Document F - XSG revised RA-RM high level principles for substances version

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This document lays down the over-arching principles for risk assessment and risk management regarding food contact material and article safety and it is for each sector/supply chain to demonstrate how it complies with them. This voluntary guide is a way forward for sectors to develop their own detailed guidelines.

- All substances potentially migrating from food contact materials (FCM) and articles (FCA), whether IAS or NIAS, must be risk assessed and/or risk managed. It is the responsibility of the business operator. Risk = exposure x hazard
- This shall happen throughout the supply chain with each business operator using the information supplied to them from other supply chain operators along with their own expertise. Some examples of a supply chain operator follow. An upstream operator is an operator supplying raw materials or (starting) products to a formulator, or a formulator supplying products to a converter or a converter supplying an article to a packer or filler. The downstream operator is the operator receiving such goods.
- It should be made clear to the next business operator in the supply chain that a risk assessment has been undertaken. Information on the methods used with sufficient detail should be provided to the receiving operator as needed. The receiving operator should assess if a new risk assessment should be performed
- Every business operator in the supply chain has a responsibility to know what assessment/information is required. Each FCM/FCA sector is encouraged to define what information should be transmitted up and down the supply chain.
- Risk assessment and management will vary with the position of the business operator in the supply chain. All operators should use internationally recognised scientific principles in their assessment. The supporting documentation should state which approaches have been used and why.
- Knowledge of hazard and exposure is required in order to perform risk assessments. In most cases the higher up the supply chain the greater the knowledge of hazard whereas the lower down the supply chain the greater the knowledge of exposure, therefore relevant information must be transmitted up and down the supply chain. Therefore, suppliers need to provide sufficient information on the substances which need to be assessed and the scope of application, whereas converters and food industry are better placed to evaluate exposure related to their own use. Information necessary to perform risk assessment should be passed on in the supply chain, where relevant.
- The hazard evaluation of substances should be undertaken by the first operator in the supply chain that introduces those substances.
- Each business operator must ensure that they comply with the risk management measures transmitted to them or they must undertake their own risk assessment and issue appropriate risk management measures to the next business operator.

- The risk assessment and risk management processes used must be documented and form part of the retained supporting documentation, which is auditable and available to Competent Authorities on request.
- information needed for a risk assessment/management must be transferred within the supply chain. A business operator must provide downstream users with information needed for risk assessment/risk management. This may include involvement of third parties to protect confidential information.
- Risk assessment and risk management processes should take into consideration the following components:

1. Identification of the substances and materials present in FCM/FCA including substances anticipated to be generated within the supply chain.
2. Assessment of the ability of substances to migrate into food under intended and foreseeable conditions of use.
3. Assessment of the toxicological hazard to human health of those migrating substances including possible read-across to comparable substances.
4. Based on the hazard assessment, calculate limits considered safe for human exposure to the substance (TDI, TWI, DNEL, thresholds derived from a TTC approach etc., including those self-derived).
5. Consideration of possible applications of the substance if known, which could be routes of relevant human exposure.[1]
6. Setting of Risk Control Limits [RCL] (limit of migration, concentration of the migrant in the food) which reflect the maximum tolerable exposure.
7. Perform a compliance assessment and document using worst case calculation, modelling, analytical testing, etc., which show that, under defined conditions of use (time, temperature, functional barrier, etc), the RCL are not exceeded.
8. Define conditions of use for the downstream user based on the compliance assessment carried out[2]
9. Ensure that the conditions of processing and usage conform to those defined in the risk assessment and risk management and are transferred down the supply chain.

These steps are not all necessarily carried out by the same operator. Thus, communication within the supply chain must ensure that the whole risk assessment and risk management process can be fully completed.

[1] This step and the following (up to step 6), even if part of a normal risk assessment, may be difficult to conduct for some actors within the supply chain. Actors may therefore rely on existing risk assessments already performed by authorities to set an RCL for food packaging and/or on other publicly available reference values.

[2] If downstream users would deviate from the conditions of use defined by their suppliers, it will be the downstream users' responsibility to assess the products for their use in such new conditions.