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report for review CL 2016/27-PR Request for comments at Step 6 on the Draft Guidelines on Performance Criteria for Methods of [Sub-review]

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summary

Title	**CL 2016/27-PR Request for comments at Step 6 on the Draft Guidelines on Performance Criteria for Methods of [Sub-review] (Id 182)**
Description	
End Date	**27 Feb 2017 12:00 AM**
Review Status	**In Progress**

participants

Name	Status	Role	Summary	Comments	Last Activity
Council of the European Union	Not Started	Author		0	
European Union	Completed	Owner	Revised version 05.01.2017 Final EU comments were sent to the Codex Secretariat via OCS on 16.1.2017 at 16.21h B Klink	36	16 Jan 2017 4:22 PM

T (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating
S (Status) - A = Accepted, C = Closed, O = Open, W = Withdrawn
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Para	Text	T	Comment	S	Author Comment
18	**A.** Applicability	**P**	**Proposed Change (68) by European Union on 5 Jan 2017 11:13 AM** *Category : SUBSTANTIVE* **A.** ~~Applicability~~ **Method Documentation** **European Union (5 Jan 2017 11:13 AM)**	A	**European Union (5 Jan 2017 11:13 AM):** Accepted
		C	**Comment (63) by European Union on 5 Jan 2017 10:46 AM** *Category : SUBSTANTIVE* **European Union (5 Jan 2017 10:46 AM)** European Union (22 Dec 2016 9:46 AM) The title "Applicability" does not reflect the content of the paragraph.	A	**European Union (5 Jan 2017 10:46 AM):** Accepted
75	10. The process of method validation is intended to demonstrate that a method is *fit-for-purpose*. This means that when a test is performed by a properly trained analyst using the specified equipment and materials and exactly following	**C**	**Comment (55) by European Union on 21 Dec 2016 4:18 PM** *Category : SUBSTANTIVE* **European Union (21 Dec 2016 4:18 PM)** A method cannot be continously assessed by proficiency testing since those only occur periodically.	A	**European Union (5 Jan 2017 10:47 AM):** Accepted
		P	**Proposed Change (56) by European Union**	A	**European**

	the method protocol, accurate and consistent results can be obtained within specified statistical limits for sample analysis. The validation should demonstrate the identity and concentration of the analyte, taking into account for matrix effects, provide a statistical characterization of recovery results, and indicate if the rates of false positives and negatives are acceptable. When the method is followed using suitable analytical standards, results within the established performance limits should be obtained on the same or equivalent sample material by a trained analyst in any experienced residue testing laboratory. To ensure that validation of the method remains appropriate over time, the method should be continuously assessed using on-going proficiency testing and appropriate quality control samples (e.g. including recovery spikes).		**on 21 Dec 2016 4:19 PM** *Category : SUBSTANTIVE* ~~10.~~ 10. The process of method validation is intended to demonstrate that a method is *fit-for-purpose*. This means that when a test is performed by a properly trained analyst using the specified equipment and materials and exactly following the method protocol, accurate and consistent results can be obtained within specified statistical limits for sample analysis. The validation should demonstrate the identity and concentration of the analyte, taking into account for matrix effects, provide a statistical characterization of recovery results, and indicate if the rates of false positives and negatives are acceptable. When the method is followed using suitable analytical standards, results within the established performance limits should be obtained on the same or equivalent sample material by a trained analyst in any experienced residue testing laboratory. To ensure that validation of the method remains appropriate over time, the method should be continuously assessed using on-going ~~proficiency testing and appropriate quality control samples~~ **method validation** (e.g. ~~including~~ recovery spikes). **European Union (21 Dec 2016 4:19 PM)**		**European Union (5 Jan 2017 10:47 AM):** Accepted
82	**b.** concentration range covered by the validation (e.g. “0.01-10 mg/kg”);	**P**	**Proposed Change (53) by European Union on 21 Dec 2016 11:27 AM** *Category : SUBSTANTIVE* ~~**b.**~~ **b.** concentration range covered by the validation ~~(e.g. “0.01-10 mg/kg”)~~; **European Union (21 Dec 2016 11:27 AM)**	A	**European Union (5 Jan 2017 10:50 AM):** Accepted
		C	**Comment (64) by European Union on 5 Jan 2017 10:49 AM** *Category : SUBSTANTIVE* **European Union (5 Jan 2017 10:49 AM)** This is an unrealistic range and thus confusing; therefore it is better to delete it.	A	**European Union (5 Jan 2017 10:49 AM):** Accepted
85	**e.** if required, a quantitative result should be reported together with the expanded measurement uncertainty (MU).	**C**	**Comment (47) by European Union on 7 Nov 2016 10:14 AM** *Category : SUBSTANTIVE* **European Union (7 Nov 2016 10:14 AM)** The measurement of the uncertainty should always be calculated during the validation of the method, although not necessarily reported.	A	**European Union (5 Jan 2017 10:50 AM):** Accepted
		P	**Proposed Change (8) by European Union on 4 Nov 2016 5:02 PM** *Category : SUBSTANTIVE* **e.** ~~if required,~~ a quantitative result ~~should be reported together with~~ **of** the expanded measurement uncertainty ~~(MU)~~**(MU) of the**	A	**European Union (5 Jan 2017 10:50 AM):** Accepted

			method has to be calculated in the validation procedure and reported, if required. **European Union (4 Nov 2016 5:02 PM)**		
88	14. As a general principle, selectivity should be such that interferences are inconsequential. The ultimate test of selectivity involves the rates of false positives and negatives in the analyses. To minimally estimate rates of false positives and negatives during method validation, an adequate number (suggested >5 each) of diverse matrix blanks (not from the same source) should be analysed along with spiked matrices at the analyte reporting level. Validations of screening methods (presence/absence analyses) are discussed in paragraphs 32-34.	**P**	**Proposed Change (9) by European Union on 4 Nov 2016 5:05 PM** *Category : SUBSTANTIVE* ~~14.~~ 14. As a general principle, selectivity should be such that interferences are inconsequential. The ultimate test of selectivity involves the rates of false positives and negatives in the analyses. To minimally estimate rates of false positives and negatives during method validation, an adequate number ~~(suggested >5 each)~~ of ~~diverse matrix~~ blanks **per matrix** (not from the same source) should be analysed along with spiked matrices at the analyte reporting level. ~~Validations of screening methods (presence/absence analyses) are discussed in paragraphs 32-34.~~ **European Union (4 Nov 2016 5:05 PM)**	A	**European Union (5 Jan 2017 11:16 AM):** Accepted
		C	**Comment (65) by European Union on 5 Jan 2017 10:53 AM** *Category : SUBSTANTIVE* **European Union (5 Jan 2017 10:53 AM)** It is not necessary to specify the number of blanks per matrix as the text indicates: "an adequate number", which remains at the discretion of the analyst. Unnecessary in the context of the paragraph.	A	**European Union (5 Jan 2017 10:53 AM):** Accepted
97	18. In general, the use of weighted-linear regression or weighted-quadratic function is recommended rather than linear regression for low part per billion (µg/kg) concentration determinations. The value of the intercept should be close to zero (e.g. <20% of the lowest calibration standard) to reduce errors in calculating residue concentrations at low levels.	**P**	**Proposed Change (54) by European Union on 21 Dec 2016 11:38 AM** *Category : SUBSTANTIVE* 18. In general, the use of weighted-linear regression or weighted-quadratic function is recommended rather than linear regression for low part per billion (µg/kg) concentration determinations. The value of the intercept should be close to zero ~~(e.g. <20% of the lowest calibration standard)~~ to reduce errors in calculating residue concentrations at low levels**, although the calibration curve should not be forced through the origin without justification**. **European Union (21 Dec 2016 11:38 AM)**	A	**European Union (5 Jan 2017 10:54 AM):** Accepted
		C	**Comment (59) by European Union on 22 Dec 2016 9:55 AM** *Category : SUBSTANTIVE*	A	**European Union (22 Dec 2016**

			European Union (22 Dec 2016 9:55 AM) The text in brackets is not necessary and can create confusion.		**9:55 AM):** Accepted
109	26. By long-standing definition among analytical chemists, the LOQ is the concentration at which the average signal/noise ratio (S/N) equals 10 in the analysis. The LOQ in practice can only be estimated because precise determination of the actual LOQ requires many analyses of spiked samples and matrix blanks but the LOQ can change day-to-day due to the performance state of the instrument, among many other factors. Some validation guidelines require that the LOQ be verified to meet method performance criteria via spiking experiments at the LOQ, however day-to-day variations in LOQ tend to force the analyst to greatly over-estimate the actual method LOQ, which can be difficult to implement the strict definition of the LOQ (S/N = 10). Thus spiking at the Lowest Validated Level (LVL) is the more descriptive and proper approach. Furthermore, quantification of analytes should not be made below the lowest calibrated level (LCL) in the same analytical sequence. The S/N at the LCL must be ≥10 (conc. ≥ LOQ), which can be set as a system suitability check required for each analytical sequence. A quality control matrix spike can also be included in each sequence to verify that the reporting limit is achieved in the analysis (an action level that is typically greater than the LCL). In essence, the point of the validation is not to determine the LOQ, but to demonstrate that the lowest reported concentration is meeting the need for the analysis.	**C**	**Comment (66) by European Union on 5 Jan 2017 10:56 AM** *Category : SUBSTANTIVE* **European Union (5 Jan 2017 10:56 AM)** If the method is not validated at the LCL, results at that level cannot be reported. Therefore it is the LVL that needs to be checked and not the LCL.	A	**European Union (5 Jan 2017 10:57 AM):** Accepted
		P	**Proposed Change (12) by European Union on 4 Nov 2016 5:15 PM** *Category : SUBSTANTIVE* ~~26.~~ 26. By long-standing definition among analytical chemists, the LOQ is the concentration at which the average signal/noise ratio (S/N) equals 10 in the analysis. The LOQ in practice can only be estimated because precise determination of the actual LOQ requires many analyses of spiked samples and matrix blanks but the LOQ can change day-to-day due to the performance state of the instrument, among many other factors. Some validation guidelines require that the LOQ be verified to meet method performance criteria via spiking experiments at the LOQ, however day-to-day variations in LOQ tend to force the analyst to greatly over-estimate the actual method LOQ, which can be difficult to implement the strict definition of the LOQ (S/N = 10). Thus spiking at the Lowest Validated Level (LVL) is the more descriptive and proper approach. Furthermore, quantification of analytes should not be made below the lowest ~~calibrated~~ **validated** level ~~(LCL)~~ **(LVL)** in the same analytical sequence. The S/N at the LCL must be ≥10 (conc. ≥ LOQ), which can be set as a system suitability check required for each analytical sequence. A quality control matrix spike can also be included in each sequence to verify that the reporting limit is achieved in the analysis (an action level that is typically ~~greater than~~ the ~~LCL)~~**LVL)**. In essence, the point of the validation is not to determine the LOQ, but to demonstrate that the lowest reported concentration is meeting the need for the analysis. **European Union (4 Nov 2016 5:15 PM)**	A	**European Union (5 Jan 2017 10:57 AM):** Accepted
111	27. The validated range is the interval of analyte concentration within which the method can be regarded as validated. The LVL is the	**C**	**Comment (20) by European Union on 4 Nov 2016 5:23 PM** *Category : EDITORIAL* **European Union (4 Nov 2016 5:23 PM)** For the sake of clarification.	A	**European Union (5 Jan 2017 10:58 AM):** Accepted

	lowest concentration assessed during validation that meets method performance criteria. It is important to realize that the validated range is not necessarily identical to the useful range of the calibration. While the calibration may cover a wide concentration range, the validated range (which is usually more important in terms of uncertainty) will typically cover a more restricted range. In practice, most methods will be validated for at least two levels of concentration. The validated range may be taken as a reasonable extrapolation between these points of concentration, but many laboratories choose to validate at a third level to demonstrate linearity. For monitoring residue concentrations with respect to Codex standards, the analytical method must be sensitive enough so that the LVL for each analyte is at or below the current Codex maximum residue limit (CXL). The validation range should cover the existing CXL. When a CXL does not exist, the lowest level may be MRLs established by a national regulatory authority. If no CXL or MRL exists for a given analyte/matrix pair, then 0.01 mg/kg generally serves as the desirable LVL. In MRMs, the typical analytical goal is to set the LVL (and reporting level) at 0.01 mg/kg in diverse, yet representative commodities.	P	**Proposed Change (19) by European Union on 4 Nov 2016 5:23 PM** *Category : EDITORIAL* 27. The validated range is the interval of analyte concentration within which the method can be regarded as validated. The LVL is the lowest concentration assessed during validation that meets method performance criteria. It is important to realize that the validated range is not necessarily identical to the useful range of the **instrumental** calibration. While the calibration may cover a wide concentration range, the validated range (which is usually more important in terms of uncertainty) will typically cover a more restricted range. In practice, most methods will be validated for at least two levels of concentration. The validated range may be taken as a reasonable extrapolation between these points of concentration, but many laboratories choose to validate at a third level to demonstrate linearity. For monitoring residue concentrations with respect to Codex standards, the analytical method must be sensitive enough so that the LVL for each analyte is at or below the current Codex maximum residue limit (CXL). The validation range should cover the existing CXL. When a CXL does not exist, the lowest level may be MRLs established by a national regulatory authority. If no CXL or MRL exists for a given analyte/matrix pair, then 0.01 mg/kg generally serves as the desirable LVL. In MRMs, the typical analytical goal is to set the LVL (and reporting level) at 0.01 mg/kg in diverse, yet representative commodities. **European Union (4 Nov 2016 5:23 PM)**	A	**European Union (21 Dec 2016 4:31 PM):** Accepted
114	29. Examples of the factors that a ruggedness test could address are: changes in the instrument, operator, or brand/lot of reagent; concentration of a reagent; pH of a solution; temperature of a reaction; time allowed for completion of a process, and/or other pertinent factors.	P	**Proposed Change (49) by European Union on 7 Nov 2016 10:20 AM** *Category : EDITORIAL* 29. Examples of the factors that a ruggedness test could address are: **small** changes in the instrument~~, operator, or~~ **,** brand/lot of ~~reagent~~**reagent or changes in the operator**; concentration of a reagent; pH of a solution; temperature of a reaction; time allowed for completion of a process, and/or other pertinent factors. **European Union (7 Nov 2016 10:20 AM)**	A	**European Union (5 Jan 2017 10:58 AM):** Accepted
		C	**Comment (50) by European Union on 7 Nov 2016 10:21 AM**	A	**European Union (21**

			Category : EDITORIAL **European Union (7 Nov 2016 10:21 AM)** For the sake of clarity.		**Dec 2016 4:32 PM):** Accepted
120	32. Screening methods are usually either qualitative or semi-quantitative in nature, with the objective being to discriminate samples which contain no residues above a threshold value (“negatives”) from those which may contain residues above that value (“indicated positives”). The validation strategy therefore focuses on establishing a threshold concentration above which results are “potentially positive,” determining a statistically based rate for both “false positive” and “false negative” results, testing for interferences and establishing appropriate conditions of use. The screening concept offers laboratories an effective means to extend their analytical scope to analytes, which potentially have a low probability of being present in the samples. Analytes that occur more frequently should continue to be monitored using validated quantitative MRMs. As in quantitative methods, screening methods should also be checked in terms of selectivity and sensitivity. In some applications, commercial test kits may be useful, but current techniques have rarely met multi-residue screening needs economically in practice. Selectivity and analytical scope are often improved when chromatography or other form of separation is used prior to detection. Another approach is to use screening methods that involve mass spectrometry (MS)-based detection, which is able to distinguish particular chemicals from each other.	**C**	**Comment (67) by European Union on 5 Jan 2017 11:01 AM** *Category : SUBSTANTIVE* **European Union (5 Jan 2017 11:01 AM)** In screening methods the terms “false positive” and “false negative” are not correct, as the results have not been identified.	A	**European Union (5 Jan 2017 11:01 AM):** Accepted
		P	**Proposed Change (25) by European Union on 4 Nov 2016 5:29 PM** *Category : SUBSTANTIVE* ~~32.~~ 32. Screening methods are usually either qualitative or semi-quantitative in nature, with the objective being to discriminate samples which contain no residues above a threshold value (“negatives”) from those which may contain residues above that value (“indicated positives”). The validation strategy therefore focuses on establishing a threshold concentration above which results are “potentially positive,” determining a statistically based rate for ~~both “false positive” and “false negative” results~~**false detects (positives or negatives)**, testing for interferences and establishing appropriate conditions of use. The screening concept offers laboratories an effective means to extend their analytical scope to analytes, which potentially have a low probability of being present in the samples. Analytes that occur more frequently should continue to be monitored using validated quantitative MRMs. As in quantitative methods, screening methods should also be checked in terms of selectivity and sensitivity. In some applications, commercial test kits may be useful, but current techniques have rarely met multi-residue screening needs economically in practice. Selectivity and analytical scope are often improved when chromatography or other form of separation is used prior to detection. Another approach is to use screening methods that involve mass spectrometry (MS)-based detection, which is able to distinguish particular chemicals from each other.	A	**European Union (5 Jan 2017 10:59 AM):** Accepted

			European Union (4 Nov 2016 5:29 PM)		
121	33. The selectivity of screening methods should be adequate and must be able to distinguish the presence of the target compound, or group of compounds, from other substances that may be present in the sample material. Selectivity of screening methods is normally not as great as that of a quantitative method. Screening methods often take advantage of a structural feature common to a group or class of compounds and may be based on immunoassays or spectrophotometric responses which may not unambiguously identify a compound.	**C**	**Comment (31) by European Union on 4 Nov 2016 5:32 PM** *Category : EDITORIAL* **European Union (4 Nov 2016 5:32 PM)** For the sake of clarification.	A	**European Union (5 Jan 2017 11:02 AM):** Accepted
		P	**Proposed Change (30) by European Union on 4 Nov 2016 5:31 PM** *Category : EDITORIAL* 33. The selectivity of screening methods should be adequate and must be able to distinguish the presence of the target compound, or group of compounds, from other substances that may be present in the sample material. Selectivity of screening methods is normally not as great as that of a quantitative method. Screening methods ~~often~~ **can** take advantage of a structural feature common to a group or class of compounds and may be based on immunoassays or spectrophotometric responses which may not unambiguously identify a compound. **European Union (4 Nov 2016 5:31 PM)**	A	**European Union (5 Jan 2017 11:02 AM):** Accepted
126	37. In addition to the selectivity of a method, the ability of the method to provide a reliable quantitative result must be demonstrated (i.e. trueness - see section F and precision – see section G). Ideally, the relative standard deviation between the original sample and replicates will be less than 30 percent.	**P**	**Proposed Change (32) by European Union on 4 Nov 2016 5:33 PM** *Category : SUBSTANTIVE* ~~37.~~ 37. In addition to the selectivity of a method, the ability of the method to provide a reliable quantitative result must be demonstrated (i.e. trueness - see section F and precision – see section G). Ideally, the relative standard deviation between the ~~original sample and~~ **concentration of the** replicates will be less than ~~30~~ **20** percent. **European Union (4 Nov 2016 5:33 PM)**	A	**European Union (5 Jan 2017 11:03 AM):** Accepted
		C	**Comment (33) by European Union on 4 Nov 2016 5:34 PM** *Category : SUBSTANTIVE* **European Union (4 Nov 2016 5:34 PM)** For consistency with paragraph 39 of this document (Acceptable mean recoveries for enforcement purposes should range from 70-120% with a RSD ≤20%).	A	**European Union (5 Jan 2017 11:02 AM):** Accepted
139	47. Current practices in qualitative (and quantitative) analysis of pesticide residues commonly involve chromatography + selected ion monitoring (SIM) or MS/MS techniques. Full-spectral (full-scan or time-of-flight) MS is also an acceptable tool that uses spectral library matching factors and/or relative	**P**	**Proposed Change (35) by European Union on 4 Nov 2016 5:38 PM** *Category : SUBSTANTIVE* 47. Current practices in qualitative ~~(and quantitative)~~ **and quantitative** analysis of pesticide residues commonly involve chromatography + selected ion monitoring (SIM) or MS/MS techniques. Full-spectral ~~(full-scan or time-of-flight)~~ MS is also an acceptable tool that uses spectral library matching factors and/or relative	A	**European Union (5 Jan 2017 11:04 AM):** Accepted

	abundances of major ions within the full spectra. The latter case can be treated as ion ratios in the criteria given below using at least 3 ions. In the former case, matching factors should be ≥900 (≥90% match) for regulatory identification purposes, and the library reference spectra should be obtained from background-subtracted high purity standards on the same instrument using the same conditions as in the sample analysis. The following identification criteria should be met:		abundances of major ions within the full spectra. The latter case can be treated as ion ratios in the criteria given below using at least 3 ions. In the former case, ~~matching factors should be ≥900 (≥90% match) for regulatory identification purposes, and~~ the library reference spectra should be obtained from background-subtracted high purity standards on the same instrument using the same conditions as in the sample analysis. The following identification criteria should be met: **European Union (4 Nov 2016 5:38 PM)**		
		C	**Comment (51) by European Union on 7 Nov 2016 10:24 AM** *Category : SUBSTANTIVE* **European Union (7 Nov 2016 10:24 AM)** Delete the brackets. Full spectral is clear enough. Besides, full scan and time of flight refer to different things (acquisition mode and analyser) and it´s possible to work in full scan using a time of flight instrument but also a single quadrupole or orbitrap. Matching factors depend on the specific software used, so it´s not correct to use the same threshold for all of them. Furthermore it is not clear the scientific basis applied.	A	**European Union (5 Jan 2017 11:04 AM):** Accepted
140	**a.** Analyte retention time reference values must be determined from contemporaneously analysed (within the same batch) high concentration calibration standards in solvent-based solutions (matrix-matched calibration standards may be used if it is known that no interferences are present).	C	**Comment (38) by European Union on 4 Nov 2016 5:41 PM** *Category : SUBSTANTIVE* **European Union (4 Nov 2016 5:41 PM)** It is preferable to determine the reference values in the same matrix or from the same commodity group than the samples to be analysed.	A	**European Union (5 Jan 2017 11:05 AM):** Accepted
		P	**Proposed Change (37) by European Union on 4 Nov 2016 5:41 PM** *Category : SUBSTANTIVE* ~~**a.**~~ **a.** Analyte retention time reference values must be determined from contemporaneously analysed (within the same batch) high concentration **matrix-matched** calibration standards ~~in solvent-based solutions (matrix-matched calibration standards may be used~~ if it is known that no interferences are ~~present)~~**present otherwise using solvent based solutions**. **European Union (4 Nov 2016 5:41 PM)**	A	**European Union (5 Jan 2017 11:05 AM):** Accepted
145	48. The minimum acceptable retention time for the analyte(s) should be at least twice the retention time corresponding to the void volume of the column. The retention time of the analyte in the extract should	P	**Proposed Change (39) by European Union on 4 Nov 2016 5:42 PM** *Category : TECHNICAL* 48. The minimum acceptable retention time for the analyte(s) should be at least twice the retention time corresponding to the void volume of the column. The retention time of	A	**European Union (5 Jan 2017 11:06 AM):** Accepted

	correspond to that of the reference value (47a) within ±0.2 min or 0.2% relative retention time, for both gas chromatography and liquid chromatography.		the analyte in the extract should correspond to that of the reference value (47a) within ±0.2 min or 0.2% relative retention time, for both gas chromatography and liquid ~~chromatography~~**chromatography (preferably ±0.1 min if possible)** . **European Union (4 Nov 2016 5:42 PM)**		
		C	**Comment (40) by European Union on 4 Nov 2016 5:42 PM** *Category : TECHNICAL* **European Union (4 Nov 2016 5:42 PM)** For a better harmonisation with SANTE/11945/2015 and performance of the new LC and GC instruments.	A	**European Union (5 Jan 2017 11:06 AM):** Accepted
199	d) ≤10 ppm	P	**Proposed Change (41) by European Union on 4 Nov 2016 5:44 PM** *Category : TECHNICAL* d) ~~≤10 ppm~~ **European Union (4 Nov 2016 5:44 PM)**	A	**European Union (5 Jan 2017 11:08 AM):** Accepted
		C	**Comment (60) by European Union on 22 Dec 2016 9:57 AM** *Category : TECHNICAL* **European Union (22 Dec 2016 9:57 AM)** New HRMS instruments have typically mass errors <5 ppm in MS2.	A	**European Union (22 Dec 2016 9:57 AM):** Accepted
215	Derivatization	C	**Comment (44) by European Union on 4 Nov 2016 5:45 PM** *Category : SUBSTANTIVE* **European Union (4 Nov 2016 5:45 PM)** Derivatization is not a detection method.	A	**European Union (5 Jan 2017 11:06 AM):** Accepted
		P	**Proposed Change (43) by European Union on 4 Nov 2016 5:45 PM** *Category : SUBSTANTIVE* ~~Derivatization~~ **European Union (4 Nov 2016 5:45 PM)**	A	**European Union (5 Jan 2017 11:06 AM):** Accepted
217	LC-immunogram	P	**Proposed Change (45) by European Union on 4 Nov 2016 5:45 PM** *Category : TECHNICAL* ~~LC-immunogram~~**LC-immunoaffinity** **European Union (4 Nov 2016 5:45 PM)**	A	**European Union (5 Jan 2017 11:07 AM):** Accepted
		C	**Comment (46) by European Union on 4 Nov 2016 5:46 PM** *Category : TECHNICAL* **European Union (4 Nov 2016 5:46 PM)** Immunogram is the result, not the detection method.	A	**European Union (5 Jan 2017 11:06 AM):** Accepted

15.docx (DraftGuidelinesOnPerformanceCriteriaForMethodsOfAnalysis_F_2016-07-15.docx)

no comments to show.

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report for DraftGuidelinesOnPerformanceCriteriaForMethodsOfAnalysis_S_2016-07-15.docx (DraftGuidelinesOnPerformanceCriteriaForMethodsOfAnalysis_S_2016-07-15.docx)

no comments to show.