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Agenda Item 9 **CX/PR 16/48/13-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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COMMENTS at Step 3 on THE PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS FOR THE DETERMINATION OF PESTICIDE RESIDUES,

submitted by Australia, Canada, Chile, El Salvador, Japan and African Union

Australia

The Australian Delegation thanks the electronic working group, under the leadership of the United States of America, China and India, for their work on the Draft Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues. Australia is grateful for the opportunity to comment on this document.

(i) General Comments

The document defines a number of parameters differently to the CAC/GL 72-2009, Guidelines on Analytical Terminology (e.g. Fitness for Purpose, Applicability, Trueness, LOQ, Linearity, Measurement Uncertainty, Precision, Recovery, Repeatability conditions, Reproducibility conditions, Ruggedness, Selectivity). As this could be confusing to users of this document, Australia suggests the definitions should better reflect those in CAC/GL 72-2009.

The Reference section should only list references that are identified in the document. Other references could be identified under Additional Reading.

(ii) Specific Comments

OBJECTIVE

Paragraph 1, second sentence. Edits suggested since some sections of the document refer exclusively to monitoring residue concentrations with respect to Codex CXLs.

*It addresses the characteristics/parameters to provide scientifically acceptable confidence in the analytical method that is fit for the intended use and **may be used** to reliably evaluate pesticide residues for either domestic monitoring and/or international trade.*

PRINCIPLES FOR THE SELECTION AND VALIDATION OF METHODS

Paragraph 8: This paragraph should reference CAC/GL 27-1997, on which the text is based.

Paragraph 9. ISO/IEC 17025 implies the current version. Separate sentences to improve clarity.

*The analytical methods should be used within the internationally accepted, approved, and recognized laboratory Quality Management System, following a standard such as ISO/IEC 17025~~:2005 (or latest version)~~, to be consistent with the principles in the document for quality assurance (QA) and quality control (QC) referenced above. **ISO/IEC 17025 requires that** on-going performance **is** ~~must be~~ monitored through the Quality Management System in place in the laboratory.*

PERFORMANCE PARAMETERS FOR ANALYTICAL METHODS

Paragraph 16. Suggested terminology is less prescriptive and more appropriate for a guidance document.

*Replicate measurements are needed to provide an empirical estimate of uncertainty. ~~In the absence of specific guidance, the following should apply for the initial method validation (for univariate linear calibration):~~ **The following calibration procedures are recommended for the initial method validation**:*

16d

the calibration by interpolation between two levels is acceptable providing the difference between the 2 levels is not greater than a factor of 10 and providing the response factors of the bracketing calibration standards are within acceptable limits. ~~The response factor of bracketing calibration standards at each level should not differ by more than 20% (taking the higher response as 100%).~~

Paragraph 17. Deleted wording is unnecessarily prescriptive for a guidance document.

Linearity can be tested by examination of a plot of residuals produced by linear regression of the responses on the concentrations in an appropriate calibration set. Any curved pattern suggests a lack of fit due to a nonlinear calibration function. If this is the case, another function such as quadratic should be tested and applied~~, using at least five concentration levels~~. Despite its current widespread use as an indication of quality of fit, the coefficient of determination (R^2) may be misleading because it places greater significance on standards with higher concentrations.

Paragraph 27. An LVL at or below the CXL is relevant to monitoring with respect to Codex standards. Delete last two sentences since a LVL much lower than at 0.1 mg/kg, say 0.01 mg/kg, will very often be appropriate in the absence of Codex and national MRLs. Default MRLs at 0.01 mg/kg often apply at a national level in such circumstances.

The validated range is the interval of analyte concentration within which the method can be regarded as validated. The lowest validated level (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 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 labs choose to validate at a third level to demonstrate linearity. ***For monitoring residue concentrations with respect to Codex standards, t~~T~~****he analytical method must be sensitive enough so that the LVL for each analyte is at or below the current 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 0.1 mg/kg generally serves as the desirable LVL. In MRMs the typical analytical goal is to set the LVL (and reporting level) at 0.1 mg/kg in diverse, yet representative commodities.~~*

PERFORMANCE ACCEPTABILITY CRITERIA OF SCREENING METHODS

Paragraph 32, last sentence. The meaning of 'universal in scope' is unclear.

Another approach is to use screening methods that involve mass spectrometry (MS)-based detection, which are often ~~universal in scope and~~ able to distinguish particular chemicals from each other.

Paragraph 34, second sentence. SANTE 11945/2015 supersedes the reference quoted.

*For each commodity group (**SANTE 11945/2015** ~~SANCO 12571/2013~~ Annex A commodity groups and representative commodities), a minimal validation should involve analysis of a recommended number of at least 20 samples spiked at the estimated SDL.*

PERFORMANCE ACCEPTABILITY CRITERIA OF QUANTITATIVE METHODS

Paragraph 36. penultimate sentence. To improve clarity.

The nature and quantities of such co-extracted material can vary markedly based on the ~~particulars and method of the individual sample~~ matrix, method and analytes of interest.

Paragraph 38. Suggested terminology is less prescriptive and more appropriate for a guidance document

Acceptability criteria for a quantitative analytical method should be demonstrated at both initial and on-going validation stages, as being capable of providing acceptable mean recovery values at each spiking level. For validation, ***it is recommended that*** *a minimum of 5 replicate~~s~~* ***tests be performed*** *~~is required~~ (to check the recovery and precision) at the targeted LVL, LOQ, or reporting limit of the method, and at least one additional higher level, for example, 2-10x the LVL or the MRL. If a method is being used for compliance testing (i.e. if a commodity is compliant with an established MRL) the MRL (or CXL) should ~~must~~ be one of the spiking levels. When the residue definition includes two or more analytes, then whenever possible, the method should be validated for all analytes.*

Paragraph 39, second sentence. The use of 'normally' is consistent with following sentences which note that recoveries outside this range may be acceptable.

Acceptable mean recoveries for enforcement purposes should ***normally*** *range from 70-120% with a RSD ≤20%.*

Paragraph 39, last sentence. Less definitive wording suggested.

~~*Furthermore, r*~~***R****ecoveries >120%* ***are likely to be attributable to a positive interference or bias that should be investigated.***~~*can only be explained through an interferent or bias that should be addressed in the method, including re-assessment of calibration.*~~

Paragraph 40, second paragraph. To better group the guidance on recoveries, it is suggested that the following text be moved up to the end of Paragraph 39, and delete final sentence to remove duplication with paragraph 41.

At relatively high concentrations, analytical recoveries are expected to approach one hundred percent. At lower concentrations, particularly with methods involving extensive extraction, isolation, and concentration steps, recoveries may be lower. Regardless of what average recoveries are observed, recovery with low variability is desirable so that a reliable correction for recovery can be made to the final result, when required. ~~*Recovery corrections should be made consistent with the guidance provided by the CAC/GL 37-2001.*~~

Paragraph 41. Suggest deletion of first sentence, since corrected results will be more accurate than uncorrected results and be associated with decreased measurement uncertainty.

Suggest deletion of third sentence since it details the provisions of CAC/GL 37-2001, already cited.

~~*In general, residues data do not have to be adjusted for recovery when the mean recovery is within the range of 70-120%.*~~ *Recovery corrections should be made consistent with the guidance provided by the CAC/GL 37-2001.* ~~*It is of over-riding importance that all data, when reported, should (a) be clearly identified as to whether or not a recovery correction has been applied and (b) include the amount of the correction and the method by which it was derived, if a recovery correction has been applied.*~~ *This will promote direct comparability of data sets. Correction functions should be established on the basis of appropriate statistical considerations, and documented, archived and made available to the client.*

PERFORMANCE ACCEPTABILITY CRITERIA OF METHODS FOR ANALYTE IDENTIFICATION AND CONFIRMATION

Paragraph 45, third sentence

Table 1 gives criteria described in ~~*SANCO/12745/2015*~~ *SANTE/11945/2015.*

In a number of places in the bullet points, text refers to “must”. It is preferable that these are replaced by “**should”** in a guidance document.

Canada

General comments: replace “SANCO/12571/2013” with “SANTE/11945/2015” throughout the draft document.

Paragraph 5: Replace “the maximum residue limit or level (MRL, or CXL in Codex) with “the maximum residue limit or level (MRL) or Codex maximum residue limits (CXL)”

Paragraph 17: By the end of paragraph 17, add “In this case, an appropriate weighting factor such as 1/x or $1/x^2$ should be considered.

Paragraph 45: Replace “Full-spectral (full-scan or time-of-flight)” with “Full-scan”.

Paragraph 45: Need more explanation for “matching factors should be ≥ 900 (≥ 90% match). What is a matching factor? Why is ≥ 900 required?

Paragraph 46: The first sentence should be read: Methods based on high-resolution mass spectrometry are considered to provide improved reliability through ~~precise~~ accurate measurement of the mass/charge of the ion ~~that~~ compared to that can be obtained using unit-resolution mass spectrometry techniques.

Table 1 d): Delete “no specific requirement for mass accuracy”. Replace with ≤ 10 ppm.

Table 1: Add a table note after “Ion ratio within ±30% (relative) of average of calibration standards from same sequence” as such “If the precursor mass accuracy is less than 5 ppm and the product ion mass accuracy is less than 10 ppm, ion ratio tolerance is optional” as table note f).

Appendix II: Delete reference 21.

Chile

I. General Comments

Chile appreciates the important work done by the electronic Working Group, led by the United States of America and co-chaired by China and India, to review and coordinate the development of the current Guidelines document as well as the consideration that was given to the contributions made by our country.

Following the above, Chile supports that the completion of the work related to this proposed draft be made during the 48th session of the CCPR for forwarding to the 39th CAC for adoption.

Similarly, it is suggested that it would be useful to include at the end of the document a summary table with the criteria for limits, accuracy and precision.

II. Specific comments

Here are some specific comments to the Spanish version of the Proposed Draft Guidelines made mainly with the aim of improving the translation of the terminology and the understanding in this language:

Page	Paragraph	Comment	Justification
Page#	Paragraph#	The added text is indicated in bold and underlined, deleted text is crossed out.	
3		Defining the Purpose of the Method and **Scope**	
3	4	The intended purpose of the method is usually described in a statement of scope **which** ~~determines~~ **defines** the analytes (residues), the matrices, and the concentration ranges. It also states whether the method is intended for screening, quantification, identification, and/or confirmation of results	Improve translation and drafting.
3	5	In **regulatory** applications, the maximum residue limit or level (MRL, or CXL in Codex) is expressed in terms of the "residue definition,"	Improve translation.
6	23	For single-laboratory validation, two types of precision sets of conditions are relevant: (a) **repeatability**, the variability of measurements within the same analytical sequence, and (b) within-laboratory reproducibility, the variability of results among multiple sample sets	"Repetibilidad" is the correct term in Spanish.
3	6	Fitness-for-purpose criteria ~~can be based~~ **could be based** on some of the characteristics described in this document, but ~~ultimately will be expressed in terms of acceptable combined uncertainty~~ **recently the acceptability of the method is being expressed in terms of uncertainty** (IUPAC, 2002).	Improve comprehension of the paragraph.
4	12	b. concentration range covered by the validation (e.g. "0.01-10 mg/kg"); d. protocol, describing the equipment, reagents, detailed step-by-step procedure (~~with the inclusion of~~ **including** permissible variations (e.g. "heat at 100 ± 5 °C for 30 ± 5 min"), calibration and quality procedures, special safety precautions required, and intended application and critical uncertainty requirements; e. if required, a quantitative result should be reported together with the **measurement of the expanded uncertainty** (MU).	Improve comprehension of the paragraph.
5	16	a. **certain replicates** ~~replicate determinations~~ at five or more concentrations should be performed; b. the calibration standards should be evenly spaced over the concentration range of interest and the calibration ~~range~~ **curve** should encompass the entire concentration range ~~likely to be encountered~~ **for the intended purpose**~~;~~	Improve translation and comprehension of the paragraph.

Page	Paragraph	Comment	Justification
9	36	The requirement to recover a range of different pesticide residues in one extraction increases the potential for compromised selectivity in MRM**s** compared to single analyte methods. Using less selective extraction and clean-up procedures is likely to result in greater co-extracted matrix material in the final extract. The nature and quantities of such co-extracted material can vary markedly based on the particulars and method of the individual sample. Care is therefore required when setting criteria for the precision and trueness of MRM**s** to ensure that quantification will not be affected by chemical interferences	Add “s” to MRM because it is plural.
9	38	Acceptability criteria for a quantitative analytical method should be demonstrated at both initial and on-going validation stages, as being capable of providing acceptable mean recovery values at each **spiking** level.	“Adición” is the correct term in Spanish.
10	44	GC-MS and LC-MS tools (full-scan, selected ion mode, high-resolution, tandem MS/MS, hybrid systems, among other advanced techniques) provide many **measurable** parameters	“Medible” is the correct term in Spanish.
11	45	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 ~~will correspond~~ **should correspond** to that of the reference value (point a.)	Improve drafting.
14		**Fortification:** Addition of analytes for the purposes of determining the recovery (also known as **spiking**).	“Adición” is the correct term in Spanish.

El Salvador

We believe that it is a very comprehensive paper. In a future review, consider incorporating a list or Table containing representative crops by family to perform validations and this will be an important tool for laboratories.

We support the advancement of the paper in the Codex Steps.

Japan

Japan appreciates the efforts of United States of America, China and India, in leading the Electronic Working Group (EWG) to prepare the proposed draft guidelines. In order to improve the readability of the guideline, we would like to provide the following editorial comments to the document CX/PR 16/48/13:

Page	Section/Paragraph	Original text	New text
2	**CONTENTS:**	MS-Based Identification	A. MS-Based Identification
		Confirmation	B. Confirmation
3	**PRINCIPLES FOR THE SELECTION AND VALIDATION OF METHODS**	**Defining the Purpose of the Method and Scope**	**A. Defining the Purpose of the Method and Scope**
		Supplementing other Codex Alimentarius Commission Guidelines	**B. Supplementing other Codex Alimentarius Commission Guidelines**
		Method Validation	**C. Method Validation**

Page	Section/Paragraph	Original text	New text
10	**PERFORMANCE ACCEPTABILITY CRITERIA OF METHODS FOR ANALYTE IDENTIFICATION AND CONFIRMATION**	**MS-Based Identification**	**A. MS-Based Identification**
12		**Confirmation**	**B. Confirmation**

Japan notes some typographical errors in the following paragraphs. It is necessary to correct these texts adequately before finalizing the revision of the document.

Page	Section/Paragraph	Original text	New text
3	2	residues and/or their metabolites and **degradents** in food commodities per the residue	residues and/or their metabolites and **degradants** in food commodities per the residue
4	12 d.	detailed step-by-step procedure **(**including permissible variations (e.g. “heat at 100 ± 5 °C for 30 ± 5 min”), calibration and quality procedures	detailed step-by-step procedure including permissible variations (e.g. “heat at 100 ± 5 °C for 30 ± 5 min”), calibration and quality procedures
7	27	**The lowest validated level (LVL)** is the lowest concentration assessed during validation that meets method performance criteria.	**The LVL** is the lowest concentration assessed during validation that meets method performance criteria.
7	27	If no CXL or MRL exists for a given analyte/matrix pair, then **0.1** mg/kg generally serves as the desirable LVL. In MRMs, the typical analytical goal is to set the LVL (and reporting level) at **0.1** mg/kg in diverse, yet representative commodities.	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.
9	Title	PERFORMANCE **ACCEPTIBILITY** CRITERIA OF QUANTITATIVE METHODS	PERFORMANCE **ACCEPTABILITY** CRITERIA OF QUANTITATIVE METHODS
9	37	The ability of the method to provide a reliable quantitative result must be demonstrated (i.e. trueness - see F p.**7** and precision - see G p.**7**)	The ability of the method to provide a reliable quantitative result must be demonstrated (i.e. trueness - see F p.**6** and precision - see G p.**6**)
9	40	Because the same sentence appears in paragraph 41, it should be amended to “can be made to the final result, when required. **Recovery corrections should be made consistent with the guidance provided by the CAC/GL 37-2001.**	Because the same sentence appears in paragraph 41, it should be amended to “can be made to the final result, when required. **[Delete]**
10	41	if a recovery correction has been applied**,**. This will promote direct comparability of	if a recovery correction has been applied. This will promote direct comparability of
10	45	Table 1 gives criteria described in **SANCO/12745/2015**.	Table 1 gives criteria described in **SANTE/11945/2015**.

Page	Section/Paragraph	Original text	New text
11	46	The criteria for identification based on **SANCO/12745/2015** are provided in Table 1.	The criteria for identification based on **SANTE/11945/2015** are provided in Table 1.
12	47	Examples of analytical techniques that may be suitable to meet criteria for confirmatory analytical methods are summarized in Table **3**.	Examples of analytical techniques that may be suitable to meet criteria for confirmatory analytical methods are summarized in Table **2**.
14	**ANNEX I: DEFINITIONS**		
	Analyte	The chemical substance sought or determined in a sample (CAC/GL **2009**).	The chemical substance sought or determined in a sample (CAC/GL **72-2009**).
	Analyte protectant	thereby reducing the analyte **interaction s** with those active sites and	thereby reducing the analyte **interactions** with those active sites and
	False positive	A result wrongly indicating that the analyte is present or exceeds a specified concentration (e.g. **CXL** or reporting level).	A result wrongly indicating that the analyte is present or exceeds a specified concentration (e.g. **CXL/MRL** or reporting level).
	False negative	A result wrongly indicating that the analyte is not present or does not exceed a specified concentration.	A result wrongly indicating that the analyte is not present or does not exceed a specified concentration **(e.g. CXL/MRL or reporting level)**.
15	**Repeatability conditions**	**Repeatability conditions** The title of "Repeatability conditions" should be amended to "**Repeatability**	**Repeatability**
	Reproducibility conditions	**Reproducibility conditions** The title of "Reproducibility conditions" should be amended to "**Reproducibility**"	**Reproducibility**
	Sensitivity	Quotient of the change in the indication of a measuring system and the corresponding change in the value of the quantity being measured (CAC/GL **2009**).	Quotient of the change in the indication of a measuring system and the corresponding change in the value of the quantity being measured (CAC/GL **72-2009**).
18	**ANNEX II: REFERENCES** Reference No. 25	Since reference No. 25 is the same article as reference 13, it is desirable to remove reference 25.	

African Union

Background:

During the 44th Session of the CCPR, it was decided to recommend the revocation of Analysis of Pesticide Methods: Recommended Methods (CODEX STAN 229-1993) and to establish an EWG to prepare a discussion paper on the development of performance criteria for suitability assessment of methods of analysis with consideration given to the relevant documents developed or under development in the Committee on Residues of Veterinary Drugs in Foods as Well as other Codex texts.

During the 47th Session of the CCPR it was agreed to further revise the Guidance taking into account comments submitted at this session and those provided by members of the electronic working group.

Position: AU welcome the work of the Electronic Working Group, led by the United States of America and co-chaired by China and India on the Guidelines. The guidelines provide useful information for laboratories to improve quality assurance systems, especially for laboratories in developing countries. AU welcomes the progress made by the EWG on this work.

Specific Comments:

1. Overall AU proposes the sectioning of the document as follows:

The document should have a Scope. The numbering of the document should make flow to avoid confusion in referencing the document i.e. sections starting from A (Defining the Purpose of the Method and Scope), B (Supplementing other Codex Alimentarius Commission Guidelines) and C (Method Validation) should not be numbered in the "Contents" page.

The "contents" page should rename to "Table of contents" to be consistent with other formats used in Codex texts. The proposal to include the scope will also be consistent with other Codex guidance documents.

2. AU proposes that the headings be worded as follows:

"Section I: PRINCIPLES FOR THE SELECTION AND VALIDATION OF METHODS"

"Section II: PERFORMANCE PARAMETERS FOR ANALYTICAL METHODS"

Rationale:

This will provide consistency with headings in other Codex texts.

3. AU proposes the paragraphs should all be numbered – some have not been numbered e.g. one after Paragraph 40 has no number and discusses a new idea in "The Analysis of incurred matrix to support method validation…" and paragraph after number 45 that discusses the idea "Current practices in qualitative (and quantitative) analysis of pesticide residues commonly involve chromatography…"

Rationale:

This will provide consistency in numbering paragraphs that bring different ideas, and provide for ease of referencing.

4. AU proposes the changing of "PERFORMANCE PARAMETERS FOR ANALYTICAL METHODS" to read "METHOD VALIDATION PARAMETERS"

Rationale:

The discussion in the paragraph currently titled as "Performance parameters for analytical methods" gives the general overview of Method validation requirements, however, the specific paragraphs currently numbered A (just above current paragraph 12) to K (just above paragraph 30) discuss the Method Validation parameters, in detail. This will provide clarity on the specific parameters considered in method validation as specified in the paragraphs.

5. AU proposes the deletion of "12571/2013" with "SANTE/11945/2015" e.g. in paragraph 34, (Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed). However, since the EU guidance document is reviewed periodically. AU proposes that the reference number is deleted altogether and the text be replaced with the title of the document "Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed", and refer guide the reader to ensure that they refer to the current edition of the guidance document.

Rationale:

The current SANTE guidance document should be referenced accurately. However, using the suitable reference title will make it easier for reference after the Codex guideline has been adopted.

6. In the Title of Table 2, "….Miskolc consultation" referred to. This citation should make reference to the detailed text on page 16 of the Annex II: References. This can be done through use of a reference to read "Table 2. Examples of detection methods suitable for the confirmatory analysis of substances, as recommended by the Miskolc Consultation Annex II: References 19 "

Rationale:

It is not clear from the Title of Table 2 is the same as the same referred to in the Annex II references.

7. AU proposes a change in the Definitions Annex 1: for Trueness. The definition should be changed from “Refers to the closeness of agreement between a test result and the accepted reference value of the property being measured” to “Refers to the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value”.

However, it is not clear which definition terms should be used in the document, since also the definition of trueness in ISO 5725:1-1994 (also cross referenced with ISO 3534-1) is given as “The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value”. While the two definitions may be similar, consistency in the cross referencing of definitions with other Codex texts should be consistent.

Rationale:

This will be consistent with the definition in the Codex reference CAC/GL 72-2009, which is also referred to in the guidance document.

8. AU proposes that the change of the following text in Paragraph 45: “In a. AU proposes the change of Ion ratio reference values are to be set in the same way as in Section 45 a”, to read as “Ion ratio reference values are to be set in the same way as in Paragraph 45 a”.

Rationale:

The reference to “Section” is confusing to the reader.

9. AU proposes that in line 4 of the paragraph 45, the symbol ‘%’ should be written in full, ‘percentage’.

Rationale:

This will provide completeness in understanding the symbol.

10. The guidance document makes reference to “laboratory” and “lab”. AU proposes that the short forms of lab should be changed to laboratory for consistency within the whole document. Such places are for example: Paragraph 13 line 5, should read “…..laboratory contamination,...”, Paragraph 24 First line should read…”In single-laboratory…..”; Paragraph 42 in the last line.

Rationale:

Since this is a guidance document, it would be prudent to use words in a consistent and complete manner hence replace the word “lab” with “laboratory”.