

**SARAF WEBINAR 17 December 2025**  
**on Commission Implementing Regulation (EU) Regulation 2021/808**

**FAQ**

**Coordinated replies (3 EURLs, EC) to questions raised during the webinar**

<b>Q1</b>	<b>I have a question for Joachim: if I understood correctly, if a substance with MRL in 2010/37 for which there is recommendation to control that substance for illegal prescription, from now on we have to use the MRL value? I am referring to clenbuterol and some corticosteroids.</b>
<b>A1</b>	<i>No - the first approach should be to presume an illegal treatment. After the finding, it should be checked whether the origin of the residues was a legal treatment based on a very specific indication by a veterinarian or not.</i>
<b>Q2</b>	<b>I would like to have had more information about the percentage of methods or compounds already validated with Reg 2021/808 in each country.</b>
<b>A2</b>	<i>It should be possible to put the Dec 2024 inquiry in the EURLs website in restricted areas.</i>
<b>Q3</b>	<b>If Belac accreditation approach for validation of the method can be used from other laboratories or states it will be OK this for DG sante mission.</b>
<b>A3</b>	<i>It could be an idea to make an initiative at EA to develop a commonly used flexible technical guide (there are some in other areas) - The BELAC guideline could help - but it has to be checked to which extent it is in line with 2021/808</i>
<b>Q4</b>	<b>BELAC guideline prescribed somehow the way to perform the approach for qualitative confirmation, but can everyone apply that approach which determines the CCa according to method 2 (if I understood correctly their approach...).</b>
<b>A4</b>	<i>- The CCa-Method2 for prohibited substances with 20 representative blanks is no longer applicable as mentioned in 2021/808;          - The CCa-Method2 for MRL substances is correct =&gt; <math>MRL + k \cdot (Combined)StdMU</math></i>
<b>Q5</b>	<b>A database with where to find analytical standards would be great.</b>
<b>A5</b>	<i>Suppliers lists are posted on the individual EURL websites - Also the database ALMANAC is already available and includes information on potential suppliers.</i>
<b>Q6</b>	<b>Selection of substances with regard to new substances that may appear in products as residues.</b>
<b>A6</b>	<i>EURLs are constantly monitoring new substances but no specific list has been delivered. This matter is constantly being discussed at the EURL/NRL workshops.</i>
<b>Q7</b>	<b>Do the NRLs in Belgium organize PTs themselves for OCLs or do they rely on the goodwill of the EURLs to include the OCLs?</b>
<b>A7</b>	<i>This is not foreseen on the VMPPR side. Including larger numbers of EU-MS field labs in our EURL PT would require more money and thus an additional budget. Could be discussed on a case to case basis with the concerned NRLs.</i>
<b>Q8</b>	<b>Being so picky about stability data will not allow the use of already published data, as this data will not be complete. The same applies to PT data.</b>
<b>A8</b>	<i>Existing data is acceptable with flagging levels. A first draft of the guidance will be made available to NRLs for comments in the coming months. The database shall be at a correct level of reliability of the stability data.</i>
<b>Q9</b>	<b>Given the inter-day variability in LC-MSMS conditions, is it still advisable to use it for stability checks of stock standard solutions?</b>
<b>A9</b>	<i>It is a compromise between efforts and output - but it is true: the present variabilities do not allow to make a very precise decision on the usability of a new stock solution</i>
<b>Q10</b>	<b>For cc alpha &amp; cc beta calculation as per 808, are any templates available?</b>
<b>A10</b>	<i>Please contact EURLs for further possible sharing of templates.</i>
<b>Q11</b>	<b>Is there any database or calculator available to estimate cascading MRLs (Maximum Residue Limits)?</b>
<b>A11</b>	<i>There is no specific calculation. This issue is generally addressed at the EURL/NRL Workshops. Please contact EURLs for further possible sharing of information.</i>
<b>Q12</b>	<b>Please could we have more information about CCalpha and CCBeta?</b>

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<b>A12</b>	<i>Option 1 : please see the guidance documents on the EURL portal include link and if not sufficient Option2 : ask EURLs for support</i>
<b>Q13</b>	<b>For MRL substances, is there a limit on how much higher the CCalpha can be compared to the MRL? Specifically, what is the maximum percentage over the MRL that is still acceptable? 10%?</b>
<b>A13</b>	<i>CCalpha max calculation. If necessary see EURL for support.</i>
<b>Q14</b>	<b>2021/808 needs a revision to accommodate HRMS guidelines, am I not wrong?</b>
<b>A14</b>	<i>CIR 2021/808 already sufficiently addresses the concept. But technical details will be explained in the 2026 coming HRMS technical guidance to be relased on the EURL websites and cluster portal.</i>
<b>Q15</b>	<b>Is this HRMS guidance already available?? Please reply!</b>
<b>A15</b>	<i>CIR 2021/808 already sufficiently addresses the concept. But technical details will be explained in the 2026 coming HRMS technical guidance to be relased on the EURL websites and cluster portal.</i>
<b>Q16</b>	<b>Could you suggest a technique with 4 identification points?</b>
<b>A16</b>	<i>Please refer to Tables 3 and 4 of the Annex 1 of CIR 2021/808</i>
<b>Q17</b>	<b>Validation/revalidation of qualitative methods (microbiological screening method - 5-plate) at what level should substances be tested? Is CCbeta = STC at 0.5 MRL or higher acceptable, or should we test substances at 0.1 MRL, or does this apply to quantitative methods?</b>
<b>A17</b>	<i>Qualitative screening methods shall be validated against the 2021/808 according to the Technical Guidance for the Validation of screening methods. There is no need to further evaluate/validate the screening methods down to 0.1 MRL if they are used only for Plan 1 and Plan3 for regulatoy control at MRL levels.</i>
<b>Q18</b>	<b>Is the calculation of LOQ required or not? If required, is it above or below the cc alpha?</b>
<b>A18</b>	<i>LOQ is not required in VMPR legislation (but in pesticide legislation)</i>
<b>Q19</b>	<b>Validation should, of course, include all routinely tested matrices. In the case of kidneys, should we also distinguish (test) kidneys of different species when testing them?</b>
<b>A19</b>	<i>Yes, validation per matrix per species is needed.</i>
<b>Q20</b>	<b>Is there a minimum acceptable value/range for absolute recovery in veterinary drug residues in milk? Else even with 20% absolute recovery if recovery corrected (through internal standard or matrix fortified calibration) value falls between 80-120% will this be acceptable ?</b>
<b>A20</b>	<i>Using an internal standard or matrix fortified calibration, it is correct.</i>
<b>Q21</b>	<b>Are there any recommendations on which substances from the antibiotic groups should be tested and how many of these compounds should be included in the validation of screening methods?</b>
<b>A21</b>	<i>Lists of substances are discussed internally in the EURL/NRL workshops when setting up analytical methods.</i>
<b>Q22</b>	<b>How should commercially available screening tests for antibacterial residues be validated? How should the levels be selected in relation to the MRL and manufacturer-specified test sensitivity?</b>
<b>A22</b>	<i>Qualitative screening methods including commercially available screening tests for antibacterial residues shall be validated against the 2021/808 according to the Technical Guidance for the Validation of screening methods available in the EURL websites.</i>