欧州プラスチック規制改正案が食品接触用途向けプラスチックに与える影響について

Impact of EU Commission Proposed Update to EU Plastics Regulation: Quality Amendment

April 2, 2024

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日本語解説：難波　多加志
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Basic EU Requirements for Plastics

- Must comply with:
  - **Framework Regulation (EU) No. 1935/2004**
    - Article 3 – general safety standard
  - **Good Manufacturing Practice Regulation (EC) No. 2023/2006**
    - Starting substances excluded from GMP regulation
  - **Plastics Regulation (EU) No. 10/2011**
    - Monomers and additives must be listed in Annex I
      - Applicable SMLs and OMLs need to be evaluated
      - Listing may include Specification/Limitations
      - PPAs, Aids to Polymerization, Colorants, Solvents excluded from Positive List Requirement
    - Non-intentionally added substances ("NIAS") must be risk assessed (Article 19)
    - Declaration of Compliance (including 15th Amd. requirements)

プラスチックに関する規制の基礎

- 以下の法令に準拠しなくてはならない。：
  - **フレームワーク規制 (EU) No. 1935/2004**
    - 第３条 – 安全に関する一般要求事項
  - **GMP - Good Manufacturing Practice Regulation (EC) No. 2023/2006**
    - 原材料については、GMP規制の対象外
  - **プラスチック規制 (EU) No. 10/2011**
    - モノマー及び添加物はAnnex Iに収載されていなくてはならない。
      - 対応するSML及びOMLについて確認が必要
      - 収載内容には、規格や制限に関する項目が含まれる場合がある。
      - PPAs（ポリマー製造助剤）, 重合助剤, 着色剤、溶媒は、ポジティブリストの対象から<u>除外</u>
    - 非意図的添加物 (“NIAS”) についても、リスク評価が必要 (第１９条)
    - 適合宣言書 (第１５回改正で追加された項目)

18th Amendment to Plastics Regulation

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- Released for Public Consultation on March 13, 2024
- Surface biocides now subject to only Biocidal Products Regulation
- New labeling requirements
  - Repeated use articles
  - Materials not yet in contact with food
- Revises some requirements for migration testing
  - SMLs and OML in Plastics Regulation apply if plastic layer of MMML in contact with food
  - Small packages (< 500 ml or grams) – must use real S/V ratio
- "High degree of purity" requirement

プラスチック規制に対する第１８回改正案

- 2024年3月13日に意見募集の為、公開
- 表面殺生物剤は、殺生物製品規制の対象に
- ラベル表示に関する新たな要求項目
  - 繰り返し使用される成形品
  - 食品と未だ接触していない材料
- 移行試験の項目について、いくつかの変更
  - プラスチック規制で規定されているSMLs及びOML が、多素材多層構造体の食品接触層に対して適用される
  - 小容量包装 (500 ml or グラム未満) 規定が無くなり、実際の表面／容積比を使用しなくてはならなくなる
- 「高純度規定」の追加

Offcuts and Scraps

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- Updates the rules for "re-processed plastics" (i.e., offcuts and scraps)
  - Must be collected in accordance with **GMP** (GMP Reg., 2023/2006 also updated)
  - Compositional requirements of Plastics Regulation must be met
  - Must ***not*** contain:
    - Substances that could exceed migration limits
    - Substances that impact compliance with Article 3 of Framework Regulation
    - Constituents originating from food, printing, coating, or adhesive <u>unless</u> such constituents are **identified** and **risk assessed** under Article 19

端材およびスクラップ

- 「再加工プラスチック」に関する規定の改正 (端材及びスクラップ)

  - **GMP** (GMP Reg., 2023/2006 also updated)の規定に則って回収されなくてはならない。

  - プラスチック規制の組成規定に合致したものでなくてはならない。

  - 以下のものを**含んではならない。**：
    - 許容移行量を超える可能性がある物質
    - 含有することによりフレームワーク規制第３条に適合しなくなる物質
    - 食品、印刷、コーティングあるいは接着剤由来の物質。ただし、第19条の規定に基づき、同定されリスク評価により安全性が確認されているものを除く。

High Degree of Purity Requirement

- Also, known as the “Quality Amendment”
- DG Sante first discussed in 2022
  - Concern that recycled materials from waste and substances from natural origin could introduce unassessed impurities
  - Believed that existing regulation was not sufficient
  - Need to consider potential for ***full migration*** of impurities to food
- Draft text imposes requirements on all starting substances
  - Broader than just materials from waste and natural substances

高純度規定

- “Quality Amendment”「品質に関する改正」とも呼ばれる。

- DG Sante(健康と食品の安全のための総局欧州委員会総局)で2022年に初めて議論された。
  - リサイクルおよび天然由来の、未評価の不純物に対する懸念
  - 現在の規制では不十分と考えられた。
  - 不純物が食品に「全移行」した場合を想定する必要性を認識

- 改正案の文言では、あらゆる出発物質が対象とされた。
  - 廃棄物や天然由来物よりも対象が広い。

- All substances must meet purity specification

- <u>Impurity must be</u>:
  - Included on Positive List
  - Risk assessed per Art. 19
  - If genotoxicity ruled out, migration cannot exceed 50 ppb
  - If unknown, or unassessed, migration cannot exceed 0.15 ppb

Must assume FULL MIGRATION to food

Article 3a

High degree of purity

A substance used in the manufacture of plastic materials and articles shall be considered as having a high degree of purity where all of its constituents form part of its identity, and it otherwise contains only a minor amount of contaminants and non-intentionally added substances that fulfil one of the following conditions:

(i) they comply with the specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any;

(ii) they have been subject to a risk assessment in accordance with Article 19 and considered compliant;

(iii) they have been subject to an individual toxicological assessment which concludes that genotoxicity is ruled out, in accordance with the relevant guidance adopted by the Authority, and they are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to an individual migration of any of them resulting in their presence in food exceeding 0.05 mg/kg;

(iv) they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

- あらゆる物質は、純度規定を満足しなくてはならない。

- 不純物は以下の条件を満たすこと:
  - ポジティブリストに収載
  - 第19条に基づきリスク評価済み
  - 遺伝毒性がある可能性を排除できる場合、移行量は50 ppbを超えてはならない。
  - 遺伝毒性が不明な場合あるいはリスク評価がされていない場合、移行量は0.15 ppbを超えてはならない。

食品への全移行を前提として評価しなくてはならない。

Article 3a

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- All substances must have a high degree of purity
  - Not just monomers and additives, but also PPAs, aids to polymerization, colorants, solvents, etc.
- Paragraph (2) covers natural materials
- Must document high degree of purity
- And allow competent authority to take samples to verify purity

Article 8

General requirements on substances

1. Substances used in the manufacture of plastic materials and articles, including those manufactured from waste, shall be of a high degree of purity and shall be of a technical quality suitable for the intended and foreseeable use of the materials or articles.

   Manufacturers of plastic materials and articles and of products from intermediate stages of their manufacturing shall know the composition of the substance and make it available to the competent authorities on request.

3. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that documentation showing compliance with paragraphs 1 to 2 is part of the documentation referred to in Article 16.

4. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that competent authorities can take samples to verify their degree of purity and their composition, including that of the substances and materials used for their manufacture.

- すべての物質は高純度でなくてはならない。
  - モノマーや添加物だけでなく、製造助剤や重合助剤、着色剤、溶媒なども対象
- 第2項は天然由来物を対象とする。
- 高純度であることを確認する文書、記録が無くてはならない。
- 更に、当局が純度を確認する為の試料を提供しなくてはならない。

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Purity as a Specification of Starting Material

- Proposed amendments to Articles 3a and 8 impose **specification**
  - Cannot just disclose identity and concentration of impurities (in DoC)
  - If starting material does not meet "high degree of purity" cannot be used in plastic food-contact material or article
  - Requirement is not limited to Annex I listed materials
    - Would also apply to all "substances used in the manufacture of…"
    - Purity specification also applies to colorants, PPAs, aids to polymerization, solvents, etc.

- Applies to virgin materials, as well as products of natural origin and materials produced from waste

- **Key Takeaway**: Amendment does not tell you what to do with already identified impurities, but establishes an LOD for measuring them…

出発原料に求められる純度規格について

- 第３a条及び第8条によれば、**規格**は、
  - 不純物について、物質の特定と含有量を開示するだけでは不十分（適合確認書に記載が必要）
  - 出発原料が「高純度規定」を満足しない場合、食品接触材料や成形品には使用できない。
  - この要求事項は、Annex Iの収載された物質以外も対象になる。
    - 「・・・の製造に使用される物質」とある為、製造に使用されるすべての物質が対象になると考えられる。
    - 純度規定は、着色剤、製造助剤、重合助剤なども対象になる。

- バージン材だけでなく、天然由来物、廃棄物由来のものも対象とする。

- **重要**: 改正案は、既知の不純物についてどう対応すべきか言及していないが、純度規定への適合を確認する為にあるべき検出限界(LOD)を規定するものになっている。

Somewhat Favorable Change from Proposal

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> they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

- Change may indicate a recognition that some losses of impurities could occur during polymerization or manufacture of material/article
- Not clear how a raw material producer will know extent of loss, and change may have no ACTUAL impact on what must be done

改正案に含まれる、やや好ましい変更点

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they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

- 重合中や材料や成形品の製造中に一部の不純物が一定量失われる場合があることを認識しているように思われる。
- しかし、原料メーカーが（川下工程で）どの程度不純物が減少するかを知る方法は明確でなく、原料メーカーでなすべきことについて、実際上の影響はないかも知れない。

Impact on Purity of Typical Monomer

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- **Example**: consider impurity in **dimethyl terephthalate** (DMT):
  - If impurities are not lost during polymerization, impurities present at more than 0.1 ppm in monomer, will result in migration exceeding 0.15 ppb
- Assumptions:
  - Impurity concentration = 0.1 ppm (in DMT)
  - Thickness of PET article = 40 µm
  - Density = 1.4 g/cm^3
  - Use level of DMT = 65%

<M> = 0.1 x 10^{-6} g-imp/g-DMT x 0.65 g-DMT/g-PET x 1.4 g-PET/cm^3 x 40 µm-PET x 1 cm/10,000 µm x 600 cm^2/kg-food x 1000 mg/g

= 0.00015 mg/kg-food

高純度規定が意味する所の検証
代表的なモノマーを例にして

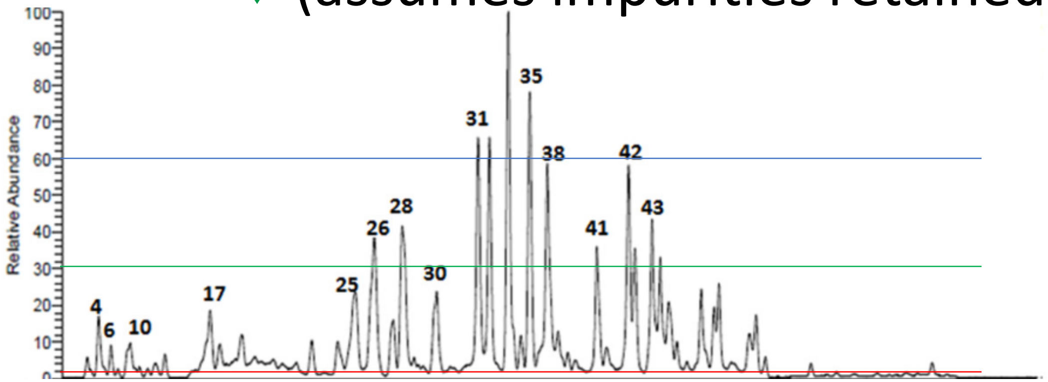
- **<u>例</u>: ジメチルテレフタレート**(DMT) の場合:
  - 重合中に不純物は減らないとして、モノマー中の不純物含有量が0.1 ppm超の場合、移行量は0.15 ppb超となる。
- 想定:
  - 不純物含有量 = 0.1 ppm (in DMT)
  - PET成形品の厚み = 40 µm
  - 比重 = 1.4 g/cm^3
  - DMTの使用量 = 65%

$$\langle M\rangle = 0.1 \times 10^{-6}\ \text{g-imp/g-DMT} \times 0.65\ \text{g-DMT/g-PET} \times 1.4\ \text{g-PET/cm}^3 \times 40\ \mu\text{m-PET} \times 1\ \text{cm}/10{,}000\ \mu\text{m} \times 600\ \text{cm}^2/\text{kg-food} \times 1000\ \text{mg/g}$$

$$= 0.00015\ \text{mg/kg-food}$$

Results for Other Starting Materials

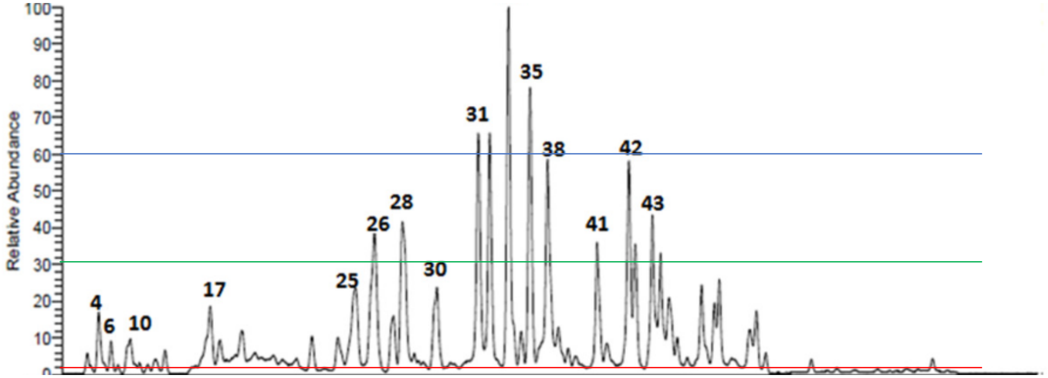
- Volatile monomer (ethylene) used in manufacture of polyolefin:
  - Even if we assume that 99.9% of an impurity is lost during polymerization, 1 ppm impurity level could be too high assuming full migration to food
- Antioxidant
  - If you assume use at 0.5% use level, and assume full migration to food, 1 ppm impurity results in migration of 0.0004 mg/kg for polypropylene, or ~3 times too high
  - (assumes impurities retained in finished material or article)



高純度規定が意味する所の検証
その他の物質について

- ポリオレフィン原料として揮発性モノマー（エチレン）を使用する場合:
  - 不純物の99.9%が重合中に失われると仮定しても、全移行を前提にすると、不純物の含有レベルが1 ppmでも高すぎる。

- 酸化防止剤の場合：
  - ポリプロピレンへの添加量を0.5%として全移行を前提にすると、酸化防止剤中の不純物の含有レベルが1 ppm の場合で、ポリプロピレンからの移行量は0.0004 mg/kgとなり、「高純度規定」で求められる基準の３倍程度になる。(不純物が最終製品や成形物にそのまま残るとして)



Declarations of Compliance

- Amendment also proposes to update DoC requirement
  - **Annex I listed substances** (subject to restrictions or specifications) must *also* be disclosed
  - This includes impurities, reaction intermediates formed during production process, decomposition or reaction products

ANNEX IV
Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

…

6) adequate information relative to the substances used, **including impurities in the substances used, reaction intermediates formed during the production process, decomposition or reaction products, in particular** ~~or products of degradation thereof~~ for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

- that are subject to restrictions **and/or specifications in Annex I and/or** in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to ~~a migration from the final material~~ **individual migration into food from the final plastic material or article** exceeding 0,00015 mg/kg food or food simulant;

適合宣言

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- 改正案中の適合宣言に関する変更点について
  - **Annex I収載済み物質について**(同表にある制限や規格も含めて） 情報の開示が必要
  - 開示すべき情報には、不純物、製造中に生成する中間物、分解生成物、反応生成物も含む。

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Alternate (Likely Incorrect) Interpretations

- Some have suggested suppliers can use “risk assessment” or “diffusion modeling” or other assumptions regarding loss of impurities when producing final material or article to limit impact of proposed change
- Text of the proposal does not support this
  - If identity of substance is unknown – **must not migrate** at levels exceeding 0.00015 mg/kg food, **assuming full migration to food**
    - If impurity identity unknown, cannot conduct an Article 19 risk assessment
    - If impurity identity unknown, cannot rule out genotoxicity
    - Diffusion modeling is not “full migration to food”
    - Considering reduction of impurity from further processing (polymerization, etc.) potential option, but may limit to certain manufacturing processes, products, or uses
- **BOTTOM LINE**: Most starting material producers do not identify all impurities down to 1 ppm (or lower) level
  - “High degree of purity” specification may be difficult to achieve commercially

(恐らく正しくない）別の解釈

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- 「リスク評価」や「拡散モデル」、あるいは最終製品や成形物の生産時に不純物が減少するという何らかの想定を使って、高純度規定に対応できるとする考え
- 改正案の文言は、そのようなやり方を許容していない。
  - 物質が特定されない場合ー**食品への全移行を前提**として、0.00015 mg/kgを**超えて移行してはならない。**
    - 不純物が特定できない場合、第19条のリスク評価は実施できない。
    - 不純物が特定できない場合、遺伝毒性がある可能性を排除できない。
    - 拡散モデルは、「食品への全移行」を想定するものではない。
    - 加工（重合など）により不純物が減少する可能性はあるが、特定の製造工程、製品、用途に限定される。
- **肝心な点：**ほとんどの出発原料メーカーは、含有量が1 ppm（あるいはそれ以下）のあらゆる不純物について同定、定量はしない。
  - 「高純度規定」を商業的に達成することは困難と思われる。

DG Sante Proposed Timeline to Adoption

- Discussed at Food Contact Materials Working Group – January 2024
- Open for Public Consultation: 13 March 2024 – 15 April 2024
- Expected Vote by Standing Committee (Plants, Animals, Food and Feed, PAFF) – 24 April 2024
- Then translated and scrutinized by European Parliament and Council
- Parliament elections in June 2024 (election recess until 10 July 2024)
- Adoption – (late) 2024 (?)

改正案施行までの予定

- 食品接触材料ワーキンググループでの議論 – 2024年1月
- 意見募集：2024年3月13日～4月15日
- Expected Vote by Standing Committee （植物、動物、食品、飼料）常任委員会での採決：2024年4月24日
- 翻訳の上、欧州議会及び欧州理事会で精査
- 欧州議会選挙：2024年6月
- （選挙による休会の後、20247月10日に開会）
- 施行 – 2024年後半 (?)

Potential Comments

- Existing Plastics Regulation sufficient to address DG Sante concerns
  - Draft text is not likely achievable, commercially
  - Should discuss impact with producers
- Rework proposal to consider intended use
  - Consider loss of impurities during processing
  - Consider diffusion or other modeling of finished article use
- Move requirement to Framework Regulation (?) and/or GMP Regulation
  - All materials should meet same purity requirements (should not be directed at just plastics)
  - Other materials also could potentially have impurities introduced from waste stream, and not proportional to assess only plastic starting materials

考えられる意見について

- DG Sangeの懸念を払しょくするのに現行のプラスチック規制で十分である。
  - 改正案は商業的に達成することができるとは思えない。
  - 製造者と影響について議論すべきである。
- 想定用途にも考慮して、改正案について再考すべきである。
  - 製造、加工工程での不純物の減少を考慮すべきである。
  - 最終成形品の使用を想定して拡散モデルなどを使うことを検討すべきである。
- 要求事項をフレームワーク規制(?)及び／又はGMP規制に移すべきである。
  - あらゆる材料について、同等の純度規定を設けるべきである（プラスチックだけを対象とするのはおかしい）。
  - プラスチック以外の素材でも、廃棄物由来の不純物が入る可能性はあるので、プラスチックの出発原料だけを評価するのは不当である。

For More Information
本件に関するフォローアップ、お問い合わせ窓口

- Send an email to existing Keller and Heckman contact(s), or
  本日の講師に直接メールをお送り頂くか、

- Email: quality_amendment@khlaw.com（こちらの専用メールアドレスまで）

- Let us know:
  - Are you interested in receiving more information about this amendment?
    本改正案に関する情報についてもっと知りたい。
  - How will this amendment impact you?
    本改正案の自社への影響を知りたい。
  - Can we prepare comments to the Commission for you to submit?
    意見書の作成、提出について相談したい。　　など

ご清聴ありがとうございました。

Thank You

質疑応答

Any questions?

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