Commission Delegated Regulation (EU) 2020/689 including at least:***

(a) the sampling schemes and diagnostic methods to be used in accordance with Annex IV to Delegated Regulation (EU) 2020/689:

(i) for the granting of the disease-free status to establishments and the maintenance of that status;

(a) Sampling schemes

1. Testing scheme in order to grant the disease-free status of establishments

Testing will be in line with provisions laid down in the Annex IV, Part II, Chapter 1, Section 1 of the Commission Delegated Regulation (EU) 2020/689.

2. Testing scheme in order to maintain the disease-free status of establishments

The status free from infection with MTBC of an establishment will be maintained if requirements of Annex IV, Part II, Chapter 1, Section 2 point 1 and 2 b) of the Commission Delegated Regulation (EU) 2020/689 are fulfilled.

By way of derogation from point 1 c) of Annex IV, Part II, Chapter 1, Section 2, taking into consideration annual percentage of establishments infected with MTBC calculated on December 31 each year, interval between tests will be extended to 36 months.

Testing will be performed each year in 1/3 of the country with the following schedule

2022 - Bjelovar - bilogora county, Dubrovnik – neretva county, Lika – senj county, Sisak-moslavina county, Split-dalmatia county, Šibenik-knin county, Zadar county and Zagrebačka county.

2023 – Karlovac county, Koprivnica – križevci county, Krapina – zagorje county, Varaždin county, Međimurje county, Istria county, Primorje-gorski kotar county and City of Zagreb.

2024 - Virovitica – podravina county, Požega-slavonia county, Brod –posavina county, Osijek baranja county and Vukovar-srijem county.

In addition to routine annual testing, additional tests will be mandatory for animals less than six weeks old entering Croatia from Member States not free from MTBC according to Commission Implementing Regulation 2021/620. Those animals have to be subjected to intradermal test by the age of 8 weeks, at the latest.

Diagnostic methods:

Diagnostic of tuberculosis is performed in Croatian Veterinary Institute Zagreb. Laboratory for Bacterial Zoonoses and Molecular Diagnostics of Bacterial Diseases in CVI Zagreb was appointed as the National Reference Laboratory (NRL) for brucellosis and tuberculosis in 2011. NRL performs serological, bacteriological and

molecular diagnostics of the most important bacterial zoonosis (brucellosis, tuberculosis, leptospirosis, coxiellosis).

For the granting and maintenance of disease-free status of establishments, following tests will be used

- single intradermal tuberculin test
- comparative intradermal comparative test

(ii) to confirm or rule out the disease in the event of a suspected case;

Suspect case

All animals positive on single intradermal tuberculin test are subjected to comparative intradermal tuberculin test in order to rule out false positive reaction or interference reaction. Animals not negative on comparative intradermal test are considered as animals suspected for infection with MTBC, and will be sent to immediate slaughter.

Animals with suspected reaction on single intradermal tuberculin test will be subjected to comparative intradermal tuberculin test. Animals not negative on the comparative test will be considered as animals suspected on infection with MTBC and sent to immediate slaughter.

Animals in herds where MTBC infection has been confirmed in the last two years or in establishments epidemiologically linked to infected establishments have to be slaughtered after positive or suspected reaction in single intradermal tuberculin test immediately, without comparative intradermal tuberculin test.

All positive reactors will be sampled during slaughter for further bacteriological investigation

All slaughtered bovine animals have to be examined for lesions suspect to tuberculosis and any such lesions should be submitted to a bacteriological examination of tuberculosis.

Samples will include abnormal lymph nodes and parenchymatous organs such as lungs, liver, spleen, etc. In the cases where the positive reactor does not present pathological lesions, samples from the retropharyngeal, bronchial, mediastinal, supramammary, mandibular and some mesenteric lymph nodes and liver will be collected for examination and culture.

Confirmed case

Infection will be confirmed by cultivation of the organism on primary isolation medium and identification by polymerase chain reaction (PCR). Direct PCR methods such as detection of the *M. tuberculosis* complex in fresh and fixed tissues can be

used for rapid detection of infection. In all cases, infection has to be ruled out by cultivation of the organism on primary isolation medium and identification by polymerase chain reaction (PCR).

If presence of MTBC is confirmed, establishment will be declared as infected.

(b) disease control measures to be applied in the event of a confirmed case;

In case of confirmation of *MTBC* in establishment keeping bovine animals, measures according to Commission Delegated Regulation (EU) 2020/689 will be implemented:

Article 24 points 1 and 2

- withdrawal of the disease-free status, with possibility of exemption of certain epidemiological units, provided that operators of such establishments fulfil conditions from Article 20 point 4 of Commission Delegated Regulation (EU) 2020/689; procedure for approval of epidemiological unit(s) will be additionally regulated by national legislation

- implementation of the measures laid down in Articles 25 to 31

Article 25

- conduct investigations and apply the measures laid down in Article 21 of Commission Delegated Regulation (EU) 2020/689 in all epidemiologically linked establishments

- epidemiological enquiry conducted by a veterinary inspector

- adapt the surveillance to the identified risk factors, taking into account the conclusions of the epidemiological enquiry.

VFSDG shall consider the need to conduct an investigation on wild animals from additional animal populations where the epidemiological enquiry reveals epidemiological links between kept and wild animals.

VFSDG shall as soon as possible inform about the situation operators and relevant authorities from the Member States concerned by the epidemiological links with the confirmed case and the competent authorities from other Member States or third countries that may be concerned by the epidemiological links with the infected establishment.

Article 26

Veterinary inspector will prohibit movements of animals from targeted animal population out of the infected establishment, unless it has authorised their immediate slaughter in a designated slaughterhouse and:

- order the isolation of the suspected and confirmed cases in the establishment where technically possible
- restrict the movements of animals from targeted animal population within the establishment
- restrict the introduction of animals from targeted animal population in the establishment
- restrict the movement of products of animals from targeted animal population from and to the infected establishment
- testing of all susceptible animals in the confirmed establishment.

VFSDG will extend the measures from Article 26 to animals and products from additional animal populations to prevent the spread of the disease when it considers necessary.

Article 27 point 1 a) and b) (ii) and c)

Following confirmation of the disease, veterinary inspector will order testing in infected establishment within a maximum period (to be determined by the veterinary inspector) of those animals whose testing is considered necessary to complete the epidemiological enquiry and subsequent testing to restore the disease-free status (as laid down in Section 2 and 3 of Chapter 1 of Part II, Annex IV of Commission Delegated Regulation (EU) 2020/689). Veterinary inspector may order additional testing that considers as necessary to ensure the swift detection of infected animals that may contribute to the spreading of the disease.

Article 27 point 2. (ii)

By way of derogation from point (b) of paragraph 1, testing shall not be ordered when disease-free status is restored in accordance with point 2 of Section 1, Chapter 1, Part II of Annex IV for infection with *MTBC*.

Article 27 points 3, 4, 5 and point 6

Veterinary inspector will order slaughter of all animals recognised as suspected cases within maximum period determined by it. Veterinary inspector may order killing and destruction of suspect animals, subjected to approval of VFSDG. Measures from Article 27 can be extended to animals from additional animal populations when this is necessary to eradicate the disease in the infected establishment.

Article 28 points 1, 2 and 4

Veterinary inspector will in all establishments infected with *MTBC* order that milk from confirmed cases shall either be fed only to animals in the same establishment

after it has been processed to ensure the inactivation of the disease agent, or it shall be disposed of.

Manure, straw, feed or any other matter and substance which has come into contact with a confirmed case or with contaminated material shall be either collected and disposed of as soon as possible or, following an appropriate risk assessment, stored and processed to reduce to an acceptable level the risk of spreading of the disease.

Veterinary inspector will order the trace-back, the processing or the disposal of any products from infected establishments that may constitute a risk of spreading the disease or affect human health when it considers necessary.

Article 29

Veterinary inspector will approve derogations from envisaged in Article 29 point 1 provided that conditions set by points 1, 3 and 4 are fulfilled.

Article 30 points 1, 2, 3 and 4

Veterinary inspector will order the operators of an infected establishments and those receiving animals from infected establishments the cleaning and disinfection or, where relevant, the safe disposal of all premises, equipment and material as listed in Article 30 points 1 a) to e).

Cleaning and disinfection is performed by designated authorised veterinary organisations with special approval from the VFSDG to perform disinfection, insect and rodent control. Veterinary inspector will not restore or grant again disease-free status to the establishment until it considers that the cleaning and disinfection, or where relevant, the safe disposal, has been completed.

Article 31

Before or upon lifting of the disease control measures, veterinary inspector will order proportionate risk mitigating measures to prevent reinfection taking into account relevant risk factors as indicated by the results of the epidemiological enquiry.

Additional measures

Additional measures will be implemented taking into consideration epidemiological investigation and extension of infection.

Additional measures may be ordered by VFSDG, and will include:

- whole herd depopulation at certain circumstances
- use of gamma-interferon assay to enable detection of the maximum number of infected animals on the establishment.

(c) biosecurity and risk mitigating measures to be implemented;

Risk mitigating measures that will be implemented will include:

- in addition to routine annual testing, additional tests will be mandatory for animals less than 6 weeks old entering Croatia from Member States not free from MTBC according to Commission Implementing Regulation 2021/620; those animals have to be subjected to intradermal tuberculin test by the age of 8 weeks, at the latest
- increased frequency of official controls will be implemented in establishments without disease-free status in the whole country continuously.

Following biosecurity measures in establishments keeping bovine animals will be implemented:

- Biosecurity measures set down by Article 10 of Regulation 2016/429, as appropriate
- General hygiene provisions for primary production and associated operations set down by Annex I of Regulation 852/2002

In all establishments with suspected and confirmed infection, cleaning and disinfection has to be performed by designated authorized veterinary organizations with special approval from the VFSDG. Cleaning and disinfection in such cases is under official supervision by veterinary inspectors.

In establishments using exemptions from Article 20 paragraph 4, operators will be obliged to comply with additional biosecurity measures between different epidemiological units consisting of physical and management means for separation of different units, procedures for entering and exiting the establishment for animals, products, vehicles and persons, procedures for using equipment, conditions for introducing animals or products into the establishment, isolation or separation of newly introduced or sick animals.

According to Article 10 of Regulation 2016/429 all operators are obliged to implement general biosecurity measures intended to prevent disease introduction into establishment, taking into consideration of species and categories of kept animals and products, the type of production and the risks involved, geographical location, climatic conditions and local circumstances and practices. Minimum requirements and means for implementation of general biosecurity measures will be set by national legislation. For all establishments in Croatia, safe disposal of dead animals and animal by-products by rendering is obligatory, and financed from the state budget.

(d) type of vaccine(s) to be used and the vaccination scheme, if relevant;

Vaccination is prohibited.

(e) measures to be implemented as regards additional animal populations, if relevant;

Not applicable.

(f) derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;

Operators of all establishment listed in Article 19 points a) to d) of Delegated Regulation (EU) 2020/689 will be exempted from the obligation to obtain and maintain disease-free status, provided that they comply with the general rules laid down in article 18 (1) a).

(g) coordinated measures with other Member States or third countries, if relevant.

Not foreseen.

(h) targeted animal populations and when applicable, additional animal populations

Targeted animal population are kept bovine animals.

8. A description of the organisation, supervision and roles of the parties involved in the eradication programme including at least:

(a) the authorities in charge of coordinating and supervising the implementation of the programme;

VFSDG of the Ministry of Agriculture is the National competent authority responsible for designing and developing the eradication programme in coordination with NRL for tuberculosis - Croatian Veterinary Institute. VFSDG is also responsible for monitoring of implementation of the programme.

Obligations of the VFSDG are to:

- coordinate and organise implementation of eradication programme
- collect, analyse and monitor the collected data
- evaluate the results of the implementation of the programme
- issue decisions and instructions to implement additional measures
- report data required by IR (EU) 2021/2002

- assure financial resources for programme implementation and compensation for the operators.

Veterinary inspectors from the State Inspectorate of the Republic of Croatia (SI) carry out supervision of the implementation of the programme.

Obligations of the veterinary inspection in the SI are to:

- perform official controls in relation to this programme
- issue decisions to operators responsible for suspected and confirmed establishments and epidemiologically linked establishments as listed in point 7 b) of this programme.

(b) responsibilities of all stakeholders involved.

Operators of establishments where bovine animals are kept have to:

- ensure that requirements of article 10 of Regulation (EU) 2016/429, Article 18 and 52 point 3 of Delegated Regulation (EU) 2020/689 are fulfilled
- give immediate notification to a veterinarian in case of any suspicion of tuberculosis
- restrict the movement of an animal suspected of being affected by disease and to prevent contact of other people and animals with the suspected animal or carcass until investigation has been completed.

Obligations of authorised veterinary organisations:

Relevant activities under the programme are carried out by authorised veterinary organisations including:

- conducting single and comparative intradermal tuberculin testing
- taking samples in slaughterhouses from animals slaughtered as positive reactors or from healthy slaughtered animals with lesions suspected for infection with MTBC and delivering them to NRL

assigning of the disease-free status to establishment in line with the DR (EU) 2020/689

- investigation of every suspicion of the disease
- timely reporting to the veterinary inspector any suspicion and confirmation of disease.

Obligations of the Croatian Veterinary Institute is to:

- perform laboratory tests in accordance with the articles 16 and 17 of Regulation (EU) 2016/429 and article 6 of Delegated Regulation (EU) 2020/689.

- report to the VFSDG, SI and the authorised veterinary organisation about the results of diagnostic tests (immediately and without delay).

9. *The estimated duration of the eradication programme.*

Estimated duration of the eradication programme is three years.

10. *The intermediate targets of the eradication programme including at least:*

(a) the expected annual decrease of the number of infected establishments;

It is expected to have less than 5 infected establishments in each year of duration of the programme.

(b) the expected annual increase of the number of disease-free establishments;

At least 99.8 % disease-free establishments representing at least 99.9 % of bovine population from 31 December 2021.

(c) the expected vaccination coverage, where relevant.

Not applicable.

Infection with Mycobacterium tuberculosis in bovine population eradication programme implemented in 2020 in Croatia - attachment 2

County	Total number of establishments 31 December 2020	Total number of animals 31 December 2020	Tested establishments 2018 ¹	Tested animals 2018	Tested establishments 2019 ²	Tested animals 2019	Tested establishments 2020 ³	Tested animals 2020	Number of establishments disease free 31 December 2020	Number of animals on establishments disease-free on 31 December 2020	% of establishments disease free 31 December 2020	Number of establishments Suspended & Withdrawn 31 December 2020	Number of animals on establishments Suspended & Withdrawn Suspended or Withdrawn 31 December 2020	Number of establishments not disease free on December 2020	Number of animals on establishments not disease free on December 2020	Number of establishments with confirmed infection with Mycobacterium tuberculosis in 2020	Number of animals with confirmed infection with Mycobacterium tuberculosis in 2020
Bjelovarsko-bilogorska ²	2243	57274	7	921	2181	37253	39	195	2240	57207	99,87	0	0	3	67	0	0
Brodsko-posavska ¹	600	15700	657	9749	15	389	17	431	599	15699	99,83	0	0	1	1	0	0
Dubrovačko-neretvanska ²	171	1877	6	30	63	878	5	16	166	1859	97,08	1	1	4	17	0	0
Grad Zagreb ³	292	2663	25	311	34	645	268	1537	290	2646	99,32	2	17	0	0	0	0
Istarska	733	8030	2	2	17	44	698	7325	727	8012	99,18	0	0	6	18	0	0
Karlovačka ³	1327	13566	5	8	6	34	1264	10405	1323	13528	99,70	1	10	3	28	0	0
Koprivničko-križevačka ³	2371	54768	10	663	10	4143	2287	35650	2371	54768	100,00	0	0	0	0	0	0
Krapinsko-zagorska ³	1308	7594	15	74	9	18	1361	6186	1308	7594	100,00	0	0	0	0	0	0
Ličko-senjska ²	1448	19579	9	123	1020	10956	286	2039	1444	19512	99,72	0	0	4	67	0	0
Međimurska	370	7978	0	0	0	0	320	5227	369	7977	99,73	0	0	1	1	0	0
Osječko-baranjska ¹	1045	79513	917	44424	69	7767	62	3469	1039	79001	99,43	5	508	1	4	3	14
Požeško-slavonska ¹	360	9046	423	5348	5	59	9	45	359	9041	99,72	0	0	1	5	0	0
Primorsko-goranska ³	243	1813	0	0	8	159	193	1450	231	1785	95,06	1	11	11	17	0	0
Sisačko-moslavačka ²	1500	29222	17	93	1561	21210	18	126	1493	29178	99,53	0	0	7	44	0	0
Šplitsko-dalmatinska	986	8681	18	112	473	3086	254	1730	972	8628	98,58	0	0	14	53	0	0
Šibensko-krninska ²	579	7263	3	6	234	3083	253	2601	571	7110	98,62	0	0	8	153	0	0
Varaždinska ³	532	6484	7	46	5	51	519	4431	532	6484	100,00	0	0	0	0	0	0
Virovitičko-podravska ¹	401	18143	444	7635	5	40	0	0	401	18143	100,00	0	0	0	0	0	0
Vukovarsko-srijemska ¹	737	25657	660	16013	2	1889	14	95	737	25657	100,00	0	0	0	0	0	0
Zadarska ²	460	7734	21	419	297	3865	37	219	453	7714	98,48	0	0	7	20	0	0
Zagrebačka ²	2169	38437	35	569	2214	18480	49	429	2166	38431	99,86	0	0	3	6	1	1
TOTAL	19875	421022	3281	86546	8228	114049	7953	83606	19791	419974	99,58	10	547	74	501	4	15

1	counties tested in 2018 in a 3 year testing cycle
2	counties tested in 2019
3	counties tested in 2020



Položaj farmi goveda na području
Republike Hrvatske

Legend

- Farme goveda
- Hrvatska

