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Self-declaration of the recovery of freedom from Bluetongue by Hungary

Self-declaration submitted to the OIE on 02 May 2018 by Dr Lajos Bognár, Delegate of Hungary to the OIE, Chief Veterinary Officer, Deputy State Secretary for Food Chain Control, Ministry of Agriculture, Hungary

I. Situation of Bluetongue in Hungary

The last bluetongue (BT) outbreak was confirmed in Hungary on 23 November 2015, more than 28 months ago (including two seasons of vector activity). Therefore, this document is to support the self-declaration that there has been no evidence of infection with bluetongue virus (BTV) in Hungary during the past two years and that the country fulfils the conditions for a bluetongue free country according to Article 8.3.3. of the OIE *Terrestrial Animal Health Code*.

II. Historical overview on the epidemiological evolution of the disease

Bluetongue was detected in Hungary for the first time on 14 October 2014 in Csongrád county (see Fig. 1.). The Veterinary Diagnostic Directorate of the National Food Chain Safety Office, which is the national reference laboratory (NRL), with the contribution of the European Union Reference Laboratory for bluetongue in Pirbright, United Kingdom, confirmed the presence of BTV serotype 4.

In 2014 the disease further spread in Csongrád, Békés, Bács-Kiskun, Tolna and Baranya counties, as shown in Table 1. In 2014, a total of 77 outbreaks were confirmed in these 5 counties (see Fig. 2).

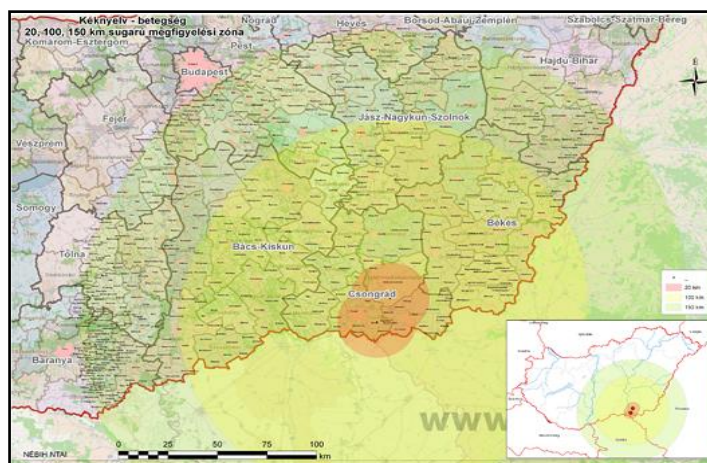


Figure 1. Location of the first bluetongue outbreaks, Csongrád county, Hungary, October, 2014

Table 1. Distribution of outbreaks of bluetongue in domestic ruminants, Hungary, 2014

County	Outbreaks	Cases		
		Cattle	Sheep	Goats
Baranya	2	3	0	0
Bács-Kiskun	38	70	4	0
Békés	3	1	2	0
Csongrád	33	99	4	1
Tolna	1	15	0	0
Total	77	188	10	1

In 2015, the disease spread to four new counties: Borsod-Abaúj-Zemplén, Győr-Moson-Sopron, Nógrád and Somogy. In 2015, a total of 37 outbreaks were confirmed (Fig.2).

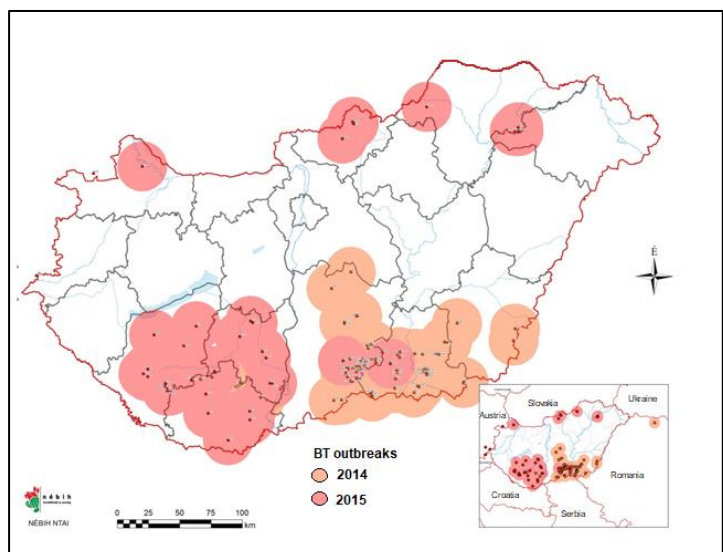
Table 2. Distribution of outbreaks of bluetongue in domestic ruminants, Hungary, 2015

County	Outbreaks	Cases		
		Cattle	Sheep	Goats
Baranya	5	4	1	0
Bács-Kiskun	1	1	0	0
Borsod	4	5	0	0
Csongrád	1	2	0	0
Győr-Moson-Sopron	1	1	0	0
Nógrád	3	5	0	0
Somogy	14	35	1	0
Tolna	8	22	0	0
Total	37	75	2	0

III. Control and eradication measures

After the confirmation and notification of the disease to the OIE and the European Commission in October 2014, protection and surveillance zones were established in accordance with Council Directive 2000/75/EC and Commission Regulation 1266/2007/EC. As new outbreaks occurred, protection and surveillance zones were further extended.

Figure 2. Distribution of bluetongue outbreaks, Hungary, 2014-2015 (Figures related to the distribution of BT in Hungary for 2014 and 2015 are presented separately in Annex 1)



All suspect cases were immediately submitted to restrictive measures. Every suspicious holding was placed under official surveillance (including movement restriction). Very few animals showed clinical signs so most of the suspicions were based on the positive laboratory results. Further samples for serology and virology were taken from the animals within the herd, using a sample size able to detect the disease of 5% prevalence with 95 % confidence.

If virus circulation was confirmed in the holding, a new case was confirmed and simultaneously, in case of the confirmation of the first case in the holding, a new outbreak was declared.

The following control measures were applied in 2014-2015:

For the infected holdings:

- Movement restriction on the holding;
- Disinfection on the holding;
- All positive animals according to virological tests on the holding were either killed or slaughtered in 2014. With the introduction of the vaccination policy in 2015, this was not applied anymore;
- Animals on the holding were treated with insecticides;
- For other holdings around the outbreaks:
 - The holdings in a 3-km radius were screened (with both serology and virology) with a sample size of the above mentioned prevalence and confidence;
 - All holdings in a 20-km radius were placed under official surveillance and were screened for clinical signs of the disease;
 - In 2015, all susceptible animals within the 20 km radius were vaccinated (after being screened)
 - In a 1-km circle radius of the outbreaks, terrestrial disinfestation and treatment of vector breeding sites were applied.

Movement of animals between established restriction zones (protection and surveillance zones) and the free zone was in line with Regulation 1266/2007/EC. Therefore, animals from high risk areas were allowed to enter low risk areas only if specific criteria were met. Decision of the Chief Veterinary Officer issued in March 2015 enabled vaccination against bluetongue. Only inactivated vaccines for BTV 4 were placed on the market and vaccination in the non-restricted zones was prohibited. The vaccination was mandatory around new outbreaks. All susceptible domestic ruminants within a 20-km circle radius around the outbreaks had to be vaccinated. In 2015, around 310,000 animals were vaccinated by mandatory vaccination. In the restricted areas voluntary vaccination enabled animal owners to vaccinate their animals, if they wanted to protect their animals against the disease or if they wanted to transport their animals outside the protection or surveillance zone. From 20 November 2015, the measures taken in the protection zones were extended to the surveillance zone, so the protection and surveillance zones were merged into one restricted zone.

IV. Bluetongue surveillance programme in Hungary

The Hungarian bluetongue surveillance programme is based on the provisions stipulated in Articles 8.3.14-8.3.17. of the *Terrestrial Code* and Annex I of Commission Regulation (EC) No 1266/2007. The main objective of the surveillance programme is to monitor the presence of the disease in domestic ruminants and to determine the seasonally vector free period in Hungary (entomological surveillance). The surveillance programme in place for domestic ruminants includes passive and active part. Active surveillance targets the cattle population, and passive surveillance, all susceptible domestic ruminants; few wild and zoo ruminants were tested as well.

4.1. Passive surveillance in ruminants

Hungarian and European Union legislation in force ensures that owners or keepers of animals as well as veterinarians must report immediately any suspicion of bluetongue to the competent authority. All

suspected cases of bluetongue must be investigated by the State Veterinary Service (clinical surveillance) and samples should be sent to the NRL in Budapest.

It has to be noted, that BTV-4 infection during 2014 and 2015 resulted only in mild clinical signs in few affected animals. Therefore, besides the virological (PCR) testing on clinical suspicions, organ and blood ruminant samples were sent to the NRL as part of further investigations (e.g. investigation of other notifiable animal diseases or due to abortion).

4.2. Active surveillance programme in ruminants

A risk based targeted surveillance approach started at the end of 2014. On the basis of the relevant recommendation of the EU Community Veterinary Emergency Team (CVET), Hungary developed a new monitoring programme for 2016, 2017 and 2018.

4.2.1. Rules of surveillance with a targeted approach in domestic ruminants at the end of 2014 and in 2015

A risk-based surveillance programme started in Hungary at the end of 2014 (and was carried out all year during 2015) with the objective to monitor the spread of the disease. This programme considered two types of surveillance in accordance with Article 8.3.16 of the *Terrestrial Code*:

- a) Serological surveillance, according to point 2 of Article 8.3.16. of OIE *Terrestrial Code* and point 3 of Annex I of Commission Regulation 1266/2007/EC (ELISA tests);
- b) Sero-virological surveillance around the confirmed outbreaks (simultaneous ELISA and PCR tests) according to the fourth indent of Article 8.3.16. of the *Terrestrial Code*.

Serological surveillance was carried out quarterly (4 times per year) using the county as the geographical unit. The quarterly sample size was designed to detect at least 5% prevalence with 95 % confidence in case of each county. In bigger counties, the sample size was proportionally higher than in smaller ones (each county was divided into about 2000 km² subunits and 59 cattle were sampled quarterly per subunits). The national target sample size was a total of 2716 samples quarterly, which meant 10864 samples per year.

4.2.2. Rules of targeted surveillance in domestic ruminants since 2016

Hungary developed a new monitoring programme for 2016 and practically applied also for 2017. The modified surveillance programme was a combination of serological/virological surveillance according to the fourth indent of Article 8.3.16., point 2. of the Article 8.3.17. of the OIE *Terrestrial Code* and point 2.2 of Annex I of Commission Regulation 1266/2007/EC. The plan for 2018 is very similar to the programme carried out during the previous two years.

The geographical (sampling) unit is the county according to the last indent of point 1 of point 1 of Annex I of Commission Regulation 1266/2007/EC. The sampling is carried out on a monthly basis. The monthly sample number will vary by counties (between 60 and 126 samples) depending on the size of the county, the geographical circumstances and the animal density, therefore the monthly sample number will be enough to detect at least 5% prevalence with 95 % confidence in case of each county.

The main philosophy of the programme is, on the one hand, that the involved herds must cover the whole territory of Hungary and not only the parts where higher number of cattle are kept. In order to achieve this goal, at least one herd per veterinary district must be selected for sampling. In areas with higher density of cattle or where the risk was higher,

more herds have to be sampled. Regarding the practical implementation of the programme, 112 (large scale) cattle farms would be selected from the 82 (81 after 1 July 2017) veterinary districts in the country. Animal density and closeness to water sources would be taken into account during selection of the farms. In each farm, 14-15 unvaccinated animals would be sampled once per month from April to November (during season of vector activity). Due to the wide spread of the disease and the effects of the previous mandatory vaccination around the outbreaks, serology does not always provide sufficient information on the actual virus circulation. In 2015, several BT cases were detected in Hungary, having PCR positive, but ELISA negative results. It means that several new cases would be undetected without simultaneous PCR tests. Therefore, virology tests are conducted in parallel to serology.

4.2.3. Results of targeted surveillance in domestic ruminants in 2015-2017

The following table shows the summary of the results of serological (ELISA) surveillance programme in Hungary during 2015, 2016 and 2017. In 2015, a higher number of sheep and goats were tested due to the serological and virological screening around the outbreaks. The table also contains the results of the further (follow up) investigations carried out after positive results in the affected herds during the surveillance programme or during the investigations in connection with the transport of susceptible animals.

Table 3. Results of the serological (ELISA) tests carried out in the frame of targeted (active) surveillance in Hungary, 2015-2017

Species	2015			2016			2017		
	No. tests	Positive	%	No. tests	Positive	%	No. tests	Positive	%
Cattle	15673	1930	12,31	12503	616	4,93	12204	523	4,29
Sheep	1295	482	37,22	237	35	14,77	180	47	26,11
Goat	149	104	69,80	60	14	23,33	0	0	0,00
Buffalo	48	7	14,58	115	6	5,22	98	1	1,02
All	17165	2523	14,70	12915	671	5,20	12482	571	4,57

The following table shows the summary of the results of virological (PCR) tests carried out in the frame of the bluetongue targeted surveillance programme in Hungary during 2015, 2016 and 2017. It also contains the results of the further (follow up) investigations carried out after positive results in the affected herds during the surveillance programme or during investigations in connection with the transport of susceptible animals.

Table 4. Results of virological tests - PCR - carried out in the frame of targeted (active) surveillance in Hungary, 2015-2017

Species	2015			2016			2017		
	No. tests	Positive	%	No. tests	Positive	%	No. tests	Positive	%
Cattle	8085	290	3,59	12324	2*	0,02	12483	0	0,00
Sheep	2299	67	2,91	233	0	0,00	223	0	0,00
Goat	357	4	1,12	56	0	0,00	8	0	0,00
Buffalo	7	0	0,00	127	0	0,00	98	0	0,00
All	10748	361	3,36	12740	2	0,02	12812	0	0,00

* Retesting from 2015, finally the bluetongue virus circulation was not confirmed in the affected herds.

A comparison of the results of surveillance in ruminants (by year) and a short analysis of the epidemiological situation is presented in Annex 2 and 3 in support to the demonstration of the absence of BT infection.

4.3. Entomological surveillance

The entomological surveillance started after the confirmation of the first outbreak on 14 October 2014 and it has been continuous since then. The rules and results for entomological surveillance are presented in Annex 4.

V. Measures implemented to maintain freedom

Early detection system. Bluetongue is a compulsory notifiable disease in Hungary according to Act No XLVI of 2008 on food chain and its official control and Decree No 113/2008 (VIII.30.) of the Minister of Agriculture and Rural Development on the rules of the notification of animal diseases.

The above mentioned legislation ensures that anyone, who handles animals (including owners or keepers of animals, as well as veterinarians), must report immediately any suspicion of bluetongue to the competent authority. All suspected cases of bluetongue must be investigated by the State Veterinary Service (clinical surveillance) and samples should be sent to the NRL in Budapest. Furthermore *from 2018, the active surveillance programme is continued in accordance with point 4.2.2.*

Movement rules. Decree No 31/2009 (III. 27.) of the Minister of Agriculture and Rural Development lays down the protective measures against bluetongue and regulates together with the Guideline on bluetongue measures - issued by the National Food Chain Safety Office - the transport within Hungary and intra-EU trade, as well as trade from third countries. Besides, transport of susceptible animals and their germinal products from restricted areas to other member states has to comply with Annex III of Commission Regulation 1266/2007/EC. The requirements for the import from third (non-EU) countries are laid down in Commission Regulation 206/2010/EU laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements. The main preventive rules for imported animals are as follows:

International movement of susceptible animals must be notified before the arrival to the chief district veterinary officer by providing data on the country of origin, the species and number of animals, place and date of arrival, and also a veterinary certificate has to accompany the animals including guarantees on BT as well. The compulsory physical isolation of the animals originating from other EU member states, third countries or other cattle holdings in Hungary for at least 30 days before their introduction to the new herd is also laid down. Over the verification of relevant data, including veterinary certificates and other documents accompanying susceptible animals, clinical examinations at the beginning and at the end of isolation are also carried out. The susceptible animals from restricted areas must be tested twice serologically or virologically during their isolation (once in the beginning and once at the end), depending on their serological status and the epidemiological status of the place of origin. If seropositivity is found in the seronegative consignment, the concerning animals are to be subjected to virological test and epidemiological inquiry has to be carried out. Depending on the results of those, epidemiological measures are implemented, such as killing of viropositive animals and re-testing and anti-ectoparasitic treatment of the remaining animals. Seropositive animals can only be transported to Hungary from restricted territories of another EU member state with a virology negative result. Besides, two PCR tests have to be performed during isolation on the whole isolated population. Viropositive animals have to be killed and disposed of in accordance with national and EU regulations on animal by-products. The above mentioned guideline lays down the detailed requirements of quarantine facilities. It also contains the rules on the introduction of susceptible zoo species to Hungary.

Certain consignments exempt from the restrictive measures (e.g. germinal products or animals for immediate slaughter) are also strictly regulated by the legal background.

The above mentioned rules demonstrate that several measures are in place in favour of preventing the introduction of infected animals to the country and of ensuring early detection of the disease by active and passive surveillance programmes.

VI. Conclusions

- *Before the outbreaks in 2014 and 2015, Hungary was free from bluetongue.*
- *After the confirmation of the first bluetongue outbreak, strict control measures were introduced, including official surveillance of the affected holdings, establishment of protection and surveillance zones, killing of viropositive animals in 2014 and compulsory vaccination in 2015.*
- *The surveillance programme was carried out according to Articles 8.3.14-8.3.17. of the Terrestrial Code and the Annex I of Commission Regulation (EC) No 1266/2007.*
- *The results of the enhanced passive and the targeted surveillance programme clearly demonstrate that there has been no evidence of infection with bluetongue virus in Hungary during more than two years, including two full seasons of vector activity.*

In accordance with the epidemiological data, the Delegate of Hungary to the OIE declares that as of 13/12/2017 the country fulfils the conditions of bluetongue free country laid down in Article 8.3.3. point 2 of the Terrestrial Code.

VII. Annexes

ANNEX 1. Maps of the distribution of bluetongue in Hungary, 2014 – 2015

Figure 3. Distribution of bluetongue, Hungary, December 2014

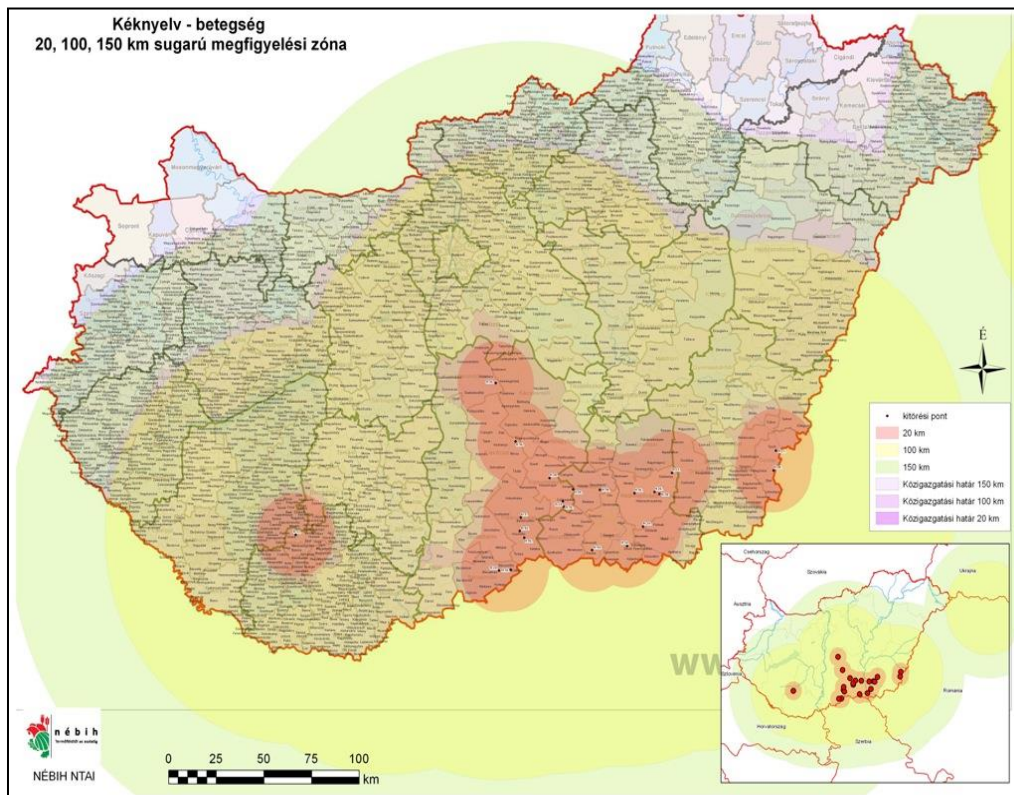


Figure 4. Distribution of bluetongue, Hungary, September 2015

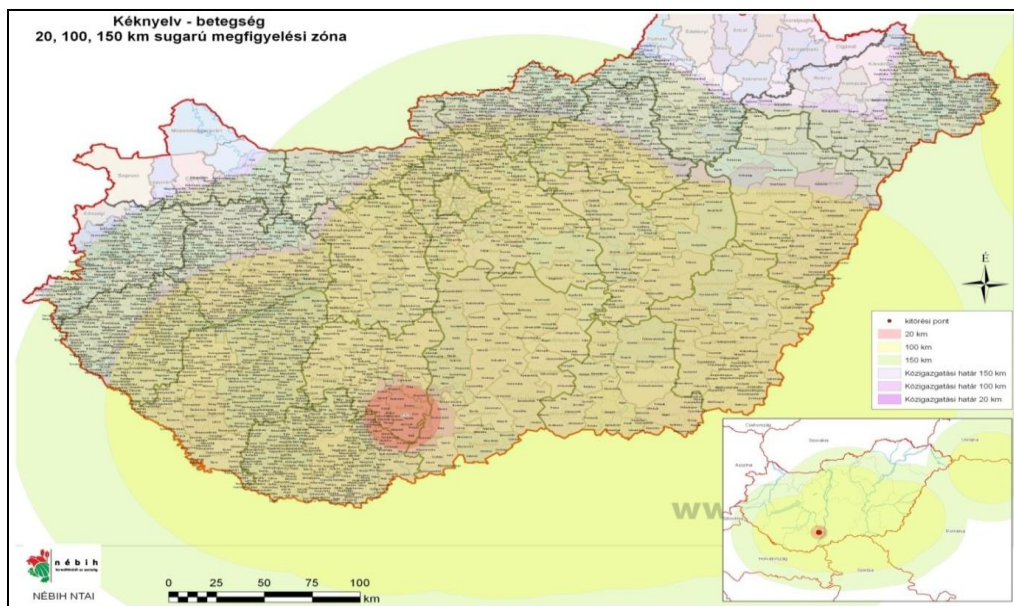
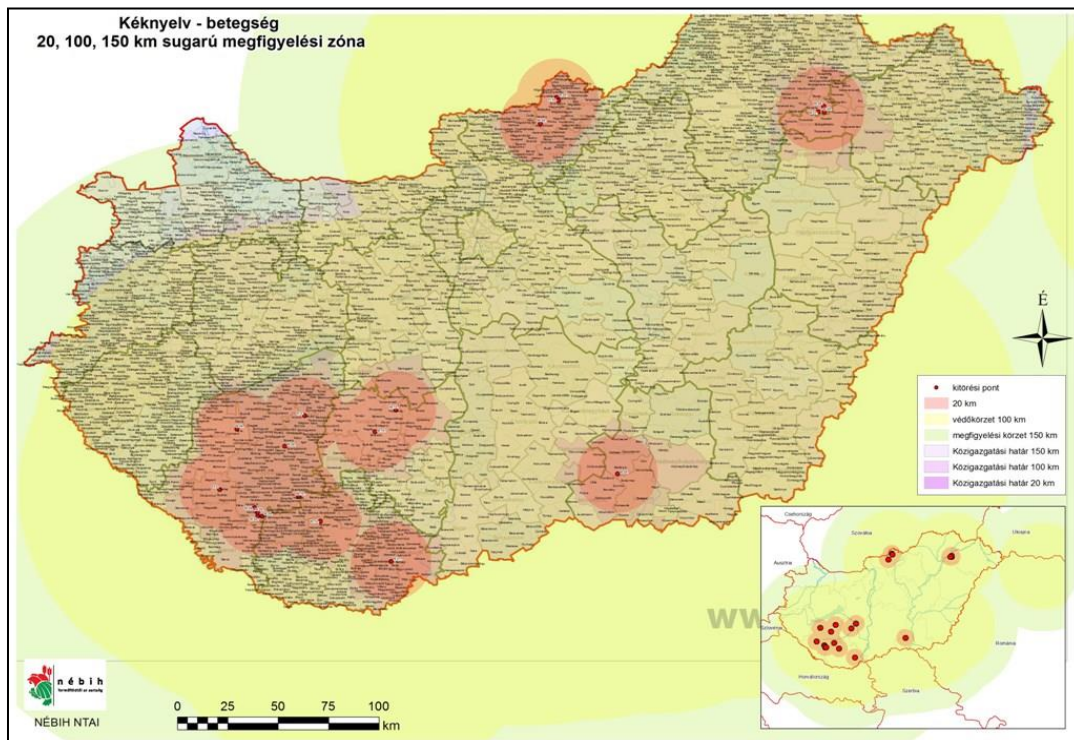


Figure 5. Distribution of bluetongue, Hungary, November, 2015



ANNEX 2. Results of enhanced passive surveillance programme in the last three years

The following table shows the summary of the results of virological (PCR) tests carried out in the frame of the enhanced bluetongue passive surveillance in Hungary during 2015, 2016 and 2017.

Table 5. Results of the PCR test conducted on clinical suspects detected via passive surveillance of bluetongue, Hungary, 2015 -2017

Species	2015			2016			2017		
	No. tests	Positive	%	No. tests	Positive	%	No. tests	Positive	%
Cattle	1029	3	0,29	941	0	0,00	626	0	0,00
Sheep	450	12	2,67	395	0	0,00	306	0	0,00
Goat	93	0	0,00	106	0	0,00	61	0	0,00
Buffalo	5	0	0,00	0	0	0,00	1	0	0,00
Wild ruminants	49	1	2,04	21	0	0,00	21	0	0,00
Zoo ruminants	12	0	0,00	10	0	0,00	13	0	0,00
All	1638	16	0,98	1473	0	0,00	1028	0	0,00

ANNEX 3. Comparison of the yearly results of surveillance in ruminants and short analysis of the epidemiological situation

After studying the results of our surveillance programme during the last three years, we can note that almost 96% of the PCR positive results were found during the targeted (active) surveillance and only about 4% of the PCR positive results were detected in the frame of the enhanced general (passive) surveillance. Therefore, we can only draw reliable conclusions from the comparison of the yearly results of targeted (active) surveillance regarding the bluetongue virus circulation.

The next table contains the number of PCR tests carried out in the frame of the targeted surveillance 2016 and 2017 in comparison to the number of PCR tests carried out in 2015.

Table 9. Comparison of the number of the PCR tests carried out in the frame of targeted surveillance in 2016 and 2017 with the number of PCR test carried out in 2015

Species	2015	2016		2017	
	No. tests	No tests	Rati to tests carried out in 2015	No tests	Ratio to tests carried out in 2015
Cattle	8085	12324	152,43 %	12483	154,40 %
All	10748	12740	118,53 %	12812	119,20 %

A higher number of PCR tests were carried out in 2016 and 2017 than in 2015, especially in case of the targeted cattle population.

The following table shows the number of the PCR tests carried out in the frame of the targeted surveillance, number of the positive results and the rate of positive results during the last three years.

Table 10. Comparison of the percentage of the positive ELISA tests carried out in the frame of targeted surveillance in 2016 and 2017 with the percentage of positive ELISA test carried out in 2015

Species	2015			2016			2017		
	No tests	Positive	%	No tests	Positive	%	No tests	Positive	%
Cattle	15673	1930	12,31 %	12503	616	4,93 %	12204	523	4,29 %
All domestic ruminants	17165	2523	14,70 %	12915	671	5,20 %	12482	571	4,57%

In case of serological investigation, the rate of sero-positivity is significantly decreased in 2016 (5,20 %) and 2017 (4,57 %) in comparison with 2015 (14,70 %).

Table 11. Comparison of the percentage of the positive PCR tests carried out in the frame of targeted surveillance in 2016 and 2017 with the percentage of positive PCR test carried out in 2015

Species	2015			2016			2017		
	No. tests	Positive	%	No. tests	Positive	%	No. tests	Positive	%
Cattle	8085	290	3,59 %	12324	2*	0,02 %	12483	0	0,00 %
All domestic ruminants	10748	361	3,36 %	12740	2	0,02%	12812	0	0,00%

* Retesting from 2015, finally the bluetongue virus circulation was not confirmed in the herds under investigation.

Despite the fact, that significantly more PCR tests were done in 2016 than in 2015, only 2 positive results were found in January 2016, from samples taken from animals that gave positive results in 2015. In addition, the rate of PCR positive results in 2015 was much higher (3,59 % in cattle and 3,36 % in all domestic ruminants) than in 2016 (0,02 %). Furthermore, in 2017, there were no PCR positive results, so the last positive PCR test was detected in January 2016, more than 26 months ago. **Therefore, these results clearly demonstrate that there was no virus circulation in Hungary during the last two years, including two full seasons of vector activity.**

ANNEX 4. Entomological surveillance

Rules of entomological surveillance

Vector monitoring aims to identify the genus and species of the insects captured with mosquito traps (Mosquito Trap M3). This is conducted throughout the year with one trap per county. Generally, samples are taken once per month, but this frequency is increased in March, April, November and December to once per week. The traps operate from early afternoon till dawn. The trapped midges are collected, and transported to the NRL, where the vector species is determined. *Culicoides imicola* was never detected in Hungary. The majority of midges (63.5%) belonged to the *C. pulicaris* complex. However, the proportion of *C. pulicaris sensu stricto* was negligible (< 0.2%), and the majority of midges (99.7%) belonged to two species (*C. newsteadi* and *C. punctatus*) within *C. pulicaris* complex. *C. obsoletus* complex, *C. nubeculosus* complex and other *Culicoides* spp. (*C. pictipennis*, *C. festivipennis*, *C. fascipennis*, *C. salinarius/circumscriptus* and *C. parroti*) represented 11.7%, 12.3% and 12.5% of the total number of midges, respectively. The main role of the entomological monitoring in our surveillance programme is to determine the seasonally vector free period in Hungary.

Results of entomological surveillance during the last three years

The following three tables show the monthly results of the entomological surveillance in Hungary during the last three years:

Table 6. The results of entomology surveillance in 2015 by month

Month	Number of trap contents investigated by NRL	Number of trap contents investigated by NRL with <i>Culicoides</i> species	Number of trap contents investigated by NRL with 5 or more parous <i>Culicoides</i> species
January	5	1	0
February	2	0	0
March	19	3	0
April	51	34	28
May	32	29	28
June	41	38	34
July	25	23	20
August	21	20	16
September	29	22	18
October	23	7	4
November	44	18	9
December	33	1	0
Total	325	196	157

Table 7. The results of entomology surveillance in 2016 by month

Month	Number of trap contents investigated by NRL	Number of trap contents investigated by NRL with <u>Culicoides species</u>	Number of trap contents investigated by NRL with 5 or more parous <u>Culicoides species</u>
January	1	0	0
February	2	0	0
March	11	0	0
April	47	24	19
May	36	18	14
June	28	19	15
July	22	14	10
August	26	17	15
September	21	11	6
October	20	10	5
November	22	8	6
December	13	1	0
Total	249	122	90

Table 8. The results of entomology surveillance in 2017 by month

Month	Number of trap contents investigated by NRL	Number of trap contents investigated by NRL with <u>Culicoides species</u>	Number of trap contents investigated by NRL with 5 or more parous <u>Culicoides species</u>
January	1	0	0
February	0	0	0
March	21	4	1
April	35	16	8
May	31	20	10
June	24	18	12
July	26	18	10
August	21	13	7
September	20	12	4
October	15	6	2
November	30	9	3
December	16	2	0
Total	240	118	57