Evaluation of a substance used in coatings for food contact materials - a template for a comparative exercise among MS

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Purpose of the Task within the Grant :

to develop and make available a common strategy for the risk assessment (RA) of coatings.

Outline

The Task Group is developing a comparative scheme between the RA approaches for coatings starting from the assessment made by IT and NL on a common substance

The differences in the approaches (if any) will be deepened to draw up a final proposal for a common risk assessment on coatings.

Different options for critical aspects will be considered

Aim: to develop a table with all the necessary steps and the type of information necessary for the RA of a coating with the actions/ information for each step

Target: to describe the approach to RA of coatings, by both a narrative part and a decision tree (or flow scheme).

Tools: To visualize the evaluation steps, here a general evaluation process of coating is described . An extra column with an example is presented,

Additional columns/lines will be inserted for options/proposals from MS in order to prepare a working document to be used as a basis for discussion with the final aim to agree a common approach for the assessment of substances used for coatings

THIS PRESENTATION

the appraoch of the IT authority for the evaluation of a cross-linker used for coating of FCM is used as a model example to collate views and approaches from other MS

The general approach to RA of coatings

The safety of the coating is established based on consumer exposure scenario and toxicity of migrants in food occurring under the intended conditions of use

Migrants of potential concern include:

- coating substance(s) and its oligomers < 1000D
- eventual impurities of coating substance(s)
- NIAS (e.g. by-products or degradation products)

Exposure estimates

from the measured migration of all the migrateables (when technically feasible) or calculated from the use level (total transfer)

default assumptions :

- 1 kg food/day
- 60 kg body weight
- 6 dm^2/kg food

.. but ad hoc parameters would be possible for special cases

Toxicological assessment of migrants from coatings

coating substance(s): based on experimental data (full or reduced dossier depending on migration level);

oligomers (< 1000 D): experimental data (no gentox) if needed based on exposure;

impurities: literature data, read-across and SAR, TTC. New experimental studies considered case-by case;

NIAS (e.g. by-products or degradation products): read-across with coating substance, SAR, TTC. New experimental studies considered case-by case

Step in the evaluation process	Details to be provided	Example
Receiving technical dossier		Dossier of a crosslinker XYZ
Completeness check and Checking quality of the submitted data	_INFO: detailed description of the substance,(s) the process, the intended use, the final food contact material	Specified: structure, maximum use level, process conditions, intended use
	MiGRATION: detailed description of the methods, analytical proofs, validation data set , technical reports	Migration tests in non-fatty food simulants Methods provided, some validation performed
	TOXICOLOGICAL DATA : detailed description of the tox tests, availability of the technical reports -	Tox studies and/or argumentation on the parent compound, impurities , NIAS and oligomers

ADMINISTRATIVE

Step in the evaluation process	Details to be provided	Example
Evaluation of non-toxicological data	INFO: structure physicochemical, manufacturing, final use	AVAILABLE INFORMATION crosslinker XYZ for a coating Parent compound XX has three main impurities/process by-products By-products after application to substrate (NIAS) Oligomers <1000 Da: 1 peak deriving from the product, structure not identified

Step in the evaluation process	Details to be provided	Example
Evaluation of non-toxicological data	MIGRATION Contact conditions, methods, validation data , expression of results Migration data	AVAILABLE MIGRATION DATA Migration tests in non-fatty food simulants Extraction with solvent for fatty contact Methods provided, some validation performed Migration results: 1. Parent compound XX: up to 108 µg/kg food 2. Di-isopropylamine (DIPA) impurity: up to 678 µg/kg food 3. Acid derivative of XX: up to 120 µg/kg food 4. Amino ester of XX: up to 74 µg/kg food 5. Ethyl ester of XX: up to 67 µg/kg food 6. DAE impurity: < 3 µg/kg food 7. Oligomers of XX: up to 12 µg/kg food total transfer

Step in the evaluation process	Details to be provided	Example
Evaluation of toxicological data		
Parent compound	Is migration shown to be less than 5 mg/kg food? no → Full dossier (according to the SCF and EFSA approach for plastic FCM)) yes → Reduced dossier, (tiered, depending on migration, according to the SCF and EFSA approach for plastic FCM)	AVAILABLE TOX DATA For [1]: migration >50 ppb, <5000 ppb → three genotox tests and oral 90 days tox study (SCF approach for plastic FCM) Results: non-genotoxic, MoE >10,000 derived from NOAEL from the 90 days study. No safety concern

Step in the evaluation process	Details to be provided	Example
Evaluation of toxicological data		
Oligomers and by-products	Toxicological data as for parent compound depending on migration Read-across, SAR	For [3], [4] and[5]: read across based on [1] Result: no genotoxicity expected based on [1]; NOAEL for [3] extrapolated from [1] 20 mg/kg [4] and [5] hydrolysed to [1] and ethanol / adipic acid No safety concern For [7]: no genotoxicity expected based on [1], no other data needed based on migration level of 12 µg/kg (SCF)

Step in the evaluation process	Details to be provided	Example
Evaluation of toxicological data		
Impurities and NIAS	Toxicological data depending on expected migration TTC	For [2] migration > 50ppb, < 5000ppb: three gentox tests and oral 90 days toxicity study (SCF) Results: non-genotoxic, MoE >10,000 derived from NOAEL from the 90 days study. No safety concern For [6], TTC approach No structural alerts for genotoxicity Cramer Class III, TTC 1.5 µg/kg bw Estimated human exposure <0.05 µg/kg bw No safety concern

Step in the evaluation process	Details to be provided	Example
Evaluation of toxicological data		
Impurities and NIAS		One impurity is secondary amine; may be nitrosated to genotoxic carcinogenic nitrosamine. Human exposure due to use of coating is factor > 30,000 lower than the highest dose of the amine which (together with high dose of nitrite) did not have detectable carcinogenic effect in rats. No safety concern

Going ahead :

To complete the Table with the NL input (short term)

To check the differences/criticalities/commonalities and to refine the Table in cooperation with NL (short term)

To develop a first harmonized draft (narrative and then graphic) in cooperation with NL (medium term)

…. To discuss within the Group and finalize the proposal (long term- final deadline)