

The Director General

Maisons-Alfort, 24 November 2021

## **OPINION of the French Agency for Food, Environmental and Occupational Health & Safety**

### **on the "assessment of the risks associated with mechanical removal of packaging material from former foodstuffs reused as animal feed"**

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*ANSES undertakes independent and pluralistic scientific expert assessments.*

*ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.*

*It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.*

*It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).*

*Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 24 November 2021 shall prevail.*

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On 12 December 2017, ANSES received a formal request from the Directorate General for Consumer Affairs and Fraud Control (DGCCRF) to carry out the following expert appraisal: assessment of the risks associated with mechanical removal of packaging material from former foodstuffs reused as animal feed.

#### **1. BACKGROUND AND PURPOSE OF THE REQUEST**

Former foodstuffs (FFSs) are defined as: "foodstuffs, other than catering reflux, which were manufactured for human consumption in full compliance with the EU food law but which are no longer intended for human consumption for practical or logistical reasons or due to problems of manufacturing or packaging defects or other defects and which do not present any health risks when used as feed" (Regulation (EU) No 68/2013).

By-products used for animal feed (e.g. oilseed cakes, molasses) are not considered to be included among these FFSs. They differ from FFSs in that they are not themselves foodstuffs but result from food production processes and were never intended for human consumption. Professionals define them as "products intentionally and unavoidably created in the same process and at the same time as a main product".

The DGCCRF notes that the FFS reuse sector is steadily growing. This activity is in line with a political will to develop the circular economy, demonstrated, for example, by the requirement resulting from the Grenelle II Act for companies to sort their biowaste for reuse. More recently, the Act of 11 February 2016 on combating food waste explicitly imposed "reuse for animal feed" as one of the actions to reduce waste.

The foodstuffs concerned by this use in animal feed are highly diverse (biscuits, chocolate, dairy products, syrups, bakery products, etc.). This formal request concerns downgraded foodstuffs that are packaged. This packaging consists of primary packaging in direct contact with the food and secondary (outer) packaging, defined as follows:

- primary packaging is:
  - packaging directly in contact with the food and designed to constitute a sales unit for the final consumer and,
  - packaging that allows products to be grouped together in purchase units.
- secondary packaging is used to facilitate the transport and handling of goods and protect the food product as a whole.

Packaging and parts thereof are included in the list of prohibited raw materials established by Regulation (EC) No 767/2009 on the placing on the market and use of feed. The companies transforming FFSs into animal feed (known as "processors") therefore carry out a mechanical unpacking step. This step has been added to the glossary of processes, which constitutes Part B of the Annex of the Catalogue of Feed Materials in Regulation (EU) 2017/1017. However, it is important to reiterate that according to Article 24 of Regulation (EC) No 767/2009, this catalogue is a tool for improving labelling, without prejudice to the applicable safety requirements. It should also be noted that this process was added to Part B of the Annex without specifying any requirements associated with its implementation<sup>1</sup>, whereas Annex III of the same Regulation includes "Packaging from the use of products from the agri-food industry, and parts thereof" in the list of prohibited materials for incorporation into animal feed, in Point 7 of Chapter I.

However, the mechanisation of the packaging removal process very often leaves packaging residues in the finished product. Due to its composition, packaging used in the food industry can be a vector of physical (plastic, metal or glass residues) or chemical hazards, which can pose a risk to animals, the environment and humans. There is no threshold limit for packaging residues in current European regulations. Some European countries (Germany and Belgium) have set tolerance thresholds, whose figures (varying from 0.1 to 0.2% of packaging residues in the flours obtained, depending on the country) have been established mainly on the basis of the RIKILT method or according to the As Low As Reasonably Achievable (ALARA) principle. The RIKILT method (see Chapter 2.3.1.1 of the report) is a technique for detecting and quantifying packaging residues that has been validated and recognised by the European Union. In France, no threshold has yet been set for official controls, due to an inability to justify the choice of a quantified maximum tolerated value.

Given the wide variety of packaging materials used by the food industry, it is impossible to have a complete understanding of the nature of their chemical constituents, which may be plastic, paper/cardboard, glass, metal, etc. For example, paper and cardboard may be coated with plastic, silicone or paraffin. Multi-layer packaging can combine layers of paper or cardboard with layers of plastic.

In view of the above, the Agency was asked, on the basis of current scientific knowledge, to identify the physical and chemical hazards associated with the presence of residues of packaging components commonly found in animal feed. Its opinion should specify:

- whether the identified hazards are a threat to humans, animals or the environment;
- the implications for foodstuffs derived from animals that have consumed this type of feed;
- the risks for the environment associated with the droppings of animals that have consumed foodstuffs containing packaging residues, mainly in the event of their use in agriculture (spreading);
- pairs of packaging/matrices posing a particular risk.

In order to manage the risks associated with this practice, ANSES was asked to assess:

- whether the definition of a single maximum tolerance threshold for packaging residues in feed is appropriate in terms of risk management;
  - if such a threshold is appropriate, can it technically be defined?
  - if so, what value should this threshold have?

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<sup>1</sup> In contrast to Process 56, for example, which specifies maximum levels of free aldehydes

The Agency was also asked to clarify the following points, if possible:

- the impacts of manufacturing process variables on packaging residue risks, in particular:
  - the temperature and duration of the shredding and mechanical unpacking steps (interactions between the packaging and the former foodstuffs before and during the separation step);
  - the consequences of the heat-treatment step on the mixture containing packaging residues;
- whether dilution with by-products free of packaging residues reduces the chemical risk.

## **2. ORGANISATION OF THE EXPERT APPRAISAL**

The expert appraisal fell within the sphere of competence of the Expert Committee (CES) on Animal feed (CES ALAN), which led the work, the CES on Assessment of physico-chemical risks in food (CES ERCA), and the Working Group (WG) on Assessment of substances and processes subject to authorisation in human food (ESPA WG).

ANSES entrusted the expert appraisal to the Working Group on Packaging residues. The methodological and scientific aspects of the work were regularly submitted to the CESs. They were adopted by the CES ALAN during its meeting of 14 September 2021.

Hearings were needed in order to collect data for the expert appraisal. These were carried out by the WG and involved the following professional unions:

- VALORIA: Professional union for the reuse as animal feed of by-products and waste from food production;
- SNIA and *La Coopération Agricole*: National unions for the animal nutrition industry;
- Hearing with the DGCCRF/DGAL's SCL 35 laboratory.

Visits to sites producing FFSs for animal feed (BONDA and TROTEC plants) were also organised during the expert appraisal.

However, requests to packaging unions for representative data on the levels of use of the identified chemicals remained unanswered.

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General requirements of Competence for Expert Appraisals (May 2003)".

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the <https://dpi.sante.gouv.fr> website.

## **3. ANALYSIS AND CONCLUSIONS OF THE WG ON PACKAGING RESIDUES AND THE CES ALAN**

### **3.1. Expert appraisal methodology**

#### **3.1.1. Identification of the main packaging involved**

The WG first referenced the main types of packaging used in FFS reuse practices. For this purpose, the WG drew up a list of packaging categories and the associated materials. The links between them had been established in the context of the CIMAP 3 formal request<sup>2</sup> and reflect the main types of packaging found on the market. This list of packaging and associated materials was submitted to the VALORIA professional union so that it could indicate the categories of foods in contact with this packaging. VALORIA also provided frequencies of occurrence of the packaging/food category pairs encountered within the reuse sector. This information was used to identify packaging that was not or only rarely

<sup>2</sup> ANSES opinion on the ranking of biological and chemical hazards in order to optimise food safety (2016-SA-0153)

processed in the plants, and which was therefore not considered in the work to respond to the formal request (see Table 2 of the report associated with this opinion).

### 3.1.2. Choice of animal species

Following the various hearings with professionals and visits to FFS reuse sites, the WG decided to limit the expert appraisal to the main species currently concerned by the use of FFSs in their feed: pigs, laying hens and dairy cows.

The risk assessment was carried out for these three species and for the animal products intended for human consumption derived from them. The rates of FFS incorporation in feed set by the experts are presented in the report (Table 3) and were estimated on the basis of the hearings with animal nutrition professionals.

### 3.1.3. Hazard identification and characterisation

#### 3.1.3.1. Physical hazards

Because the presence of residual packaging fragments in FFS products cannot be ruled out, it is primarily a physical hazard to animals. These particles can include glass from bottles, metal from tins or cans, and soft or hard plastic. Due to the potential presence of these physical hazards, several adverse effects on animal species consuming these FFSs can be considered: trauma, disrupted transit, and inflammation of the digestive mucosa.

#### 3.1.3.2. Chemical hazards: identification and selection of substances of concern

In addition to the physical hazards, the residual fragments may also represent a chemical hazard. To identify these hazards, the WG took the substances of concern used in the formulation of food contact materials (FCMs) as a basis for consideration. These FCMs are required to comply with the "principle of inertness", i.e. the material must not pose a danger to human health, must not lead to organoleptic changes in the food (except for active packaging), and must not alter the composition of the food (except for active packaging). This principle of inertness is expressed in terms of the overall migration limit (OML) and the specific migration limit (SML). The OML is the sum of the migrations of all the non-volatile substances that make up the material, whereas the SML is defined for an individual substance.

The experts point out that substances found in parts of primary packaging not in contact with food were not systematically assessed as FCMs, due to the presence of functional barriers that delay their migration into the food. These substances could not be considered in this assessment because they are not included on any positive list: information on their characteristics and their presence in packaging is not therefore available.

The hearings and site visits revealed that secondary packaging is removed manually before any mechanical unpacking. Nevertheless, during these site visits, the experts observed primary packaging whose outer surface was in direct contact with FFSs during storage prior to mechanical unpacking, and even secondary packaging in contact with unpackaged FFSs. The duration of this storage phase and the associated temperature conditions – which can both have an influence on migration phenomena – appear to be variable. As a consequence, the migration of substances associated with the packaging during the storage phase was taken into account through the migration limit.

The methodology for identifying substances of concern (SoCs) used in the formulation of FCMs is described in the opinion in response to the CIMAP 3 formal request (Opinion on the ranking of biological and chemical hazards in order to optimise food safety (2016-SA-0153)). The main steps of this methodology and the list of these SoCs are set out in Annex 2 of the report associated with this opinion.

To begin with, the SoCs used in the formulation of FCMs were identified. They meet all the criteria listed below:

- Substances with a known adverse effect on health;
- Substances used and intentionally added to the formulation of FCMs (unintentionally added substances were excluded from this formal request);
- Substances referenced in positive and/or inventory lists at European level (Regulation (EU) No 10/2011 on plastics, Council of Europe resolution and the EFSA Scientific Cooperation (ESCO) list). There are 82 of them.

Then, the WG selected the hazards for which there are toxicological benchmarks for humans. For the 82 SoCs previously identified and used in the formulation of FCMs, the WG decided to give priority to the human risk assessment in this expert appraisal. As some SoCs have several toxicological benchmarks, the WG made the methodological choice to consider only those for which robust health-based guidance values (HBGVs) had been identified and validated by ANSES at the time this WG was set up. This led to the list of 18 SoCs (table below), whose main applications and uses, quantities incorporated in packaging materials and migration limits are provided in Annex 3 of the report.

**List of substances of concern selected by the WG**

<b>Selected substances of concern</b>	<b>Full name</b>
<b>BPA</b>	Bisphenol A
<b>4MBP</b>	4-methyl benzophenone
<b>Acrylamide</b>	
<b>Benzophenone</b>	
<b>DIDP</b>	Diisodecyl phthalate
<b>DINP</b>	Diisononyl phthalate
<b>BADGE</b>	Bisphenol A diglycidyl ether
<b>Manganese</b>	
<b>BBP</b>	Benzylbutyl phthalate
<b>DEHP</b>	di(2-ethylhexyl) phthalate
<b>DnBP</b>	Di-n-butyl phthalate
<b>DCHP</b>	Dicyclohexyl phthalate
<b>DEP</b>	Diethyl phthalate
<b>DIBP</b>	Diisobutyl phthalate
<b>DnOP</b>	Di-n-octyl phthalate
<b>Zn</b>	Zinc
<b>Aluminium</b>	
<b>PFOA</b>	Perfluorooctanoic acid

### **3.1.3.3. Exposure assessment methodology**

- Packaging types taken into account in the assessment

It should be noted that SoCs can be found in FFSs after mechanical packaging removal due to two simultaneous phenomena:

- o migration of SoCs from the packaging into the food before the mechanical packaging removal step (not initially considered in the formal request);
- o the presence of packaging residues, containing non-migrated SoCs, in the FFSs after the mechanical packaging removal process.

The WG established four main categories of packaging: plastics, paper/cardboard, metals and alloys, and glass.

- Data on migration limits for SoCs

For data on migration limits, the WG drew on European or national regulations as well as Council of Europe resolutions, the Council of Europe's Guide on Metals and Alloys used in food contact materials and articles, the ESCO list and technical documents from the DGCCRF.

Two types of migration limit were defined: the overall migration limit (OML) and the specific migration limit (SML). The OML is the sum of the migrations of all the non-volatile substances that make up the material, whereas the SML is defined for an individual substance.

Where several SMLs were available for the same substance in the packaging, due to the associated materials (as mentioned above), the WG selected the highest SML for that substance. If SMLs were not available, the WG used the value of 60 mg/kg (OML).

- Data on the incorporation of SoCs in packaging
  - ✓ Multi-material packaging

With regard to data on the rates of incorporation of SoCs in packaging, one of the main difficulties was the fact that the same substance can be found in the formulation of several different materials, and that packaging consists of multiple different materials. In addition, material-specific regulations are not systematically harmonised. The same substance may therefore have different incorporation levels (QSi) or migration limits depending on the material in question. In this context, the WG listed all the materials used in each of the four packaging categories, and identified the SoCs that can be used in these four packaging categories and in the associated materials. Aluminium was a specific case, as it is an authorised technological additive in plastic materials, but can also be virtually the only constituent of certain types of packaging (cans, tins). The WG chose to consider only the case of aluminium as a packaging material (100% of the packaging).

The SoCs selected for the risk assessment (with the exception of the specific case of aluminium) were found in all four packaging categories. The ubiquitous nature of these SoCs is due to the fact that they are virtually all used in plastics and/or in inks and/or in varnishes and coatings (mostly in the associated materials).

- ✓ Levels of SoCs in the different materials

In order to obtain representative data on the levels of use of these SoCs in the formulation of materials, ANSES contacted various packaging unions. However, it received no response to its requests. As a result, in the absence of data from the formulators of these materials, the WG relied on expert knowledge and expertise on FCMs, as well as input data used in *in silico* predictive models to predict the migration of certain families of SoCs.

- ✓ Proportions of different materials in packaging

Nor was it possible to obtain information on the proportion of each material in the different packaging. In the absence of this knowledge, values estimated by the WG were used to determine maximum SoC QSi values for a given item of packaging, as follows:

- the highest level of this SoC was selected according to its categorisation (monomer, additive, plasticiser) within all packaging materials;
- this level in a given material was assigned to all packaging.

- Quantities of SoCs in FFSs after mechanical packaging removal

In order to determine the quantity of SoCs within the FFSs, the WG established a simplified model. Modelling took into account the two phenomena mentioned above, i.e. the migration of SoCs into the FFS before packaging removal, and the SoCs still present in the packaging residues left over from the mechanical packaging removal processes, by considering these two quantities of SoCs additively.

**The WG points out that these theoretical and extreme assumptions had to be considered due to the fact that no data were provided by the packaging industry.**

- Alternative bibliographic approach

In view of these extreme assumptions, especially for estimating SoC QSi values in packaging, the WG then studied an alternative potentially closer to the industrial conditions of packaging manufacture, which consisted in refining the data on the maximum levels of SoCs in packaging based on the literature, in order to use them as QSi values in the assessment model. These QSi data were not available for all packaging and for all SoCs: the literature only reported data on plastic and paper/cardboard packaging. It was therefore not possible to carry out this work for the other packaging types.

This approach revealed great diversity in the QSi data, probably due to differences in regulations between countries for these SoCs, regulatory changes in these levels over time, changes in the analytical techniques associated with these substances, and a high degree of variability in the incorporation of SoCs in a given type of packaging depending on its use.

Despite this great diversity and the lack of data for some "packaging x SoC" combinations, the WG decided that in the case of plastic and paper/cardboard packaging, an alternative risk assessment (RA) should be conducted to the one based on theoretical QSi values for animals, humans and the environment, using the maximum level (calculated or observed in the literature) of the SoC in the packaging in question.

In the case of the human RA, this approach was followed for the five SoCs making the greatest contribution to their HBGVs using the theoretical QSi approach (see Chapter 3.1 of the report) and was then extended to the same five SoCs for the environmental RA (see Chapter 3.3 of the report).

Regarding the animal RA, the approach was extended to the eight SoCs exceeding the toxicological benchmark value with the theoretical QSi approach (see Chapter 3.2 of the report).

#### 3.1.4. Risk assessment method

- **Assessment of the risks to humans**

The principle of this RA was to compare cumulative intakes of each SoC via the three foodstuffs of animal origin in question (pork, eggs, milk) with its HBGV in humans, using theoretical QSi and SML (or OML) values.

The WG then chose to take this RA further using QSi values from the literature for the five SoCs making the greatest contribution to their HBGVs.

These ingested quantities of SoCs were obtained from zootechnical data for the target species in question, which made it possible to calculate their ingestion of FFs and then SoCs on a daily basis, as well as from data on the apparent transfer of SoCs from their ingestion by the animal to the foodstuff of animal origin produced. When transfer data were not available for a "target animal species x SoC" pair in the literature, a value of 100% was used, which is an overestimate of the actual transfer rate, due to the likely metabolism of this SoC in the animal's body.

- **Assessment of the risks to target animal species**

For each target animal species considered separately, the approach compared intakes of each SoC via the animal's diet to a toxicological value, referred to in the report as the "benchmark value" for the animal species, calculated by extrapolation from the HBRV in humans. This was characterised from:

- a. Zootechnical data on these target species, which made it possible to calculate their ingestion of FFs and then SoCs on a daily basis.
- b. Since there are no data on specific HBRVs for each of the SoCs assessed and for each animal species studied, the WG followed the same approach to characterise the hazard in animals as that adopted to respond to the formal request on the assessment of the risks associated with "carry-over" additives<sup>3</sup>.

Thus, in order to characterise the hazard posed by the SoCs to animal health, the experts sought to assign a toxicological benchmark value to the SoC, defined as the no observed adverse effect level (NOAEL), in the animals considered in the formal request: pigs, cattle and poultry. This was obtained by dividing the NOAEL by a safety factor. Determining the benchmark value from the HBGV took into account the fact that all HBRVs considered in this formal request were derived from laboratory animal data, and therefore only a safety factor of 10 was required.

In keeping with the approach adopted for humans, the WG studied an alternative approach potentially closer to the industrial conditions of packaging manufacture, based on QSi values from literature data for the eight substances exceeding their benchmark values.

- **Assessment of the risks to the environment**

The environmental risk assessment is understood in this opinion to be the assessment of the possible impact of packaging residues due to the droppings of animals that have consumed feed containing FFs with packaging residues. The objective here was to determine, for the SoCs in the four types of

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<sup>3</sup> *Opinion on an assessment of the risks associated with the use in animal feed of former foodstuffs containing additives not authorised in animal feed (Request 2017-SA-0248).*  
<https://www.anses.fr/fr/system/files/ALAN2017SA0248.pdf>

packaging (paper/cardboard, plastic, glass and tins), the contamination of the droppings produced by the three types of livestock when fed with FFSs. It was assumed that the total quantity of a SoC ingested by the animal was found in its faeces, implying no absorption by the animal.

Therefore, for each type of livestock and each type of packaging, the aim of the approach was to estimate the contamination (for the targeted SoCs) that these unpacking practices may cause, via the animals' feed, for two environmental compartments (soil, interstitial water/surface water), in order to define the exposure levels (PEC – Predicted Environmental Concentration) and compare them to the toxicity threshold values (PNEC – Predicted No Effect Concentration). The comparison value is therefore  $PEC/PNEC = 1$ .

The approach developed in this opinion was based on the recommendations and values of the European Chemicals Agency (ECHA, 2017)<sup>4</sup> and the French National Institute for Industrial Environment and Risks (INERIS)<sup>5</sup>.

Aluminium was not considered in the assessment as there are no soil-water partition coefficient data for it, nor any PNEC data for the different compartments.

## 3.2. Results of the risk assessment

### 3.2.1. Result for humans

The report presents the contribution of each foodstuff of animal origin considered separately and the total contribution of these three foodstuffs of animal origin to the HBGVs of the different SoCs for humans, in the case of animals that have consumed FFSs containing the four types of packaging selected: plastic, paper/cardboard, metal tins or glass jars.

Regardless of the packaging in question, the cumulative contribution of the three foodstuffs of animal origin to the HBGV varied according to the SoC, with a large range of variation between 0.3% and about 68,000% of the HBGV (680 times the HBGV).

The five SoCs with the highest contributions of the three foodstuffs to their HBRVs were benzophenone, DEHP, DCHP, DnBP and PFOA.

- For benzophenone, DEHP and DCHP taken individually, the cumulative contribution of the three foodstuffs of animal origin was nevertheless lower than the HBGVs of these SoCs (contribution of 30-60% of the HBGV).
- For DnBP and even more so for PFOA, this cumulative contribution greatly exceeded their HBGVs, being nearly 10 times and 680 times the HBGV respectively. For DnBP, the main contribution was due to the consumption of dairy products followed by eggs, with pork contributing the least. In the case of PFOA, all the foodstuffs of animal origin made a large contribution to the HBGV.

As presented in the methodology, the WG decided to refine the SoC assessment by taking into account the QSi values reported in the literature. This work was carried out on the five SoCs making the greatest contribution to their HBGVs, for plastic and paper/cardboard packaging alone.

The report presents the individual contribution of each foodstuff of animal origin, and the total contribution of the three foodstuffs of animal origin to the HBGVs of these five SoCs for humans, based on their maximum levels from literature data.

- For DEHP and DCHP (regardless of the packaging) and benzophenone (paper/cardboard packaging), the total contribution of foodstuffs of animal origin to the HBGVs of these SoCs was greatly reduced and always below 100% of the HBGV.
- For DnBP, regardless of the packaging, the total contribution of foodstuffs of animal origin was also greatly reduced and ranged from 44 to 88% of the HBGV.
- For PFOA, the cumulative contribution of the three foodstuffs of animal origin came to more than 600 times the HBGV (paper/cardboard packaging, not determined for plastic packaging). All foodstuffs of animal origin made a very large contribution to the HBGV for PFOA.

<sup>4</sup> ECHA (2017) *Guidance on the Biocidal Products Regulation; Volume IV Environment – Assessment and Evaluation (Parts B + C)*. Version 2.0. European Chemicals Agency, Helsinki, Finland, October 2017

<sup>5</sup> <https://substances.ineris.fr/fr/>



### 3.2.2. Result for the target animal

#### Physical hazards

There are virtually no data in the scientific literature on the risk of trauma and inflammation from particles in the context of the animal species concerned by this formal request.

Regarding the risk of digestive tract disruption, few data are available for plastic and metal particles.

The WG could only conclude that the residual levels of glass particles in FFSs are far below the levels of soil particles consumed spontaneously by free-ranging animals, and therefore pose only a negligible risk.

#### Chemical hazards

The report presents the contribution of incorporated FFSs to the benchmark values of the different SoCs for the target animal species that consumed FFSs containing packaging made of plastic, paper/cardboard, tins or glass in their diet.

- **In pigs and laying hens**, regardless of the type of packaging, the ingestion of FFSs led to highly variable contributions to the benchmark values of these SoCs, ranging from 0.5% (4MBP) to more than 70,000% of the benchmark value (PFOA).  
The benchmark values were exceeded for the following eight substances: acrylamide, DIDP, DINP, BPA, DCHP, DEHP, DnBP and PFOA. Exceedance ranged between 104% (laying hens) and 70,000% (pigs) of the benchmark value for PFOA.
- **In dairy cows**, regardless of the type of packaging, the ingestion of FFSs led to highly variable contributions to the benchmark values of these SoCs, ranging from less than 0.1% (4MBP) to more than 60,000% of the benchmark value (PFOA).  
However, the benchmark value was only exceeded for DnBP (more than 1,300% of the benchmark value) and PFOA (more than 6,200% of the benchmark value).

As with the human RA, the WG decided to refine the assessment by taking into account the QSi values available in the literature for the eight SoCs for which FFS intake exceeded the benchmark values (> 100% of the benchmark value). It was only possible to study literature data for plastic and paper/cardboard packaging. **In pigs and laying hens**, regardless of the packaging considered in these categories, 100% of the benchmark value for DEHP, DnBP and DCHP was approached or exceeded following consumption of FFSs. For PFOA (paper/cardboard packaging), FFS consumption led to more than 600 times the benchmark value for pigs and almost 500 times that for laying hens.

**In dairy cows**, regardless of the packaging considered, FFS consumption led to a contribution below the benchmark value for all the SoCs studied, with the exception of DnBP (paper/cardboard and plastic packaging) and PFOA (cardboard packaging, more than 60 times the benchmark value).

### 3.2.3. Result for the environment

The report associated with this opinion presents the PEC/PNEC ratios of SoCs released from the droppings of pigs, dairy cows and laying hens in the different compartments (soil, interstitial water and surface water), following the ingestion of FFSs resulting from mechanical food packaging removal.

Using the theoretical maximum QSi values, the PEC/PNEC ratio was never greater than 1 for the surface water and interstitial water compartments for any of the SoCs.

The PEC/PNEC ratio exceeded 1 only for the soil compartment for four compounds: DnBP, DCHP, DEP and DIBP.

Refining the RA by considering the QSi values from the literature (alternative scenario) was therefore limited to these four compounds and to paper/cardboard and plastic packaging, for which data are available in the literature. For the soil compartment, this work could only be conducted for DnBP and DCHP. The results obtained for soil show that the PEC/PNEC ratios were less than 1 under these conditions.

### 3.3. Uncertainties

As recommended by the WG on the Methodology of Risk Assessment (MER WG), a list of the sources of uncertainty that the expert appraisal had to face was drawn up on the basis of the typology suggested by the MER WG (ANSES, 2017)<sup>6</sup>. The objective was to describe the main sources of uncertainty and their impact on the decisions made in the risk assessment process and on the conclusions reached.

Uncertainty covers all the limitations related to the collection of information and knowledge in the risk assessment process. In the context of this work, the uncertainties were mainly associated with:

- the lack of information on the composition of food packaging;
- the limits of scientific knowledge on the effect of SoCs on production livestock.

Some data were obtained through the hearings with professional unions at the start of the assessment. The representativeness of these data is not precisely known.

Moreover, some hearings could not be carried out due to a lack of response to requests. Calls for data also went unanswered.

### 3.4. WG conclusions and recommendations

Former foodstuffs (FFSs) are raw materials of nutritional value for the manufacture of compound feed. Foodstuffs that are still packaged must be unpacked either manually or mechanically if they are to be authorised in feed, to ensure that the packaging is removed before the FFSs are used for this purpose.

The issue of packaging residues that was initially identified in the formal request questions, which focused on the mechanical packaging removal step, proved to be too restrictive during the analysis. The migration of substances present in the packaging, before this mechanical packaging removal step, was therefore also taken into account by the experts, as this phenomenon adds to the contamination of FFSs by these substances. This is because mechanical packaging removal involves prior storage of packaged foodstuffs under conditions that are different from usual ones. These phases needed to be taken into account in the risk assessment, without however it being possible to integrate all the parameters relating to this practice (temperature during storage or unpacking, surface/volume ratio of the packaging, partition coefficient of the substances between the packaging and the foodstuff, presence of packaging in contact with unpackaged foodstuffs, etc.). Indeed, the model used for this risk assessment became too complex due to the variability of these parameters and the uncertainties surrounding them.

The risk assessments for humans, animals and the environment depend on three common factors influencing the model separately:

- The quantity of the substance of concern (SoC) in the packaging. Because the manufacturers contacted failed to provide information on these quantities, theoretical maximum quantities were selected by using the highest level of the SoC in a packaging material and then assigning this level to all the packaging, which grossly overestimates the amount of these SoCs in the packaging (worst-case scenario). The alternative scenario of estimating these quantities of SoCs in packaging from literature data was also studied. A comparison of the results between the two scenarios was nevertheless limited for two reasons. Firstly, the alternative scenario could only be conducted for a limited number of SoCs, and only for plastic or paper/cardboard packaging. Secondly, these literature data only partially reflect the packaging available on the market.
- The specific migration limit (SML) of the SoC in the FFS. As several SMLs were available for the same SoC, the model used the highest value, or even the maximum value of 60 mg/kg FFS (overall migration limit) when no SML value had been established for a substance. It should also be mentioned that it is theoretically possible to exceed this SML (or OML) when the temperature and/or storage time of the FFS increases.
- The level of residual packaging particles in the FFS, which remained fixed in the assessment model (0.125% (m/m)) for detectable packaging particles in the FFS.

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<sup>6</sup> "Illustrations and updating of recommendations for assessing the weight of evidence and analysing uncertainty at ANSES."

In the case of the RA for humans, an additional parameter was introduced, consisting of the bioavailability rate of the SoC between the quantities ingested and those found in the foodstuffs of animal origin. When this value was not available for a "target animal species x SoC" pair in the literature, a value of 100% was used, which is an overestimate of the actual transfer, due to the likely metabolism of this SoC in the animal's body.

In the case of the RA for the environment, it was assumed that the ingested SoCs were fully excreted, without any metabolism, body uptake or secretion into foodstuffs, which is a likely overestimate of the flows of these SoCs into the different environmental compartments.

Given the methodological considerations outlined above, the human, animal and environmental risk assessments are based on a set of parameters, one of the main ones being the quantity of a SoC in the packaging. The theoretical worst-case scenario or the alternative literature scenario led to identical conclusions for some substances, but also to contradictory conclusions for others. Neither of them appears to be more relevant: the first grossly overestimates the QSi values, while the second provides heterogeneous data, which could lead to the exposure of animals, humans and the environment being underestimated. Actual data on the quantities of SoCs for FFS packaging are therefore needed.

These data, although necessary, are not enough for conducting a rigorous RA. Indeed, the SMLs used could in some cases lead to a high concentration of the SoC in the FFS, since it was assumed that all the substance migrated at its SML into the FFS. However, the maximum SML values adopted (where there were several available) may not reflect reality. Again, therefore, data are needed to accurately quantify the SMLs of the main SoCs for the two main packaging materials considered (paper/cardboard, plastics), which constituted the majority of packaging encountered during the WG's plant visits.

Analytical data on these SoCs in FFSs after mechanical unpacking could also be used to validate this RA model, or be used directly as model input parameters.

It should also be noted that the lack of validated data on toxicological benchmark values in animals could lead to a bias in the RA of some SoCs. Lastly, the absence in the literature of a bioavailability value for SoCs in animals (transfer between the quantities ingested and those found in foodstuffs) could lead to human exposure being overestimated; analytical data on the levels of these SoCs in foodstuffs of animal origin from the target species could help to resolve this problem.

**In conclusion, given the many theoretical assumptions concerning the input data for the RA model, mainly due to the fact that no data were provided by the packaging industry, the risk to humans, animals or the environment from the mechanical removal of packaging materials from FFSs in order to feed food-producing animals cannot be accurately and robustly assessed. It is therefore not possible to propose a single tolerance threshold for packaging residues in feed on the basis of the data currently available.**

**In addition, the setting of a tolerance threshold for packaging residues following mechanical food packaging removal is not the only issue involved in guaranteeing the safety of FFSs. Storage (duration, temperature, mixing of packaged and unpackaged foodstuffs) also needs to be addressed due to its chemical (migration of FCM and non-FCM substances) and microbiological risks.**

In the absence of robust conclusions, therefore, and in order to limit the risk to humans of SoCs being transferred into animal feed and foodstuffs of animal origin, then being released into the environment, the WG recommends:

- eliminating that part of the packaging designed to constitute a sales unit or that allows products to be grouped together in purchase units, leaving only the packaging in direct contact with the FFS during storage and mechanical unpacking of FFSs;
- preventing contact between unpackaged FFSs and FFSs that still have packaging, during the storage phase;
- keeping the storage time of packaged FFSs as short as possible, and controlling the storage temperature in order to minimise the transfer of SoCs into FFSs.

#### 4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The reuse of former foodstuffs (FFSs) as animal feed is one of the actions to reduce food waste set out in Act No. 2016-138 of 11 February 2016. As packaging and parts thereof are included in the list of prohibited raw materials established by Regulation (EC) No 767/2009 on the placing on the market and use of feed<sup>7</sup>, this reuse requires the prior removal of packaging from the FFSs. For economic reasons, this mainly relies on mechanical packaging removal practices.

However, the mechanisation of the unpacking process leads to risks for humans, animals and the environment due to packaging residues frequently being left in the finished products. This potentially poses:

- physical hazards to animals;
- chemical hazards to humans, animals and the environment.

Moreover, the steps prior to mechanical packaging removal, in particular the concomitant storage of FFSs to be reused with those that have undergone an initial manual unpacking step, adds to the chemical and even microbiological risks potentially posed by these finished products, especially as such a phase brings packaging surfaces not intended to be in contact with foodstuffs into contact with FFSs.

The Agency stresses that the explicit ban on packaging and parts thereof should logically have led to the inclusion of mechanical packaging removal in the "Processes" chapter of the Catalogue of Feed Materials being accompanied by conditions to be complied with during its implementation. It also reiterates that the purpose of the catalogue in Regulation (EC) No 767/2009 does not confer on the processes it contains a status that releases those who implement it from their obligations in terms of the safety of the feed produced.

Regarding the consideration of these risks, the French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions and recommendations of the CES ALAN.

The Agency notes that at this stage, the risks to humans, animals or the environment from mechanical removal of packaging material from former foodstuffs cannot be accurately and robustly assessed, and that the assumptions made have led to the identification of risk situations. In this respect, like the experts, it regrets the fact that the packaging professionals failed to provide data in the context of this risk assessment work.

No single tolerance threshold for packaging residues in feed can therefore be proposed on the basis of the data currently available. The Agency also stresses that defining such a threshold is not the only possible management measure, as the conditions associated with the steps prior to the mechanical packaging removal can also have a strong influence on the potential risks of FFS reuse to humans, animals and the environment. These include FFE storage conditions, incomplete removal of secondary packaging, etc. Among these steps, ANSES notes that deploying the mechanical packaging removal process in such a way as to guarantee the absence of prolonged contact (during storage) between packaging surfaces not intended to be in contact with food (FCMs) and previously unpacked FFSs should help clarify the risk assessment assumptions. It would also bring this process more into line with the FCM regulations.

The Agency also reiterates that although mechanical packaging removal is identified in the processes of Regulation (EC) No 68/2013 on the Catalogue of Feed Materials, all feed must comply with the applicable requirements, in particular those of Article 4 of Regulation (EC) No 769/2009. Although motivated by considerations of avoiding waste, combined with economic constraints, the Agency believes an assessment is essential in order to control the associated risks, in particular the health risks, as part of a global approach to assessing benefits and risks.

It is therefore necessary to develop and strengthen exchanges between packaging manufacturers, the food industry and FFS processors in order to assess more accurately the risks associated with feed containing FFSs and guarantee its safety, so as to allow the reuse of resources that objectively have nutritional value.

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<sup>7</sup> Point 7 of Chapter I of Annex III to the Regulation

## KEYWORDS

Anciennes denrées alimentaires, alimentation animale, emballage, résidus  
Former foodstuffs, animal feed, packaging, residues