Communication of Food Contact Compliance in the Value Chain (EU plastics and non-plastics perspective)

产业链中有关食品接触合规性的沟通（欧盟塑料及非塑料材料视角）

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EU Legislative Overview
欧盟法规概况

Framework Regulation (EC) No 1935/2004

GMP Regulation (EC) No 2023/2006

Materials specific Measures

Regenerated Cellulose
2007/42/EC

Ceramics
84/500/EEC

A & I materials
(EC) 450/2009

Plastics Regulation
(EU) No 10/2011

Recycled Plastics
(EC) No 282/2008
(amendment in preparation)

Printed FCM
(in preparation, but delayed)

Substance specific Measures

Reg.1895/2005
BADGE/NOGE

Dir. 93/11/EC
Nitrosamines

European Commission

Paper & Board
(DE, NL,IT, FR, CH)

Coatings
(DE, NL,IT, ES, BE)

Adhesives
(DE, ES,IT)

Printing inks
(CH, DE on-hold)

Silicones
(DE, F, ES, CH, NL, IT)

Rubbers
(NL,DE,ES, FR)

Member States

Glass, Wood, Cork, Textile, Metal, Ion Exchange Resins, Waxes

Declaration of Compliance DoC
符合性声明 DoC

- General requirements to issue a DoC for Plastics materials 塑料材料符合性声明的一般要求：
  - EU：Framework Regulation (EC) No 1935/2004, Art.3

    欧盟：框架法规(EC) No 1935/2004, Art.3
  - EU: Plastic Implementation Measure Regulation (EU) No 10/2011

    欧盟：塑料应用措施规定(EU) No 10/2011
- Guideline documents 指导文件：
  - Union Guideline on Regulation (EU) No 10/2011

    联盟监管指导文件(EU) No 10/2011
  - Union Guideline on Regulation (EU) No 10/2011 Regarding DoC

    联盟监管指导文件(EU) No 10/2011 DoC相关

Union Guideline on Regulation (EU) No 10/2011
法规(EU) No 10/2011指南文件

5.1 Declaration of compliance (DoC)

The **manufacturer of a food contact material should reassure the customer that the food contact material complies with the applicable EU and national legislation**. …
食品接触材料的制造商应向客户保证食品接触材料符合适用的欧盟和国家法规…

Each manufacturer has to declare compliance for the manufacturing steps under his responsibility. For example, a producer of a monomer has to ensure that the monomer is authorised and complies with the specifications relevant to it. The producer of a plastic intermediate has to ensure that monomers and additives are authorised and, as far as under his responsibility, indicate the conditions of use under which migration limits can be complied with. The manufacturer of the final article has to indicate the conditions of use under which restrictions and migration limits can be complied with. …
每个制造商都必须对其负责的制造步骤做出符合性声明。

The manufacturers of adhesives, printing inks and coatings should provide their customers, using their products in plastic materials or articles or plastic intermediates, with adequate information that allows the manufacturer of the plastic article to issue his DoC.
粘合剂，印刷油墨和涂料的制造商应为在塑料材料或制品或塑料中间体中使用他们产品的客户提供足够的信息，使这些塑料制品的制造商能够签发符合性声明。

National legislation …
成员国法规…

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain
Innovation and sustainability

Brussels, 21.02.2014

Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

DoC = Declaration of Compliance

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

Additional requirements on DoC information in the supply chain e.g.

供应链中对DoC信息的附加要求，例如：

- **Principle of sharing** the **compliance work** explained

  解释合规工作的共享原则

- **Customer** has to be **informed about non-intentionally added substances (NIAS)** where the manufacturer cannot take the responsibility

  客户必须被告知制造商无法为非有意添加物质（NIAS）承担责任

DoC = Declaration of Compliance

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain
Innovation and sustainability

Brussels, 28.11.2013

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain

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Non-Intentionally Added Substances (NIAS)
非有意添加物质（NIAS）

Plastics regulation 塑料法规 (EC) 10/2011

- Whereas 20
  During the manufacture and use of plastic materials and articles **reaction and degradation products** can be formed. These reaction and degradation products are non-intentionally present in the plastic material (NIAS). **As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance.** However it is not possible to list and consider all reaction and degradation products in the authorization. Therefore they should not be listed as single entries in the Union list. **Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.**

若主要非有意添加物质（NIAS）与风险评估有关，则应考虑包括在物质的限制范围内。虽然无法对所有NIAS进行授权，但最终材料或非有意添加物质如有潜在的健康威胁，制造商应根据国际认可的风险评估科学方法作出相应评估。

Oligomers are NIAS
低聚物属于非有意添加物质

Risk Assessment according to Art 19 of Regulation (EU) No 10/2011 is required:
根据法规（EU）No 10/2011第19条，进行风险评估是必需的：

- **Depending on the polymer production conditions oligomers could be present in different and varying amounts. Based on the actual production and sourcing conditions the type and amount of oligomers present in a plastics material might vary.**
  取决于聚合物生产条件，低聚物能以不同含量存在。根据实际生产和采购条件，塑料材料中存在的低聚物的类型和数量可能会有所不同。

- **NIAS (incl. Oligomers) are covered by the manufacturer specific risk assessment**
  非有意添加物质（包括低聚物）应该被涵盖在制造商特定的风险评估里

- **If needed limits on oligomers are expressed in the resp. DoC**
  如有需要，低聚物的限值可在相应的DoC上标识

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Specify Exposure Limits 明确暴露限值

Exposure limits are typically expressed per substance:
暴露限值通常按物质表示：

- **If needed are addressed as such in DoCs**
  如果需要，与DoC中相同

- **Both customers and enforcement need specific limits**
  客户和执法机构都需要特定的限制

Some examples…

New Substance Approval from the 6th Amendment of 10/2011 (Example)
2011年10月第6次修订的新物质批准 （例）

"871		0287916-86-3	dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α-hydro-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1-propene 12-氨基-十二烷酸与2,5-呋喃二酮-α-羟基-ω-羟基聚（氧-1,2-乙二基）-乙烯和1-丙烯的聚合物	Yes	No	No			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns simulant E, at ambient temperature or below, **and when migration of the total oligomeric fraction of less than 1000 Da does not exceed 50 µg/kg food“** 仅用于聚烯烃中，含量最高可达重量的20%。 这些聚烯烃只能与附件3的表2中分配的模拟物E在环境温度或更低温度下，且当低于1000 Da的低聚物部分的总迁移不超过50µg/ kg时，才可以与模拟物对应的食品进行接触。	(23)

Substance Limits Expressed on a DoC (Example)
DoC的物质限值（示例）

Information about restrictions regarding oligomers
有关低聚物限制的信息

Depending on the polymerization and processing conditions the **<chemical name of oligomer> (CAS <00000-00-0>)** is formed and might be detected as migrant from final polymer applications. Based on our toxicological studies and risk assessment a **migration restriction of X mg /kg food** for the oligomer is established. The migration restriction limit must be ensured by the person who places the finished food contact article on the market.
取决于聚合和加工条件，形成**<低聚物的化学名称>（CAS <00000-00-0>）**，且可能会从最终聚合物应用中检测判断其为迁移物质。 根据我们的毒理学研究和风险评估，对低聚物建立了X mg / kg食物的迁移限值。 将最终食品接触物品投放市场的人必须确保最终制品符合该迁移限值。

The Balance of Substances
物质评估的天平（权衡）

IAS [PL]
EFSA Risk Assessment
EFSA 风险评估

NLS & NIAS [SD]
INDUSTRY Risk Assessment
行业风险评估

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

2 Aim of the DoC 符合性声明的目的

The compliance of the final plastic material and article with EU provisions can only be ensured if along the supply chain relevant information exchange takes place between the supplier and the customer and vice versa.
只有在供应链中，供应商与客户之间进行相关信息交换，才能确保最终塑料材料和制品符合欧盟规定，反之亦然。

The DoC is a document delivered by the supplier to his customer at marketing stages up to but excluding the retailer. It has two main aims: DoC是供应商在营销阶段向其客户提供的文件，但不包括零售商。 它有两个主要目标：

It confirms to the customer the compliance of the product with the relevant requirements of the Plastics Regulation and the Framework Regulation.

它向客户确认产品符合“塑料法规”和“框架法规”的相关要求。

It provides the customer with relevant information necessary to establish or check the compliance of the product with relevant legislation.

它为客户提供建立或检查产品符合相关法规所需的必要信息。

In order to allow the exchange of relevant information, the information to be included in the DoC is set out in a **standard format in Annex IV of the Plastics Regulation**. This Guidance document contains details on information to be provided at the different manufacturing and marketing stages of plastics to fulfil the requirements of the Plastics Regulation.
为了满足相关信息的交流，将需要包含在DoC中的信息以“塑料法规”附录IV中的标准格式列出。 本指导文件包含在塑料的制造和销售的不同阶段需提供的资料的详细信息，以满足塑料法规的要求。

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

What can be part of the compliance work?
合规工作包括些什么?

Verification of authorization status of an intentionally added substance
验证有意添加物质的授权状态

Verification of purity criteria of an intentionally added substance
验证有意添加物质的纯度标准

Identification and risk assessment of non-intentionally added substances
非有意添加物质的识别和风险评估

Verification of compliance with SML and OML through screening or verification
通过筛选或验证来验证对SML和OML的符合性

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

4. Content of the Declaration of Compliance and Adequate Information along the supply chain
有关供应链中的符合性声明的内容和充足的信息

4.2.1 Substances for the manufacture of Plastics 用于制造塑料的物质

A) DoC for substances authorised and listed in the Annex I of the Plastics Regulation and used to manufacture plastics

1. The identity and address of the business operator issuing the declaration of compliance.

2. The identity and address of the business operator which manufactures or imports the substance.

3. The identity of the substance(物质身份信息）: at least, one of the following information should be provided: trade name, FCM Substance number, Reference number, CAS number or chemical name of the substance, as listed in Table 1 of Annex I of the Plastics Regulation (the "Union List"). In case of *dual use additive(s),* either the E-number of food additives or the FL number of flavourings should be reported as well.

In case of substances subject to restrictions included in Annex I to the Plastics Regulation or when the downstream operator is informed that further specifications of use need to be established by the downstream operators, at least the FCM Substance number and optionally also CAS number, Reference number or chemical name as listed in the Union List should be provided.受限物质的身份信息的提供不是强制性的，经营者可以保证在下游客户提供的预期使用条件下，该物质的迁移符合限量的要求，也是可以接受的。

4. The date of the declaration.

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

4. Content of the Declaration of Compliance and Adequate Information along the supply chain
4.2.1 Substances for the manufacture of Plastics 符合性声明传递足够的安全性息在塑料产业链上

5. a. Confirmation that the substance is authorized under the Plastics Regulation, together with its use in the polymer (indicated in column 5 and 6 of the Union List: monomer, and/or additive and/or polymer production aid) and supplemented with relevant information in column 10 of the Union list).

   b. Confirmation that the substance is of a technical quality and purity suitable for the intended and foreseeable use and that impurities have been assessed in line with Article 19 of the Plastics Regulation or that information is provided to the downstream user that is adequate to assess its suitability for its intended use.

   物质的技术效果和纯度符合相应的可见的应用条件

6. a. Relevant restrictions as listed in Annex I and II of the Plastics Regulation, such as SML, SML (T), *QM* or a confirmation that no restriction applies.列在附录I和附录II的限制条件

   b. Confirmation that *compositional or purity specifications* as mentioned in column 10 of the Union List are met or that no specifications apply.

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

4. Content of the Declaration of Compliance and Adequate Information along the supply chain

4.2.1 Substances for the manufacture of Plastics

符合性声明传递足够的安全性息在塑料产业链上

7. In case of dual use additive(s), where appropriate, confirmation that the substance respects the purity criteria for food additives. 对于两用物相物质，也需要遵守食品添加剂的纯度

8. Specification of use in relation to the final article as indicated in column 10 of the Union List. An indication of whether any other *specification of use* needs to be respected13 or an indication that the downstream user needs to establish, if necessary, additional specifications of use.
对最终制品的使用限制也在清单中体现，终产品企业需要确保使用条件符合这些限制要求，如果必要，可以提出额外的使用要求

…

Union Guideline on Regulation (EU) No 10/2011 Regarding DoC
法规(EU) No 10/2011 关于符合性声明（DoC）的指南

4. Content of the Declaration of Compliance and Adequate Information along the supply chain

4.3.1 Manufacturers, distributors or importers of Plastic Intermediate Materials
塑料中间体材料的制造商、分销商或进口商

DoC for a Plastic Intermediate Material, including plastic layers intended to be used in a MMML, but not yet part of it

1. The identity and address of the business operator issuing the declaration of compliance. 公司信息
2. The identity and address of the business operator which manufactures or imports the plastic intermediate materials.
3. The identity of the plastic intermediate material (trade name and *polymer type*). 产品商品名和聚合物类型
4. The date of the declaration.承诺时间
5. Confirmation that the plastic intermediate material complies with relevant requirements of the Plastics Regulation and the Framework Regulation, as described below:合规承诺
a. Confirmation that the intermediate material is manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.使用授权的单体/起始物和添加剂
b. Confirmation that intentionally added substances not subject to listing in the Union List comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. 确认有意添加物质列入正面清单并符合相应限制条件。
…

Risk Assessment Steps
风险评估步骤

Risk Assessment of NIAS e.g. Impurities, Reaction- and Degradation Products

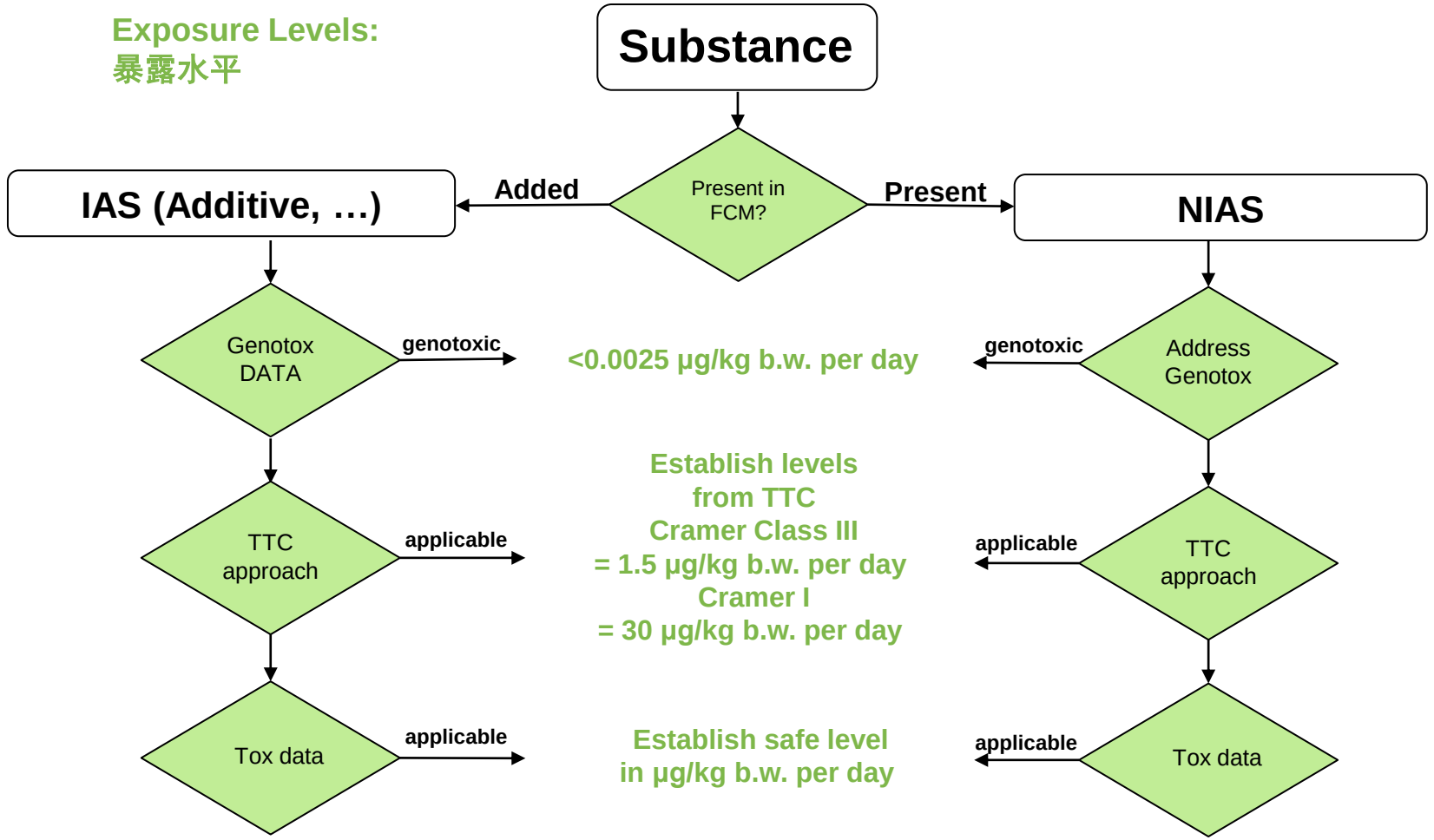
对非有意添加物的风险评估，如：杂质、反应产物和降解产物

- **Migration** into food evaluation 迁移评估

  Worst case calculation, if not OK experimental testing needed

- **Toxicology** assessment of migrants regarding CMR criteria and 毒理学评估
- **Derive** where applicable Tolerable Daily Intake (TDI) threshold 每日允许摄入量阈值导出
- **Verify** restrictions set by Authorities e.g. Primary Aromatic Amines (PAA) 验证官方设定的限制
- **Conclude** on tolerable migration into food 总结可接受的迁移量
- **File** Risk Assessment as Supporting Document (SD) 将风险评估存档作为支持文件

Substance Assessment Steps 物质评估步骤
Common Principles 一般原则



The DoC Ensures Compliance Status Along the Value Chain
DoC确保价值链中的合规状态

- **A DoC is needed for addressing the compliance of IAS and NIAS**
  需要DoC来解决IAS和NIAS的合规性问题
- **The DoC includes Risk Assessment of NIAS e.g. Impurities, Reaction- and Degradation Products**
  DoC包括NIAS的风险评估，例如 杂质，反应产物和降解产物
- **However,…然而……**
  - Clearly state to conditions of use and compliance of a product
    明确说明产品的使用条件和合规性
  - Delegate compliance work incl resp data, where applicable
    在适用情况下，委派合规工作，包括相关数据
  - The DoC is not intended to provide complete recipe disclosure|
    DoC并不是用来提供完整的配方的

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