



Publications Office  
of the European Union

# AI4LEGS

## LEGAL-INFORMATICS APPROACHES TO LMs & LAW IN LEGISLATION

### ***AI4XML project:***

Leveraging LLMS to convert unstructured documents to a structured format

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KUSTER Marc, HARDY Didier OP.D.4

25<sup>th</sup> October 2025



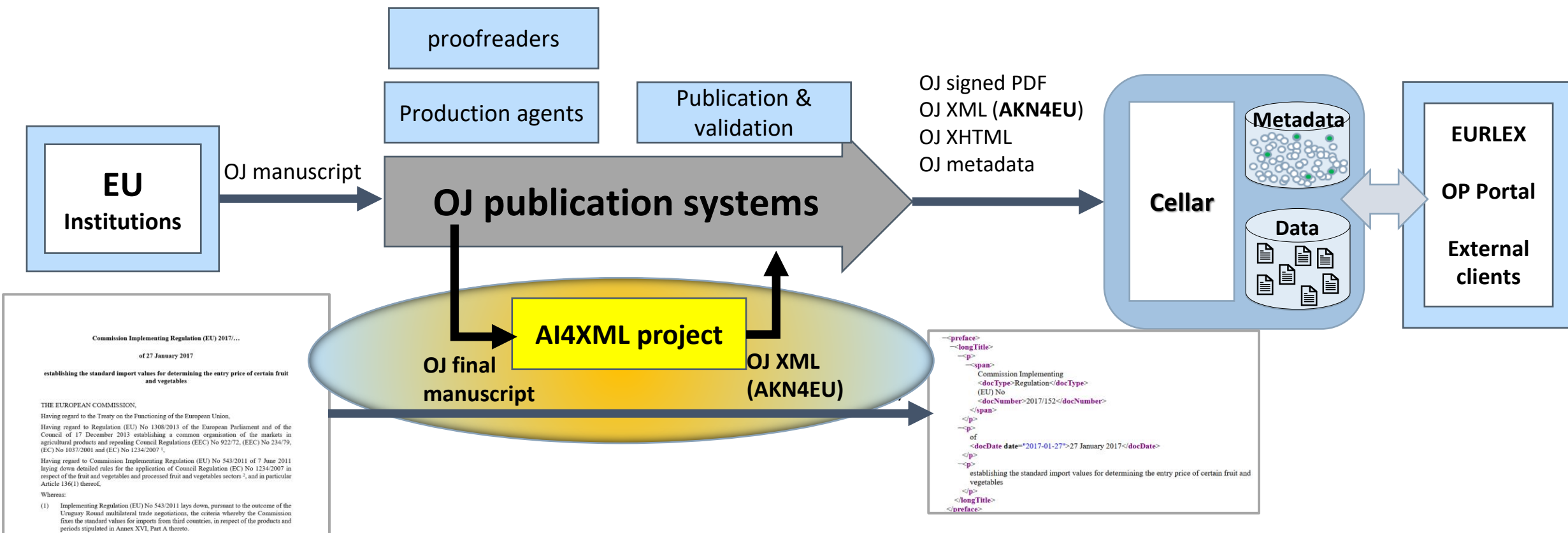


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# 1. Introduction: Objectives of the AI4XML project - global picture.

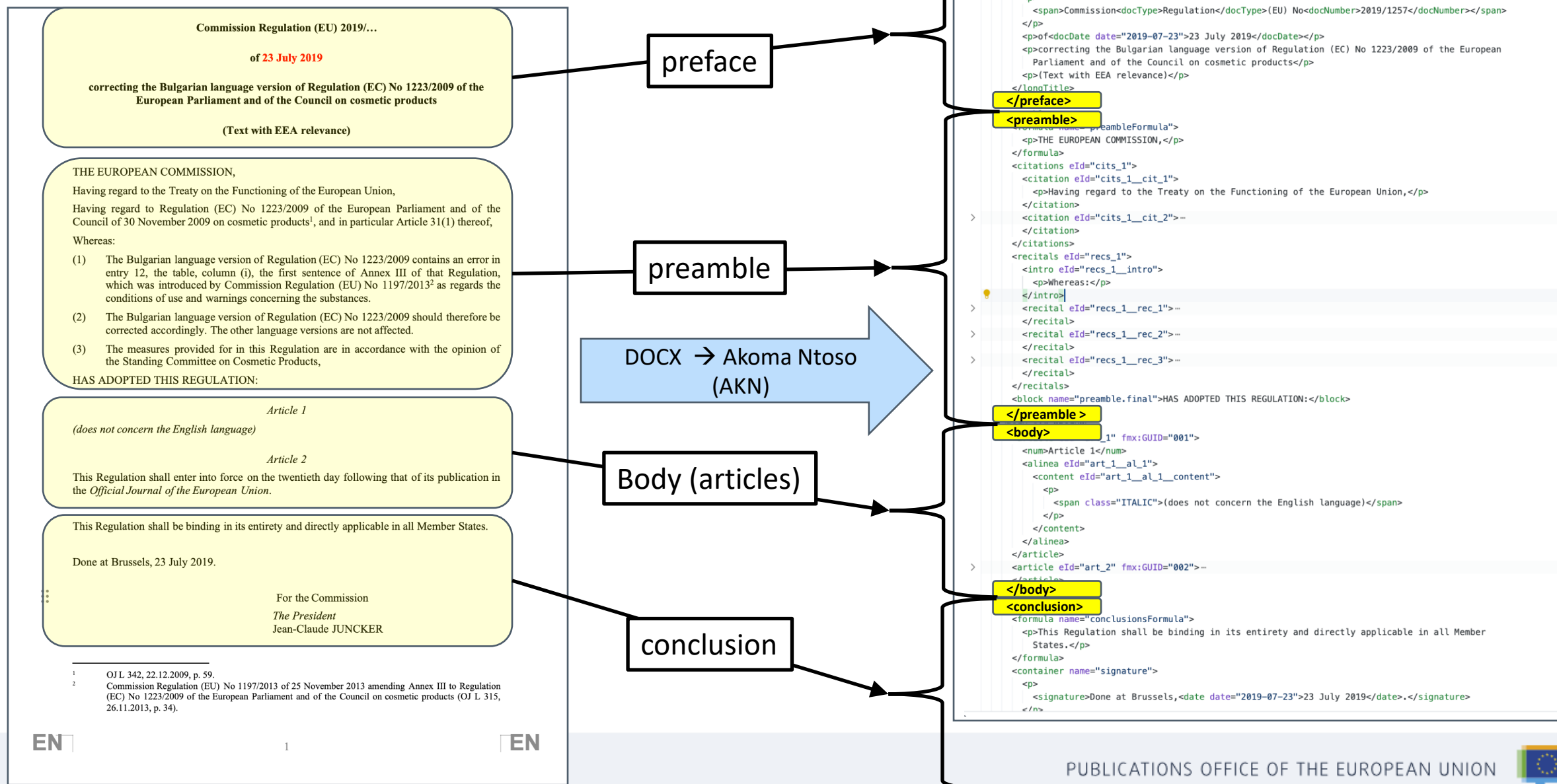


## AI4XML project Objective :

Usage of AI, particularly **Generative LLMs** models, to **automate** the XML (AKN4EU) generation.



## 2. AI4XML: technical overview - The Challenge



<sup>1</sup> OJ L 342, 22.12.2009, p. 59.  
<sup>2</sup> Commission Regulation (EU) No 1197/2013 of 25 November 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 315, 26.11.2013, p. 34).





## 2. AI4XML: technical overview - The Challenge

### Preface example

Commission Implementing Regulation (EU) 2020/...

of 19 December 2019

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Huile d'olive de la Vallée des Baux-de-Provence' (PDO))



DOCX

AKN

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    <p>approving non-minor amendments to the specification for a name entered in the register of
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      Vallée des Baux-de-Provence" (PDO))</p>
  </longTitle>
</preface>
<preamble>
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## 2. AI4XML: technical overview - problem statement

- **Problem:** Effective document structuring is vital for interoperability.
  - Important for inter-institution communication at EC
- **Traditional Limitation:** Rule-based methods (e.g., regex) struggle with flexibility and evolving standards, and struggle with multilingual support.
- **Opportunity:** Large Language Models (LLMs) offer advanced capabilities like contextual understanding and semantic parsing.







## 2. AI4XML: technical overview - The Challenge

- **Objective:**

- Enable intelligent, scalable structuring of complex documents—particularly in the legal domain—using LLMs.

- **Key Challenges:**

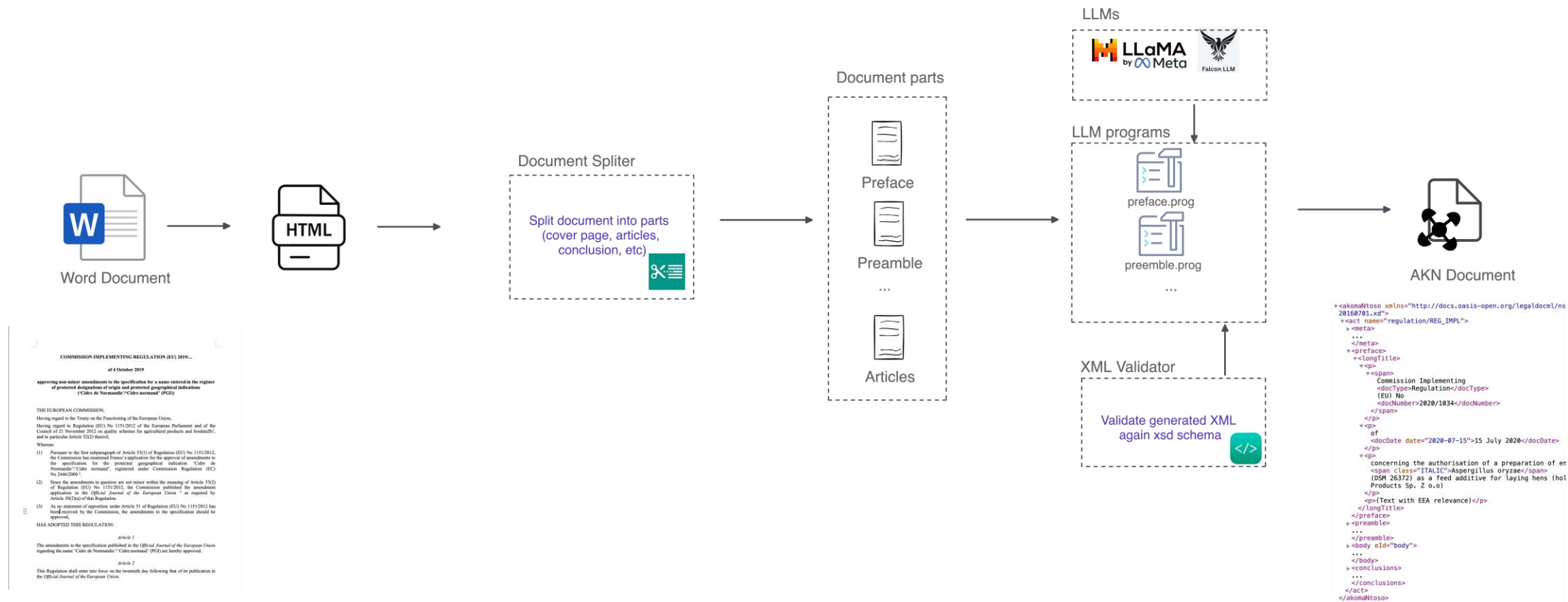
- Complex DOCX Structures: Legal documents often include deeply nested elements, inconsistent formatting, and mixed content types.
- Context Limitations: Processing documents that span hundreds of pages exceeds typical context windows of LLMs.

- **Our Approach:**

- Modular Decomposition: Break large documents into semantically coherent, manageable components.
- LLM-Orchestrated Structuring: Each component is processed using a tailored LLM prompt pipeline.
- Few-Shot, In-Context Learning: Dynamically adapts to new document styles without retraining.
- Schema Compliance: Ensures output consistency through integrated XML schema validation.

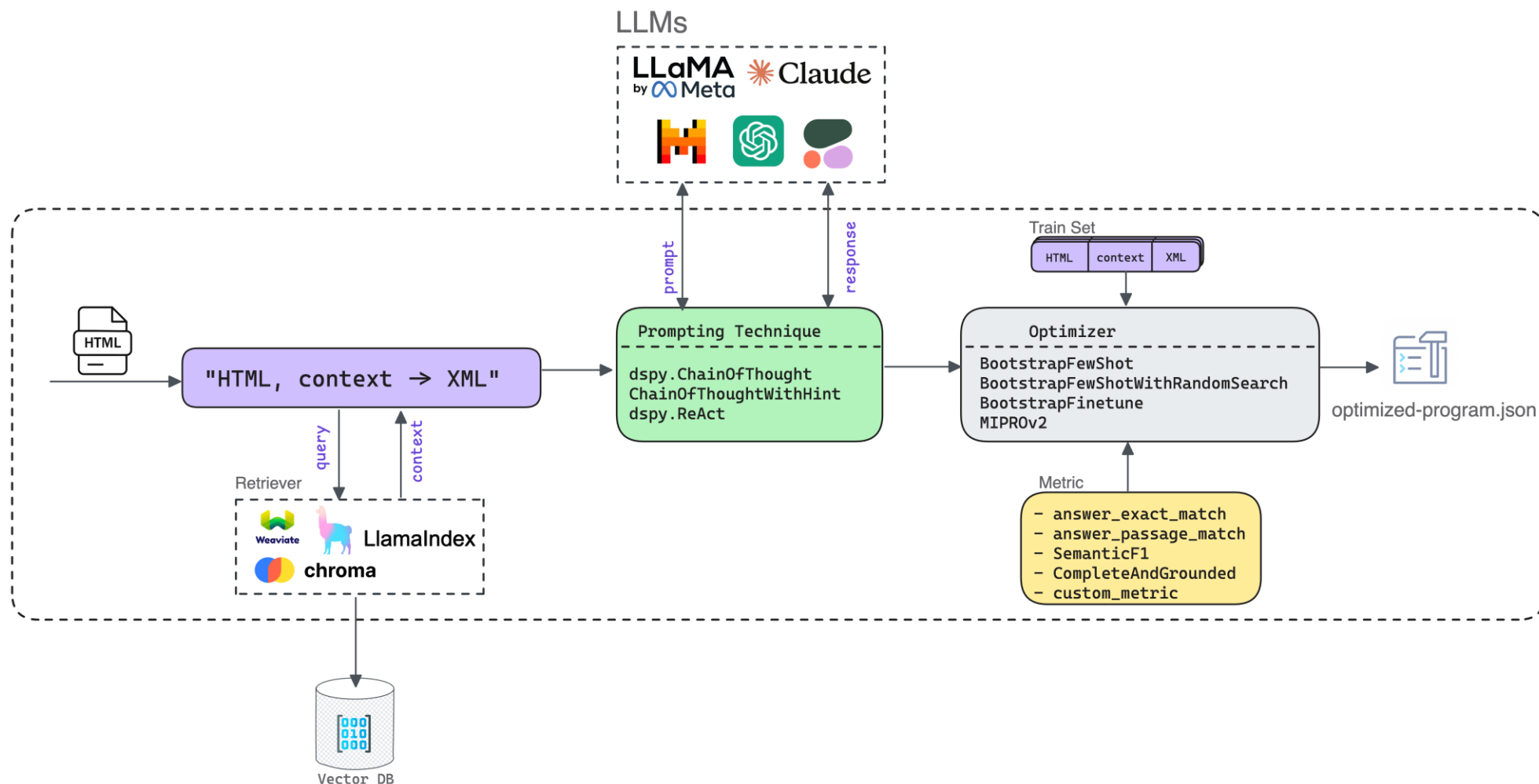


## 2. AI4XML: technical overview - LLM-based approach - LLM programs





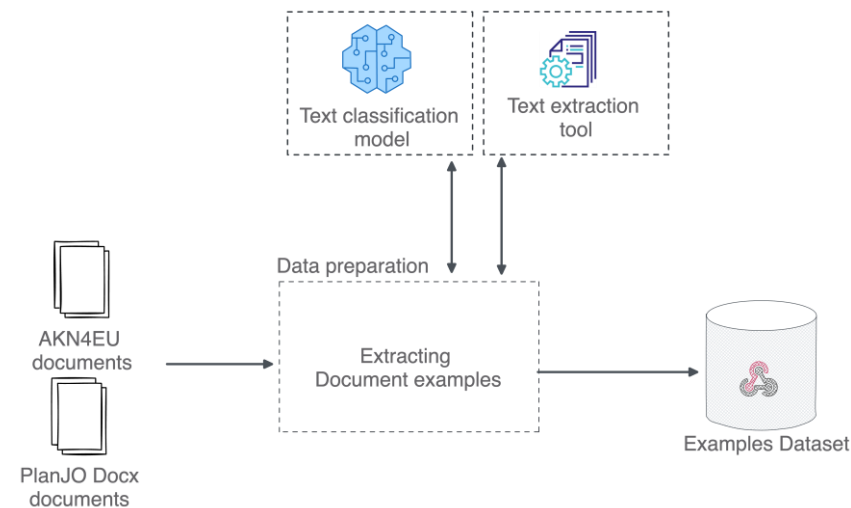
## 2. AI4XML: technical overview - LLM-based approach - LLM programs





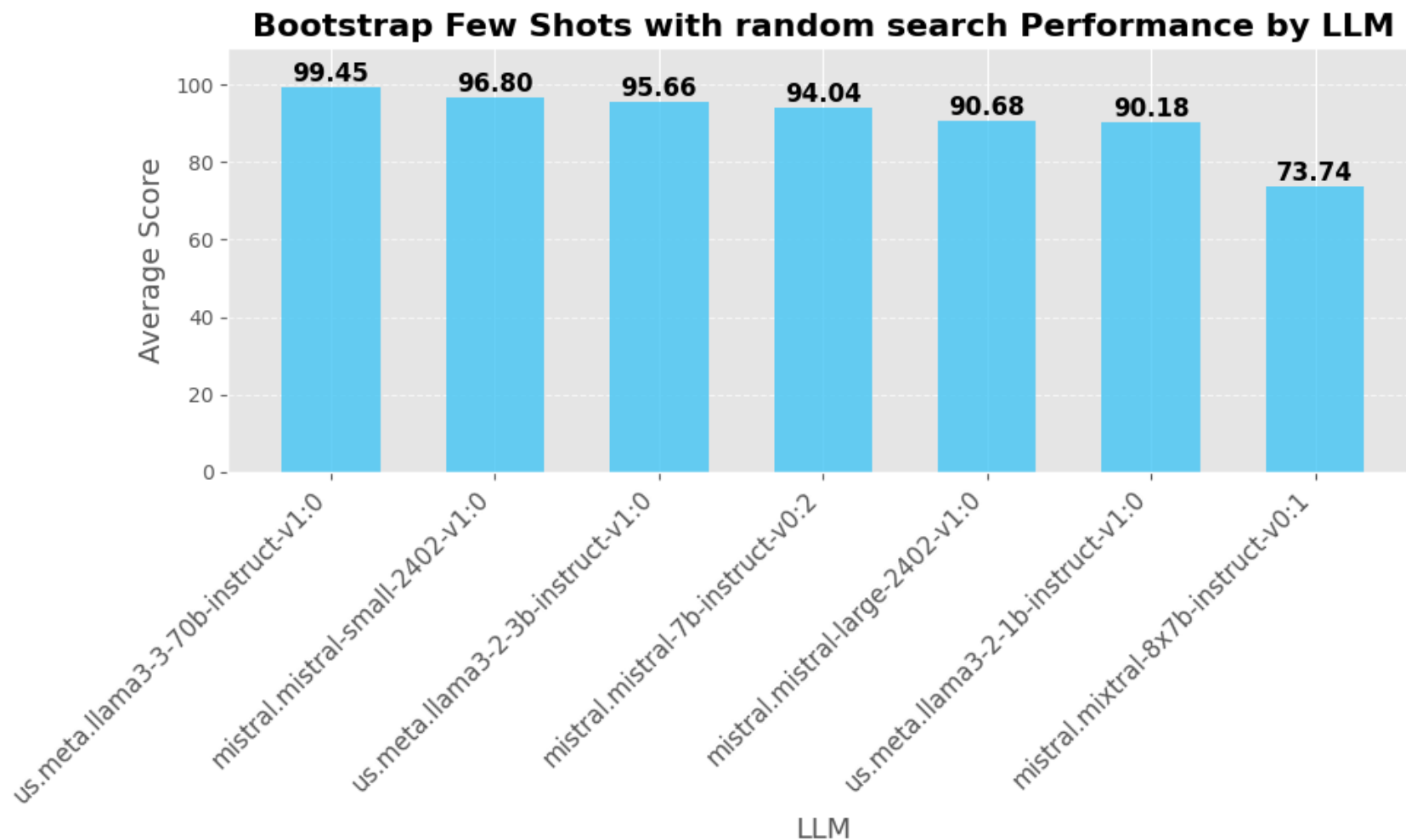
## 2. AI4XML: technical overview - Experiments set-up

- **Dataset** : Paired Legal Document Collection
  - PlanJO : Original Word documents
  - GenAI4Lex dataset : Corresponding Akoma Ntoso (AKN) XML versions
- **LLMs**
  - 4 Mistral models
  - 3 LLAMA models
- **Optimizers**
  - Bootstrap Few Shot with Random Search
    - max\_labeled\_demos= 8 (shots)
    - num\_candidate\_programs = 5
  - MiproV2
    - minibatch\_size= 35
    - num\_trials = 30
- **Context** :
  - No context provided to the model (for upcoming experiments)
- **Metric** : Custom Composite Metric:
  - XML Validation: Ensures structural integrity
  - AKN Schema Validation: Confirms compliance with Akoma Ntoso standard
  - ROUGE-L Scoring: Measures sequence-based similarity



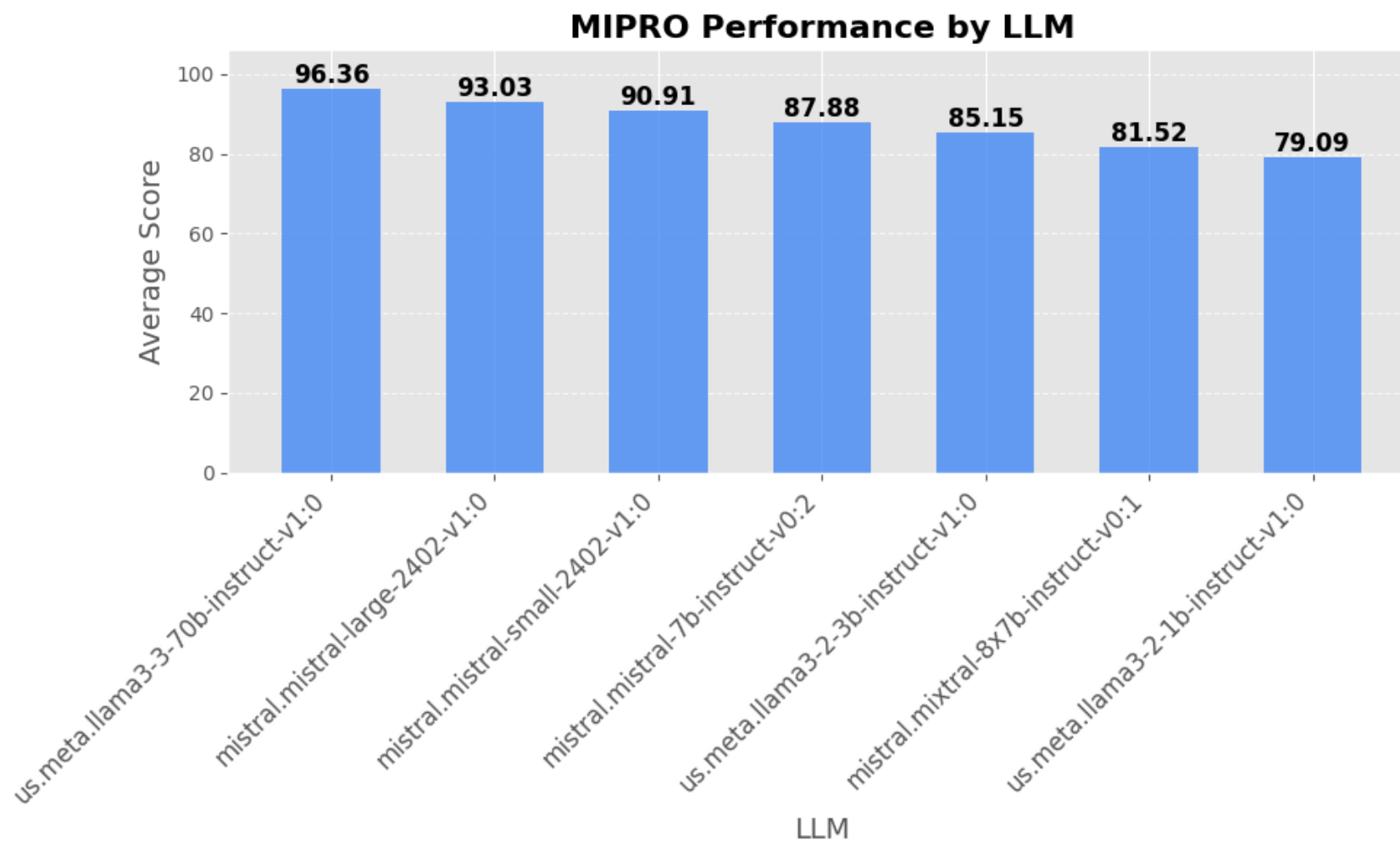


## 2. AI4XML: technical overview - Experiments results



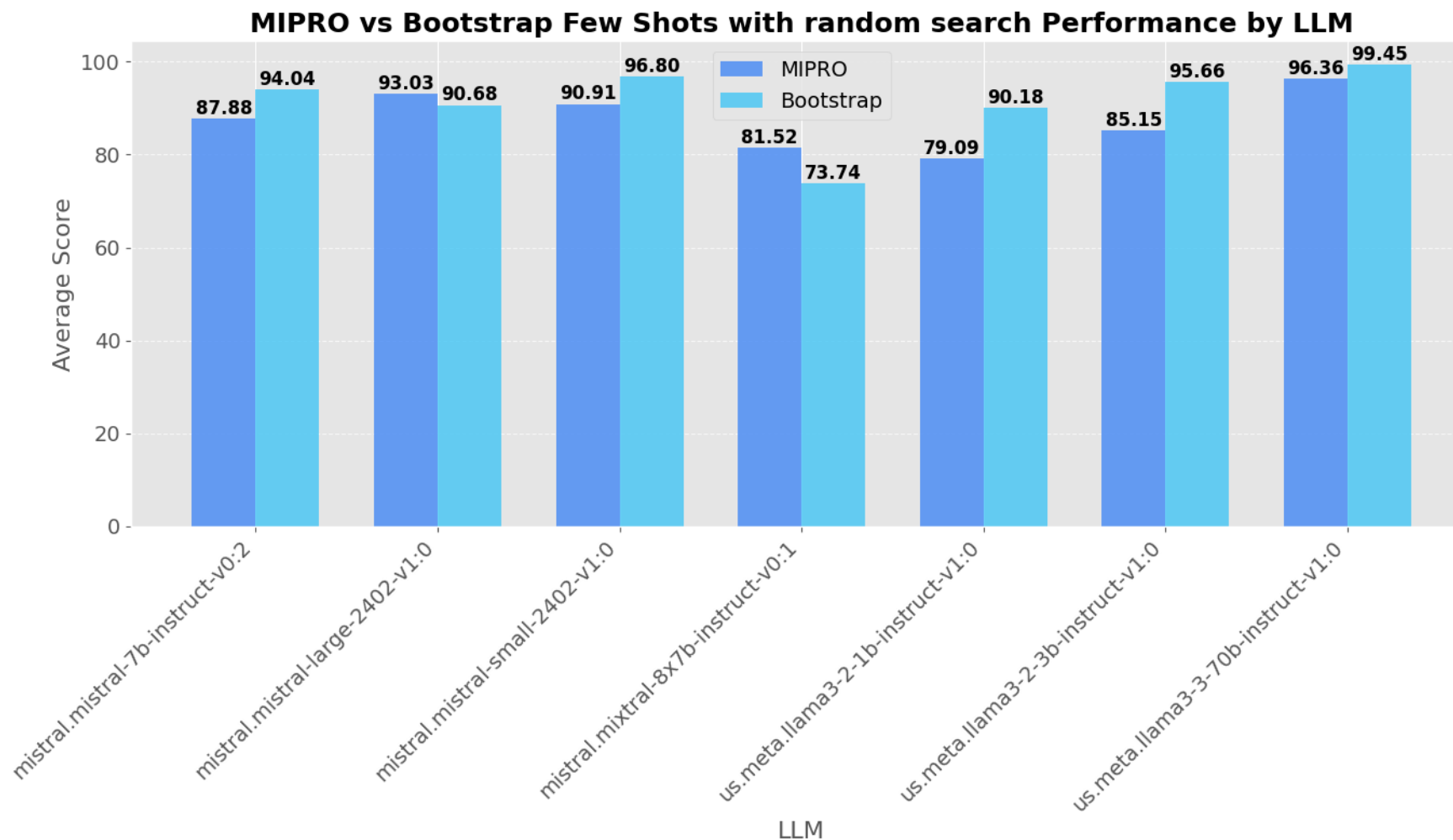


## 2. AI4XML: technical overview - Experiments results





## 2. AI4XML: technical overview - Experiments results







## 2. AI4XML: technical overview - Experiments results

- **Can LLMs be used to structure document in AKN format ?**
  - **Yes**, they can be optimized to generate a valid structured format
- **Bootstrap** outperforms **MIPRO** on most models (best: 99.45% with Llama3-70B)
- **Model size impact** varies by task complexity
  - Larger models perform better overall
  - Smaller models remain surprisingly competitive
  - Use small models for simple conversion tasks, large models for complex tasks (use LLMs routing)
- **Optimization approach matters** more than model size in some cases
  - Bootstrap with Mistral-small (96.8%) outperforms MIPRO with Llama3-70B (96.36%)



# 3. AI4XML : demonstration

<p>Commission Delegated Regulation (EU) 2024/... of 20 February 2024 supplementing Regulation (EC) 2002/4 of the European Parliament and of the Council by establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed (Text with EEA relevance)</p> <p>THE EUROPEAN COMMISSION, Having regard to the Treaty on the Functioning of the European Union, Having regard to Regulation (EC) 2019/4 of the European Parliament and of the Council of 11 December 2019 on the manufacture, placing on the market and use of medicinal feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC<sup>1</sup>, and in particular Article 7(3) thereof, Whereas:</p> <p>(1) Regulation (EU) 2019/4 lays down specific provisions regarding medicinal feed and intermediate products. Cross-contamination of non-target feed with antimicrobials has been identified as a new issue of the Union in the context of protecting animal health, human health and the environment, and should be avoided or kept as low as possible.</p> <p>(2) In accordance with Article 7(3) of Regulation (EU) 2019/4, the Commission must adopt delegated acts to supplement that Regulation by establishing, as regards the 24 antimicrobial active substances listed in Annex II thereof (the 24 antimicrobial active substances<sup>2</sup>), specific maximum levels of cross-contamination for the antimicrobial active substances in non-target feed and methods of analysis for these substances in feed. Pursuant to Article 7(3) of that Regulation, those delegated acts which establish maximum levels of cross-contamination must be based on a scientific risk assessment carried out by the European Food Safety Authority (‘EFSA’).</p> <p>(3) As the Commission’s request, EFSA assessed, in cooperation with the European Medicines Agency (‘EMA’), the specific concentrations of the 24 antimicrobial active substances resulting from cross-contamination in non-target feed for food-producing animals, below which there would be no effect on the emergence of, and/or selection for, resistance in antimicrobial active substances relevant for human and animal health (‘antimicrobial resistance’, ‘AMR’).</p> <p>(4) EFSA was also requested by the Commission to assess the levels of the 24 antimicrobial active substances which could have a growth promotion or increased yield effect, taking into account that the use of antibiotics as feed additives, other than excipients or preservatives, has been phased out since 1 January 2006 in accordance with Article 11(2) of Regulation (EC) No 1831/2003 of the European</p> <p>Parliament and of the Council<sup>3</sup>. The specific maximum level of such antimicrobial active substance in non-target feed should be below the level that causes a growth promotion or increased yield effect.</p> <p>(5) In addition, the Commission requested the Reference Laboratory, set up pursuant to Regulation (EC) No 1831/2003 (‘the Reference Laboratory’), to recommend methods of analysis for the 24 antimicrobial active substances in feed.</p> <p>(6) In its 13 Options of 15 September 2021 on maximum levels of cross-contamination for the 24 antimicrobial active substances in non-target feed<sup>4</sup> (‘Options of 15 September 2021’), EFSA could only establish specific concentrations concerning AMR for six of the 24 antimicrobial active substances and not for all relevant animal species, due to a lack of data. In addition, EFSA only identified levels causing effects on growth promotion or increased yield for 14 of the 24 antimicrobial active substances and not for all relevant animal species, again due to an absence of relevant data.</p> <p>(7) In April 2022 and February 2023, the Reference Laboratory issued two reports on the methods of analysis and minimum achievable limits of quantification (‘LOQ’) in feed for the 24 antimicrobial active substances<sup>5</sup> (‘Reports of April 2022 and February 2023’).</p> <p>(8) The specific concentrations concerning AMR established by EFSA for six antimicrobial active substances, in the Options of 15 September 2021, are significantly lower than the minimum LOQs established by the Reference Laboratory in the Reports of April 2022 and February 2023. This means, in practice, that the specific concentrations are not measurable and would, therefore, not be enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 1782/2003 of the European Parliament and of the Council<sup>6</sup>.</p> <p>(9) The lowest levels of the 14 antimicrobial active substances, for which EFSA could indicate in its Options of 15 September 2021 as causing a growth promotion or increased yield effect, are significantly higher than the LOQ for the same substances and are therefore measurable and enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 1782/2003. To avoid a growth promotion or increased yield effect, the maximum levels of cross-contamination for the antimicrobial active substances in non-target feed should be below the lowest levels causing a growth promotion or increased yield effect.</p> <p>(10) High economic investment and increased logistical costs to comply with the maximum levels of cross-contamination in non-target feed if such levels are very low is likely to result in a reduction of the production of medicinal feed. In addition, the EMA Advice</p> <p>of 28 August 2020 on implementing measure under Article 109(b) of Regulation (EU) 2019/4 of the European Parliament and of the Council on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via means other than medicated feed<sup>7</sup>, conclude that it may also result in an increased exposure to residues of oral administration of antimicrobial active substance other than medicated feed, such as the administration on the surface of solid feed, that may increase the risk of AMR and the inability to treat certain bacterial infections in certain species due to the absence of other appropriate routes of administration, for example, in aquaculture. The maximum levels of cross-contamination should, therefore, not be detrimental to the production of medicated feed, in particular, by small and medium-sized feed manufacturing plants, excluding them in practice from the production of medicated feed, which would result in possible issues for public health, and animal health and welfare. It is, therefore, appropriate to establish a maximum level of cross- contamination that is strict but also feasible to achieve by applying good practices to minimise cross-contamination. In addition to the Options of 15 September 2021, the experience gained in the Member States in applying national law indicates that a cross- contamination level in the non-target feed of 1 % of the active substance in the medicated feed, represents a good balance between feasibility and AMR control. Intermediate products contain higher concentrations of active substance than medicated feed. Therefore, where non-target feed is manufactured, processed, stored or transported after the manufacturing, processing storage or transport of intermediate products, a cross-contamination level of 1 % of the substance to be contained in the derived medicated feed, should apply.</p> <p>(11) The maximum levels of cross-contamination for some antimicrobial active substances in non-target feed should be reviewed if new scientific evidence becomes available, allowing to further control antimicrobial resistance in the non-target feed with enforceable maximum levels which are achievable by applying good practices to minimise cross-contamination.</p> <p>(12) Medicated feed or intermediate products intended for fish often contain substantially higher doses of antimicrobial active substances than medicated feed or intermediate products intended for food-producing animals other than fish. In addition, no levels of antimicrobial active substances causing a growth promotion or increased yield effect in fish, have been identified in the Options of 15 September 2021. Stricter specific maximum levels of cross-contamination in non-target feed intended for food- producing animals other than fish therefore are needed where the cross-contamination originates from medicated feed or intermediate products intended for fish, in order to avoid a growth promotion or increased yield effect in food-producing animals other than fish. Since those stricter specific maximum levels of cross-contamination in non- target feed intended for food-producing animals other than fish should be measurable and enforceable by the Member States, they should be set at the LOQ.</p> <p>(13) It should be ensured that feed derived from animals fed with the non-target feed complies with the maximum residue limits laid down in Table 1 set out in the Annex</p> <p>to Commission Regulation (EU) No 559/2009 of the European Parliament and of the Council of 22 September 2009 on, in addition, for use in animal nutrition (OJ L 26, 13.10.2009), p. 26, 434. <a href="https://eur-lex.europa.eu/eli/reg/2009/559/oj/2019_05_20_01">https://eur-lex.europa.eu/eli/reg/2009/559/oj/2019_05_20_01</a>.</p> <p><sup>1</sup> OJ L 26, 13.10.2009, p. 1, 634. <sup>2</sup> <a href="https://eur-lex.europa.eu/eli/reg/2019/4/oj/2019_05_20_01">https://eur-lex.europa.eu/eli/reg/2019/4/oj/2019_05_20_01</a>.</p> <p><sup>3</sup> <a href="https://eur-lex.europa.eu/eli/reg/2003/1831/oj/2003_12_18_01">https://eur-lex.europa.eu/eli/reg/2003/1831/oj/2003_12_18_01</a>.</p> <p><sup>4</sup> <a href="https://eur-lex.europa.eu/eli/reg/2021/1599/oj/2021_09_15_01">https://eur-lex.europa.eu/eli/reg/2021/1599/oj/2021_09_15_01</a>.</p> <p><sup>5</sup> <a href="https://eur-lex.europa.eu/eli/reg/2022/400/oj/2022_04_28_01">https://eur-lex.europa.eu/eli/reg/2022/400/oj/2022_04_28_01</a> and <a href="https://eur-lex.europa.eu/eli/reg/2023/100/oj/2023_02_01_01">https://eur-lex.europa.eu/eli/reg/2023/100/oj/2023_02_01_01</a>.</p> <p><sup>6</sup> Regulation (EC) No 1782/2003 of the European Parliament and of the Council of 28 January 2003 laying down the general principles and requirements of feed law, establishing the European Food Safety Authority and laying down procedures to monitor the safety (OJ L 31, 1.2.2003), p. 1, 434. <a href="https://eur-lex.europa.eu/eli/reg/2003/1782/oj/2003_02_01_01">https://eur-lex.europa.eu/eli/reg/2003/1782/oj/2003_02_01_01</a>.</p> <p><sup>7</sup> <a href="https://eur-lex.europa.eu/eli/reg/2020/1599/oj/2020_08_28_01">https://eur-lex.europa.eu/eli/reg/2020/1599/oj/2020_08_28_01</a>.</p> <p>EN – Clinical document 2/5</p>	<p>of 28 August 2020 on implementing measure under Article 109(b) of Regulation (EU) 2019/4 of the European Parliament and of the Council on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via means other than medicated feed<sup>7</sup>, conclude that it may also result in an increased exposure to residues of oral administration of antimicrobial active substance other than medicated feed, such as the administration on the surface of solid feed, that may increase the risk of AMR and the inability to treat certain bacterial infections in certain species due to the absence of other appropriate routes of administration, for example, in aquaculture. The maximum levels of cross-contamination should, therefore, not be detrimental to the production of medicated feed, in particular, by small and medium-sized feed manufacturing plants, excluding them in practice from the production of medicated feed, which would result in possible issues for public health, and animal health and welfare. It is, therefore, appropriate to establish a maximum level of cross- contamination that is strict but also feasible to achieve by applying good practices to minimise cross-contamination. In addition to the Options of 15 September 2021, the experience gained in the Member States in applying national law indicates that a cross- contamination level in the non-target feed of 1 % of the active substance in the medicated feed, represents a good balance between feasibility and AMR control. Intermediate products contain higher concentrations of active substance than medicated feed. Therefore, where non-target feed is manufactured, processed, stored or transported after the manufacturing, processing storage or transport of intermediate products, a cross-contamination level of 1 % of the substance to be contained in the derived medicated feed, should apply.</p> <p>(11) The maximum levels of cross-contamination for some antimicrobial active substances in non-target feed should be reviewed if new scientific evidence becomes available, allowing to further control antimicrobial resistance in the non-target feed with enforceable maximum levels which are achievable by applying good practices to minimise cross-contamination.</p> <p>(12) Medicated feed or intermediate products intended for fish often contain substantially higher doses of antimicrobial active substances than medicated feed or intermediate products intended for food-producing animals other than fish. In addition, no levels of antimicrobial active substances causing a growth promotion or increased yield effect in fish, have been identified in the Options of 15 September 2021. Stricter specific maximum levels of cross-contamination in non-target feed intended for food- producing animals other than fish therefore are needed where the cross-contamination originates from medicated feed or intermediate products intended for fish, in order to avoid a growth promotion or increased yield effect in food-producing animals other than fish. Since those stricter specific maximum levels of cross-contamination in non- target feed intended for food-producing animals other than fish should be measurable and enforceable by the Member States, they should be set at the LOQ.</p> <p>(13) It should be ensured that feed derived from animals fed with the non-target feed complies with the maximum residue limits laid down in Table 1 set out in the Annex</p> <p>to Commission Regulation (EU) No 559/2009 of the European Parliament and of the Council of 22 September 2009 on, in addition, for use in animal nutrition (OJ L 26, 13.10.2009), p. 26, 434. <a href="https://eur-lex.europa.eu/eli/reg/2009/559/oj/2019_05_20_01">https://eur-lex.europa.eu/eli/reg/2009/559/oj/2019_05_20_01</a>.</p> <p><sup>1</sup> OJ L 26, 13.10.2009, p. 1, 634. <sup>2</sup> <a href="https://eur-lex.europa.eu/eli/reg/2019/4/oj/2019_05_20_01">https://eur-lex.europa.eu/eli/reg/2019/4/oj/2019_05_20_01</a>.</p> <p><sup>3</sup> <a href="https://eur-lex.europa.eu/eli/reg/2003/1831/oj/2003_12_18_01">https://eur-lex.europa.eu/eli/reg/2003/1831/oj/2003_12_18_01</a>.</p> <p><sup>4</sup> <a href="https://eur-lex.europa.eu/eli/reg/2021/1599/oj/2021_09_15_01">https://eur-lex.europa.eu/eli/reg/2021/1599/oj/2021_09_15_01</a>.</p> <p><sup>5</sup> <a href="https://eur-lex.europa.eu/eli/reg/2022/400/oj/2022_04_28_01">https://eur-lex.europa.eu/eli/reg/2022/400/oj/2022_04_28_01</a> and <a href="https://eur-lex.europa.eu/eli/reg/2023/100/oj/2023_02_01_01">https://eur-lex.europa.eu/eli/reg/2023/100/oj/2023_02_01_01</a>.</p> <p><sup>6</sup> Regulation (EC) No 1782/2003 of the European Parliament and of the Council of 28 January 2003 laying down the general principles and requirements of feed law, establishing the European Food Safety Authority and laying down procedures to monitor the safety (OJ L 31, 1.2.2003), p. 1, 434. <a href="https://eur-lex.europa.eu/eli/reg/2003/1782/oj/2003_02_01_01">https://eur-lex.europa.eu/eli/reg/2003/1782/oj/2003_02_01_01</a>.</p> <p><sup>7</sup> <a href="https://eur-lex.europa.eu/eli/reg/2020/1599/oj/2020_08_28_01">https://eur-lex.europa.eu/eli/reg/2020/1599/oj/2020_08_28_01</a>.</p> <p>EN – Clinical document 3/5</p>	<p>to Commission Regulation (EU) No 372/2010<sup>8</sup>. Stricter specific maximum levels of cross-contamination for antimicrobial active substances in non-target feed should, therefore, be laid down in this Regulation, in particular for milk- or egg-producing animals and for animals close to the date of slaughter. Since those stricter specific maximum levels of cross-contamination in non-target feed should be measurable and enforceable by the Member States, they should be set at the LOQ.</p> <p>(14) The methods of analysis recommended by the Reference Laboratory in the Reports of April 2022 and February 2023 should be used as reference methods for the analysis of the 24 antimicrobial active substances in feed. Alternative methods of analysis should only be allowed where validated and considered as equivalent by the competent authorities of the Member States.</p> <p>(15) It is appropriate to provide official laboratories carrying out the methods of analysis for antimicrobial active substances in feed with sufficient time to adapt to the LOQs and prove their competence for carrying out such methods of analysis by generally accepted means, such as by accreditation, round-robin validation or proficiency test data targeting a timely accreditation. Therefore, this Regulation should apply 12 months after the date of entry into force.</p> <p>HAS ADOPTED THIS REGULATION:</p> <p>Article 1 Subject matter and scope</p> <p>This Regulation establishes specific maximum levels of cross-contamination in non-target feed for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4, and methods of analysis for those antimicrobial active substances in feed, as provided for in Article 7(3) of Regulation (EU) 2019/4.</p> <p>Article 2 Specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed</p> <p>1. The specific maximum levels of cross-contamination in non-target feed for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4 shall be as:</p> <p>(a) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is an intermediate product, at 1 % of the antimicrobial active substance contained in that last batch of medicated feed, relative to a moisture content of 12 % in the non- target feed;</p> <p>(b) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is an intermediate product, at 1 % of the antimicrobial active substance to be contained in the medicated feed derived from that last batch of intermediate product, relative to a moisture content of 12 % in the non-target feed.</p> <p>2. Commission Regulation (EU) No 559/2009 of 22 September 2009 on pharmacologically active substances and their distribution regarding active substances listed in Table 1 of said regulation (OJ L 31, 1.2.2009), p. 1, 634. <a href="https://eur-lex.europa.eu/eli/reg/2009/559/oj/2009_02_01_01">https://eur-lex.europa.eu/eli/reg/2009/559/oj/2009_02_01_01</a>.</p> <p>EN – Clinical document 4/5</p>	<p>2. By way of derogation from paragraph 1, the specific maximum levels of cross- contamination in non-target feed for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4 shall be set at the limit of quantification (‘LOQ’)<sup>9</sup> laid down in the Annex to this Regulation, where the non-target feed is intended for the following animals:</p> <p>(a) food-producing animals other than fish where the non-target feed is manufactured, processed, stored or transported after the manufacturing, processing, storage or transport of medicated feed or intermediate products intended for aquaculture;</p> <p>(b) animals during the production of eggs or milk intended for human consumption;</p> <p>(c) food-producing animals intended for slaughter in the period for slaughter corresponding to the longest withdrawal period for the target animal species.</p> <p>Article 3 Methods of analysis for antimicrobial active substances in feed</p> <p>The reference methods of analysis for the quantification of the level of cross-contamination in non-target feed for each antimicrobial active substance listed in Annex II to Regulation (EU) 2019/4, as referred to in Article 2(1) and (2) of this Regulation, are laid down in the Annex to this Regulation.</p> <p>However, alternative methods of analysis may be used provided they are validated in accordance with internationally accepted scientific protocols, are suitable to detect the same or a lower LOQ as the LOQ for the same antimicrobial active substance laid down in the Annex to this Regulation and are considered as equivalent by the competent authorities of the Member States.</p> <p>Article 4 Entry into force and application</p> <p>This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from 2024.</p> <p>This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, 20 February 2024.</p> <p>For the Commission The President Ursula VON DER LEYEN</p> <p>EN – Clinical document 5/5</p>
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Five pages document:



• **PREFACE**

• **PREAMBLE** with citations and 15 recitals, containing footnotes, references, dates

• **BODY** with 4 articles, containing numbered paragraphs, lists

• **CONCLUSION** with date and name of signatory





**OJ XML - AKN**

**OJ final  
manuscript**

[illegible]

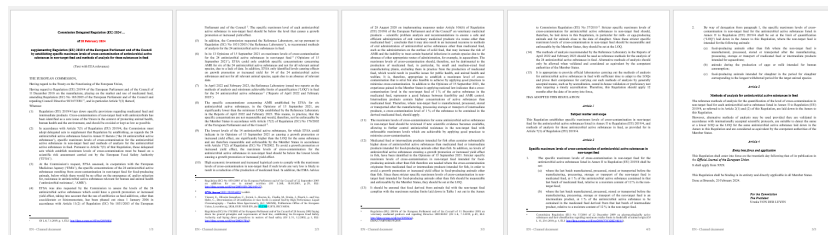


### 3. AI4XML : demonstration

Metadata

OJ XML - AKN

OJ final  
manuscript



Tag « meta »

present in the generated AKN message,  
but not updated yet

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</p>

<p>of<docDate date="2024-02-20">20 February 2024</docDate></p>

<p>supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council by  
establishing specific maximum levels of cross-contamination of antimicrobial active  
substances in non-target feed and methods of analysis for these substances in feed</p>

<p>(Text with EEA relevance)</p>

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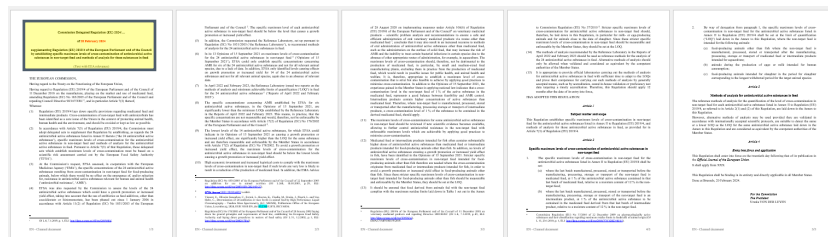


### 3. AI4XML : demonstration

Preface

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manuscript



Commission Delegated Regulation (EU) 2024/...

of 20 February 2024

supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council  
by establishing specific maximum levels of cross-contamination of antimicrobial active  
substances in non-target feed and methods of analysis for these substances in feed

(Text with EEA relevance)

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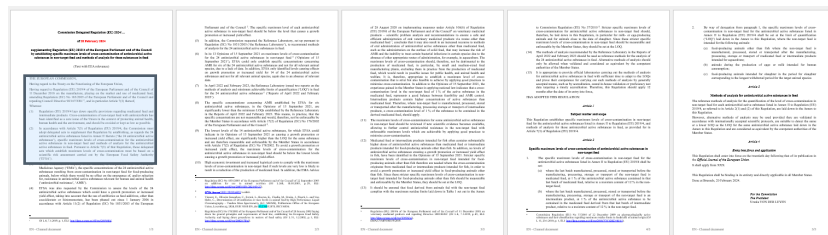


### 3. AI4XML : demonstration

Preamble

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC<sup>1</sup>, and in particular Article 7(3) thereof,

Whereas:

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<p>THE EUROPEAN COMMISSION,</p>
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<p>Having regard to the Treaty on the Functioning of the European Union,</p>
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<p>Having regard to Regulation (EU) 2019/4 of the European Parliament and of the Council
of <date date="2018-12-11">11 December 2018</date> on the manufacture, placing on the
market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European
Parliament and of the Council and repealing Council Directive 90/167/EEC<authorialNote
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L 4, 7.1.2019, p. 1, ELI: <a href="http://data.europa.eu/eli/reg/2019/4/oj">
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</p>
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and in particular Article 7(3) thereof,</p>
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<p>Regulation (EU) 2019/4 lays down specific provisions regarding medicated feed and
intermediate products. Cross-contamination of non-target feed with antimicrobials has
been identified as a core issue of the Union in the context of protecting animal health,
human health and the environment, and should be avoided or kept as low as possible.</p>
</ recital>
< recital eId="recs_1_rec_2">
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<p>In accordance with Article 7(3) of Regulation (EU) 2019/4, the Commission must adopt
delegated acts to supplement that Regulation by establishing, as regards the 24
antimicrobial active substances listed in Annex II thereto ('the 24 antimicrobial active
substances'), specific maximum levels of cross-contamination for the antimicrobial
active substances in non-target feed and methods of analysis for the antimicrobial
active substances in feed. Pursuant to Article 7(3) of that Regulation, those delegated
acts which establish maximum levels of cross-contamination must be based on a scientific
risk assessment carried out by the European Food Safety Authority ('EFSA').</p>
</ recital>
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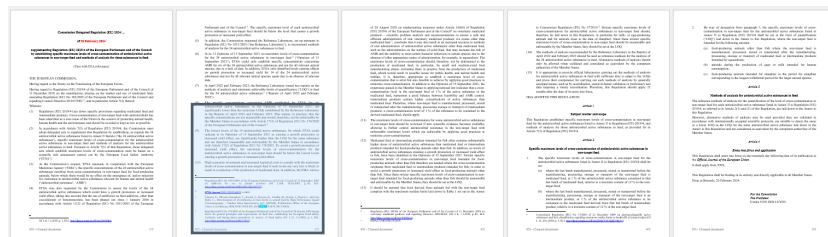


# 3. AI4XML : demonstration

Preamble

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- (8) The specific concentrations concerning AMR established by EFSA for six antimicrobial active substances, in the Opinions of 15 September 2021, are significantly lower than the minimum LOQs established by the Reference Laboratory in the Reports of April 2022 and February 2023. This means, in practice, that the specific concentrations are not measurable and would, therefore, not be enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council.
- (9) The lowest levels of the 14 antimicrobial active substances, for which EFSA could indicate in its Opinions of 15 September 2021 as causing a growth promotion or increased yield effect, are significantly higher than the LOQ for the same substance and are therefore measurable and enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002. To avoid a growth promotion or increased yield effect, the maximum levels of cross-contamination for the antimicrobial active substances in non-target feed should be below the lowest levels causing a growth promotion or increased yield effect.
- (10) High economic investment and increased logistical costs to comply with the maximum levels of cross-contamination in non-target feed if such levels are very low is likely to result in a reduction of the production of medicated feed. In addition, the EMA Advice

<sup>2</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/2021-03-27>).

<sup>3</sup> *EFSA Journal* 2021;19(10):6852 to 6865.

<sup>4</sup> Vincent, U., Oliveira Gonçalves, C., Ferrari, L., Bouten, K., Chedin, M., Stroka, J., Pinotti, L. and Von Holst, C., Determination of 24 antibiotics at trace levels in animal feed by High Performance Liquid Chromatography – Tandem Mass Spectrometry (LC- MS/MS), Publications Office of the European Union, Luxembourg, 2024, EUR 31818 EN, doi:10.2760/12878, JRC136836.

<sup>5</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

```
and February 2023').</p>
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<p>The specific concentrations concerning AMR established by EFSA for six antimicrobial active substances, in the Opinions of <date date="2021-09-15">15 September 2021</date>, are significantly lower than the minimum LOQs established by the Reference Laboratory in the Reports of April 2022 and February 2023. This means, in practice, that the specific concentrations are not measurable and would, therefore, not be enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<authorialNote class="FOOTNOTE" placement="bottom"

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        1.2.2002, p. 1</ref>, ELI: <a href="http://data.europa.eu/eli/reg/2002/178/oj">
          http://data.europa.eu/eli/reg/2002/178/oj</a>).</p>
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<p>The lowest levels of the 14 antimicrobial active substances, for which EFSA could indicate in its Opinions of <date date="2021-09-15">15 September 2021</date> as causing a growth promotion or increased yield effect, are significantly higher than the LOQ for the same substance and are therefore measurable and enforceable by the Member States in accordance with Article 17(2) of Regulation (EC) No 178/2002. To avoid a growth promotion or increased yield effect, the maximum levels of cross-contamination for the antimicrobial active substances in non-target feed should be below the lowest levels causing a growth promotion or increased yield effect.</p>

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  <p>High economic investment and increased logistical costs to comply with the maximum
    levels of cross-contamination in non-target feed if such levels are very low is likely
    to result in a reduction of the production of medicated feed. In addition, the EMA
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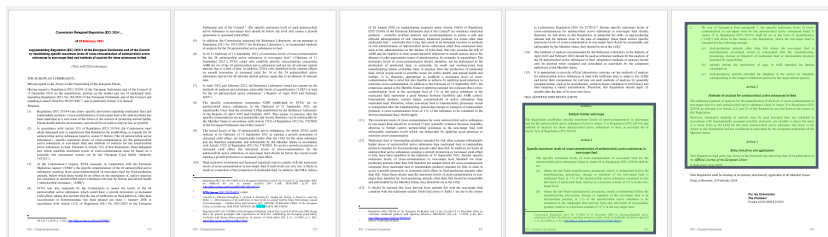


### 3. AI4XML : demonstration

Body

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Article 2

#### Specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed

1. The specific maximum levels of cross-contamination in non-target feed for the antimicrobial active substances listed in Annex II to Regulation (EU) 2019/4 shall be set:
  - (a) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is medicated feed, at 1 % of the antimicrobial active substance contained in that last batch of medicated feed, relative to a moisture content of 12 % in the non-target feed;
  - (b) where the last batch manufactured, processed, stored or transported before the manufacturing, processing, storage or transport of the non-target feed is an intermediate product, at 1 % of the antimicrobial active substance to be contained in the medicated feed derived from that last batch of intermediate product, relative to a moisture content of 12 % in the non-target feed.

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          manufacturing, processing, storage or transport of the non-target feed is
          medicated feed, at 1 % of the antimicrobial active substance contained in that
          last batch of medicated feed, relative to a moisture content of 12 % in the
          non-target feed;</p>
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          <p>where the last batch manufactured, processed, stored or transported before the
          manufacturing, processing, storage or transport of the non-target feed is an
          intermediate product, at 1 % of the antimicrobial active substance to be contained
          in the medicated feed derived from that last batch of intermediate product,
          relative to a moisture content of 12 % in the non-target feed.</p>
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## Conclusion

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    <p>This Regulation shall be binding in its entirety and directly applicable in all Member
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      <signature>
        <span class="ITALIC">For the Commission</span>
      </signature>
      <signature>
        <span class="ITALIC">The President</span>
      </signature>
      <signature>Ursula<span class="UC">von der Leyen</span></signature>
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### *Entry into force and application*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from XXX.

This Regulation shall be binding in its entirety and directly applicable in all Member States.  
Done at Brussels, 20 February 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN



### 3. AI4XML : demonstration

AI4XML - demo





### 3. AI4XML : current status

#### Current Achievements (as of today)

- We perform documents conversion with schema validation
  - Full prefaces, and preambles,
  - Articles with simple lists
  - Conclusions part
- We adopted an advanced programmable prompting approach
  - Advanced prompt generation
  - Modular pipeline allows quick switching to any other dataset or model





## 4. Additional information: Objective by the end of the Q1-2026.

- Switch to AKN4EU (based on Conval)
- Convert document with complex structures and tags (nested lists, math formulas)
- Include Schematron validation
- Metadata and cross reference support
- Full conversion of large documents [large articles, large number of pages]
- Tests with selected additional languages
- Perform experiments with additional LLMs
  - Use [GPT@EC](#)
  - Other providers (from OpenRouter)





## 4. Additional information: AI4XML from exploratory phase to innovative project.

- **Solution evolution**
  - From prototype converting preamble and prefaces to the full document conversion
  - From few simple document to all the data scope in AKN4EU v4.1.1
  - Improved Validation
- **Preparation for the industrialization**
  - How to fit into OP business processes
  - Cost benefit analysis
  - Feasibility study [OP's IT processes and IT landscape]
- **Synergies and dependencies**
  - AKN4EU standard, AI@OJ, AKN4EU@OP, EDIT, CONVAL





## 5. Conclusion

- A set of LLM have been tested
- Not everything ready yet, but a major step has been realised.  
Possible to generate AKN file from an official manuscript containing:
  - The structure:
    - **preface**, **preamble** with citation and several recitals, **body** with multiple articles, **conclusion**
  - Some complexities as
    - dates, lists, references, footnotes.
- We adopted an advanced programmable prompting approach
  - Advanced prompt generation
  - Modular pipeline allows quick switching to any other dataset, model or schema



# THANK YOU

**Keep in touch via:**

Dr KUSTER Marc (OP) [Marc.KUSTER@ec.europa.eu](mailto:Marc.KUSTER@ec.europa.eu)

**Head of Unit – OP.D.4 – “Interinstitutional Relations, Innovation, Programming and Compliance”**

