ANNEX

Commission services’ assessment of the Action Plan submitted by the competent authorities of Hungary in response to Report ref. DG(SANTE)/2016-8676-MR of the audit carried out from 04 October 2016 to 12 October 2016 in order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and food

<table>
<thead>
<tr>
<th>Nº</th>
<th>Recommendation</th>
<th>Action Proposed by the competent authority</th>
<th>Second response by the competent authority</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>To ensure that, when the minimum number of Salmonella isolates required to be subject to antimicrobial susceptibility testing by point 2.2 of Part A of the Annex to Decision 2013/652/EU are not achieved, all available Salmonella isolates are gathered and subject to antimicrobial susceptibility testing, in order to comply with Article 2(2)(a) of the said Decision. <strong>Recommendation based on conclusion No 47.</strong> <strong>Associated findings No 16, 21, 27 and 28.</strong></td>
<td>From 2016, all the eligible isolates collected in the frame of SNCP from flocks of laying hens, gathered at slaughterhouses in the frame of official control or originating from food business operators own checks and sent for serotyping to NFCSO Food Microbiological NRL in the context of Regulation (EC) No 2073/2005 will be subjected for AMR testing. Flocks, instead of holdings would be considered as epidemiological unit. Deadline: retrospectively even for 2016 isolates, as all these isolates are stored at NFCSO Food Microbiological NRL. For those categories, where the minimum number of isolates is supposed not to be achieved, competent authority considers the possibility to collect more (or all) isolates from private laboratories. Deadline: 1. April 2017</td>
<td>National Food Chain Safety Office Food and Feed Safety Directorate has a database on laboratories that are authorized for testing samples in the frame of food business operators’ own checks. An official circular letter was prepared by the director of Food and Feed Safety Directorate to contact the heads of food microbiological laboratories to collect the isolates in 2017 from carcass testing of pig for Salmonella according Regulation (EC) No 2073/2005. These isolates should be sent to the Food Microbiological NRL for serotyping. A sample record document was also prepared to collect all the information on these strains needed for checking their eligibility for the AMR monitoring program. Food Microbiological NRL will forward the serotyped strains to Veterinary Diagnostic Directorate for AMR testing. The same procedure shall follow in 2018 regarding Salmonella from poultry. Attached documents: letter_pig_Salmonella_2017 order_form_pig_salmonella_2017_</td>
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<tr>
<td>2</td>
<td>To ensure that sampling at Identification of the epidemiological</td>
<td>There is no delay in the action plan.</td>
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Date: 15 March 2017
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<th>Date: 15 March 2017</th>
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| slaughterhouses is representative, as set out by Article 2(1) and points 2.3 and 2.3.1 of Part A of the Annex to Decision 2013/652/EU, namely by allocating samples at this level on the basis of domestically produced animals and by ensuring that batches are randomly selected at slaughterhouse using an adequate definition of the epidemiological unit. |
| Recommendation based on conclusion No 48. |
| Associated findings No 34, 36, 37 and 39. |

| unit at level of flock of broiler chickens or turkeys shall be available at slaughterhouse for random and representative sampling; deadline: 31st December 2017. During allocating samples at slaughterhouse level foreign animal populations slaughtered domestically shall be excluded; deadline: 31 March 2017 |

| Flock level identification of epidemiological units at poultry shall be any effect in 2018, when sample collection restarts from broiler chicken and fattening turkey. 2017 is for caecal sampling of pigs, identifying epidemiological units at herd level. |

To provide availability of flock data for identification at slaughterhouse: Identification of epidemiological unit at level of flock in a declaration by the farmer is required as an obligation at animal transportation according to the order 87/2012. (VIII. 27.) VM rendelet. direct link: https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=a1200087.vm Members of regional authorities working on the field of animal transportation, slaughtering and sample collection in the food-chain have been informed and taught in a training at 28th February 2017 to ensure that this declaration by the farmer follow the animals to the slaughterhouse. In case of missing identification data at slaughter the NRL shall be informed and further measures shall be taken. Attached documents: list of participant on the training
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| 3 | To ensure that the samples are preserved and transported in line with documented procedures in place and that they are in line with point 4 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 (1) of the said Decision. Recommendation based on conclusion No 48. Associated findings No 41 and 63. | To ensure that the samples arrive to the laboratory within 48 hours after sampling, 2 regional laboratory facilities of the National Food Chain Safety Office (NÉBIH) Veterinary Diagnostic Directorate (ÁDI) as dedicated AMR-NRL shall be involved into the inoculation of caecal samples to obtain primary bacterium cultures; deadline: 31. January 2017. Sampling plan 2017-2018 shall stratify sample numbers and sampling days at slaughterhouse level to obtain the required number of samples and ensure fast, well-organized transportation by the official courier service; deadline: 31st March 2017. Registration of the exact sampling time on the cover letter shall be demanded; deadline: 31. 12. 2016. Exact arriving time and temperature shall be registered in the worksheet by the laboratory; deadline: 31. 12. 2016. 1 –a/ To ensure proper sampling, transportation and acceptance trainings were organized for central and regional authority and laboratory staff. Attached documents: list of participant on the training (Attendance_sheet_20170228), adapted instruction guide for collection and transportation of caecal samples and fresh meat: (instruction_guide_sampling_caecum_ARM 2017) (instruction_guide_sampling_freshmeat_ARM) improved sampling form with date and time (sampling_form_AMR_monitoring_2017) instruction guide for transportation, reception and evaluation of samples for acceptance to analysis (instruction_guide_acceptance_MU-
ANNEX

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Acceptable time and temperature for the transportation and storage of samples shall be redefined: A) regarding Isolation of ESBL-, AmpC- and carbapenemase-producing E. coli: LABORATORY PROTOCOL Isolation of ESBL-, AmpC- and carbapenemase-producing E. coli from caecal samples by the EURL-AR B) regarding Campylobacter jejuni isolation from caecum samples: Commission Decision 2007/516/EC and OIE Terrestrial Manual Chapter 2.9.3. CAMPYLOBACTER JEJUNI AND CAMPYLOBACTER COLI; B. 1. b) iii); deadline 31st December 2016. Optional freeze-storage of caecum samples has been discontinued; deadline: 31st October 2016

Temperature during transportation is available online; deadline: 31. January 2017.

11.117 amr)
1-b/
Relevant Protocol for acceptance criteria:
LABORATORY PROTOCOL Isolation of ESBL-, AmpC- and carbapenemase-producing E. coli from caecal samples published by EURL-AMR

2 – The 2 regional laboratories of the Veterinary Diagnostic Directorate (NRL-AMR) shall be involved to receive caecal sample from certain geographical locations and to prepare primary culture from caecal samples for all purposes (commensal E. coli, ESBL E.coli, Camp jejuni). After proper incubation the primary culture on the original media and a subculture of suspicious colonies shall be submitted to the central laboratory for identification, susceptibility testing and storage.

Both regional laboratory’s staff have been informed and taught about ARM in general, sample acceptance and methodology at 9th February 2017 in a training in the NRL-AMR.

The same quality assurance system
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4 To ensure that adequate documented procedures and quality controls are in place so that test results (for both the minimum inhibitory concentration determination tests and the specific monitoring of ESBL- or AmpC- or carbapenemases-producing E. coli) are obtained in line with points 3, 4 and 5 of Part A of the Annex to Decision 2013/652/EU, in order to comply with Article 4 of the said Decision.

Recommendation based on conclusion No 68.
Associated findings No 62, 63 and 64.

Protocols and Operational Instructions shall be produced or supplemented to improve laboratory practice regarding quality assurance:
- in case of revision of accreditation completed protocol for MIC-determination AST shall refer directly to CLSI M07-A10 and ISO 20776-1:2006; deadline: year 2017
- in case of revision of accreditation isolation of ESBL- or AmpC- or carbapenemases-producing E. coli shall be involved; deadline: year 2017

- procedure for sample acceptance (regarding endurance of transportation, temperature control)
- quality control procedures according to CLSI M07-A10 and ISO 20776-1:2006 (additional weakly validation of culture media containing active substances, registration of starting and finishing incubation time of seeding culture and MIC-determination

Date: 15 March 2017
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<th>5</th>
<th>To ensure that the information included in the overall description of the implementation of AMR monitoring provided to the European Food Safety Authority is complete and accurate, as required by points 2 and 2.1 of Part B of the Annex to Decision 2013/652/EU, in order to comply with Article 5 of the said Decision. Recommendation based on conclusion No 75. Associated finding No 73.</th>
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<td>In addition to the mandatory parts of the report provided to EFSA, overall description (i.e. description of sampling designs, stratification and randomisation procedures per animal populations and food categories.) shall be included. Deadline: Reporting period of the 2016 monitoring year (May 2017).</td>
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microplates, recording of the batch No. of media used for AST, parallel use of reference bacterium strains for every daily batch of AST); deadline 31.12.2016

- procedure for investigation of unusual results of MIC determination according to EURLE-AR recommendations; deadline 31st December 2016.

- procedure for regular check of inoculum concentration by colony counting method according to CLSI M07-A10; deadline 31st December 2016.

Date: 15 March 2017