

ACRYRED COST Action
views on the use of concentration limits
as a part of controlling acrylamide concentrations within foods

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This document was produced by a Task Force voluntarily formed by members of the COST Action 21149 ACRYRED. It reflects the consensus opinion of the entire ACRYRED community.

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Summary

The COST Action CA21149 ACRYRED “Reducing Acrylamide Exposure of Consumers by a Cereals Supply-chain Approach Targeting Asparagine” aims to understand the potential for mitigating acrylamide formation in foods produced from grains by establishing a multi-disciplinary research and communication network which brings together plant breeders, the agricultural grain farming community, grain traders, European food processors, toxicologists, public regulators and consumer interest groups.

Commission Regulation (EU) 2017/2158 sets benchmark levels (BMLs) on acrylamide in food, which, depending on the stakeholder involved may be considered as either challenging or insufficient. The European Commission is currently considering imposition of more stringent maximum levels (MLs) for some foods. In this document, the ACRYRED community presents its viewpoint on the appropriate use of concentration limits for the control of acrylamide.

Acrylamide is formed in some foods through the Maillard reaction, which is a reaction between sugars and amino acids, specifically free asparagine, upon thermal processing. Acrylamide is a neurotoxic and probably carcinogenic substance; however, there is uncertainty on the degree to which dietary acrylamide presents risk to consumers. We believe that the scale of this uncertainty should be adequately communicated to risk managers to inform their application of the precautionary principle, and to help prioritize different risks that are present in the food chain. Although there is uncertainty whether dietary exposure can overcome detoxification and has a health impact, the evidence for genotoxicity and lack of an acceptable margin of exposure (between doses that cause a limited tumorigenic effect in animal models and estimated upper percentile human exposure) prompted some authoritative bodies, such as the EU, to consider acrylamide as an unavoidable contaminant requiring regulatory controls.

Well-functioning regulatory systems establish a tangible link between the objective of reducing consumer risk and the control measure applied. We believe there should be periodic reviews of consumer exposure to dietary acrylamide, for the purpose of evaluating the effectiveness of acrylamide controls, in order to inform risk management on how to optimize requirements to best protect consumers. We believe that there is a complementary role for BMLs and MLs as a part of exposure mitigation. Both BMLs and MLs are concentrations specified for food categories, but the latter is a legal maximum whereas the former is not, it is a management target. Carcinogenic risk is the result of both long-term background exposure from many foods each of which contribute fractionally to overall exposure, and transient spikes of exposure from specific foods. As a part of the mitigation of background exposure, BMLs are an effective tool to manage the myriad of foods involved. However, for specific foods that may cause periodic spikes of exposure significantly above the background, MLs could help enable more focused mitigation, and their application should be restricted as such. Currently, greater effort is needed on the part of enforcement agencies to verify that foods are compliant with requirements associated with BMLs. We believe this should not in itself be a justification for the introduction of MLs. Rather, the application of MLs should be justified based on scientific and/or monitoring data related to consumer exposure and not on ease of enforcement (compared to BMLs). Since MLs result in food loss, and market disruption, and prioritize the effort of both food businesses and enforcement agencies, their application to foods should be restricted to

those products that are not adequately controlled using BMLs and in themselves contribute significantly to exposure above background. Their application is also logical in the case of products specifically intended for consumers who are likely to be most sensitive to the adverse effects; i.e. infants and young children. Food businesses have a role in systematically documenting acrylamide control and mitigation such that the information is easily available for enforcement agencies. There should be transparency on how acrylamide is being mitigated in foods in-line with the expectations of existing regulation.

Background on Current Acrylamide Management

Acrylamide and similar small reactive substances have been present in foods since human ancestors began cooking and modifying the composition of foods. Such compounds are known as 'neoformed contaminants' and are formed in the course of reactions such as the Maillard reaction, which is a reaction between reducing sugars and free amino acids during thermal processing. Even before the advent of preparing food via cooking, there would have been ancestral exposure to a myriad small reactive compounds from botanical sources. As such, humans have experienced exposure to such substances over an extended period of time and have developed physiological detoxification mechanisms. Initially studied because of its wide use in industrial processes, acrylamide was shown to exert a carcinogenic effect when metabolized in experimental animal models. Although there is uncertainty whether physiological mechanisms can fully detoxify acrylamide from dietary exposure levels, the evidence for genotoxicity, combined with an inadequate margin of exposure, prompted some regulatory systems, such as the EU, to consider acrylamide as an unavoidable contaminant requiring risk management controls, in line with the concept of the precautionary principle.

As an unavoidable contaminant, a common regulatory approach is to reduce the presence of acrylamide within food, and therefore exposure, to as low as can be reasonably achieved (ALARA). This is especially the case for substances assumed to present a genotoxic and carcinogenic hazard. The current approach to risk analysis of such substances by many authorities, including the EU, is that there is no safe level of exposure that can be defined. It is therefore assumed that even very low concentrations of these substances represent a risk. This paradigm is currently challenged by evidence suggesting that low levels of some genotoxic substances do not cause adverse effects due to detoxification mechanisms (Hartwig, *et.al.* Archives of Toxicology. 2020, Volume 94, pages 1787–1877). Furthermore, it is likely that some substances managed as contaminants in food, including acrylamide, are also produced by physiological processes occurring within the body (Goempel, *et.al.* Arch Toxicol (2017) 91:3551–3560). While the debate continues on whether risk evaluation procedures should be updated, current regulatory systems remain informed by approaches that do not recognize a tolerable level of exposure for presumed human genotoxic carcinogens.

While it is not considered possible to determine a tolerable exposure within the current risk assessment paradigm of some agencies, there are established methods to determine whether an exposure is of 'low concern'. These include the concepts of 'margin of exposure' (MoE) and 'threshold of toxicological concern'. The former is a comparison between the dose associated with a low level of effect in a pivotal toxicological study and current human exposure, with a difference $\geq 10,000$ fold being considered a low concern for human health. The latter is applied when there is a lack of toxicological

data on the substance of interest. Such thresholds of concern are well accepted in a regulatory context, having been calculated from dose-response data for many substances via large databases of information from toxicological studies. Such approaches may be used in the assessment of overall exposure from the diet but are not used in the derivation of regulatory limits for individual categories of foods (as safety concerns arise from the overall exposure from all foods). It is therefore logical that, when a safety concern is identified due to exposure from all foods, the regulatory approach is to reduce concentrations in all foods under the ALARA approach.

A number of authoritative bodies have performed risk assessments on dietary exposure to acrylamide, including the Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) (*EFSA Journal* 2015;13(6):4104). The Panel concluded that there was no safety concern related to non-neoplastic effects (non-carcinogenic), but that regarding potential carcinogenicity, although human data on the association between exposure and carcinogenicity were inconclusive the calculated MoEs at that time indicated a concern based on animal evidence. Accordingly, the EC developed regulation 2017/2158, which remains implemented, establishing the requirement for mitigation measures to be applied related to BMLs for the reduction of the presence of acrylamide in food.

The process of limit setting is based on analytical data derived from both the monitoring carried out by Member States and data provided by industry, which are subject to statistical modelling. For selected food categories, the data are modelled as a distribution and an upper percentile is selected as the proposed limit. The mathematical method of determining the distribution range of concentrations for any given category and selecting the appropriate upper percentile for limit setting is not public information and so is not available for stakeholder scrutiny. One concern is the wideness of categories of foods that are identified, in terms of the diversity of products such categories encompass. The effort required to reach the target concentration, and therefore the likelihood of consistently achieving it, can vary greatly depending on the foods considered within a given category.

Although the regulatory approach is to reduce concentrations in all foods, it is often the case that there are specific categories of foods that are influential in the overall exposure due to the concentration of the contaminant combined with the quantity and frequency of consumption. In addition, there is evidence that the absorption of acrylamide into the human body depends on the food matrix. A generic approach to all foods is therefore questionable as it does not address the differences in risk between foods (*Palus, Nutrients* 2024, 16, 2032; *Marko, ACRYRED Conference* 2024). It would be logical for specific food categories or even individual types of foods to be considered as the focus of regulation, in addition to those foods that are consumed by sub-populations that are most vulnerable to adverse effects (most often considered as infants and young children).

It is important to note that although consumer exposure to acrylamide is not periodically reviewed, the limits given by the acrylamide regulation are periodically updated based on recent data on acrylamide occurrence and concentrations in foods. Such data show that acrylamide average values have been dropping in most food categories, confirming that food businesses are effectively mitigating acrylamide formation. Nevertheless, recent studies found that some cereal-grain based products may contain acrylamide above the BMLs (*Mesías, et.al. Food Chemistry: X* 31, 2025 103039.; *Breitling-Utzmann, ACRYRED Conference* 2024). The European Commission is currently considering reduction of

BMLs and imposition of MLs for some foods, including all major cereal-grain based products. On the toxicological side, evidence of innate acrylamide detoxification mechanisms in the human body and on acrylamide's mode of action as a genotoxic compound are challenging the presumption of a carcinogenic effect at low exposures, and some toxicologists question the need to update the risk assessment approach considering the possibility of establishing a tolerable intake value (Guth, *et.al. Food Chem Toxicol. 2023, Mar:173:113632*).

As an unavoidable contaminant, acrylamide will always be present in many foods in which it can form during cooking, and the ability to make meaningful reductions has become more difficult as concentrations become lower. Acrylamide concentrations can be highly variable even within individual products that are apparently well controlled in terms of ingredients, formulation and processing. This is because formation is predominantly a surface reaction during heating, which can happen extremely quickly and is influenced by minor variations in parameters. As such, all types of regulatory limits need to be translated into 'operational limits' related to individual products and manufacturers, taking into account measured and predicted variability.

It is important to periodically review consumer exposure to inform the prioritization of foods which both contribute significantly to overall exposure and which still present opportunity for further mitigation, considering also that new types of products are appearing on the market. Unfortunately, the application of the ALARA principle does not require authoritative bodies to implement such activities. Indeed, according to the norms in which the system operates, including food law, there is a requirement to reduce contaminants to as low as reasonably achievable (in all food categories), thus preventing a general interrogation of which mitigation measures are most impactful to health or whether exposure reduction is sufficient to meet a health protection goal. A closer cooperation between authority agencies and Food Business Operators (FBOs) would be useful to answer these questions, for instance by facilitating data sharing on detailed food consumption databases maintained by EFSA and monitoring acrylamide levels in different foodstuffs.

Types of Concentration Limits

Concentration limits are designed based on two fundamental criteria, each of which have sub-criteria as follows:

- The basis upon which the limit is set
 - Safety-based
 - As low as reasonably achievable (ALARA)
 - ALARA + Safety-based
- The consequence of exceeding the set limit
 - Aspirational targets (Indicative level / Benchmark level, BML)
 - Market acceptability (Maximum level, ML)

Concentration limits can be based on any combination of the above, each of which present different challenges in their setting and operation.

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It is important to be aware that the established approach for EU regulation is to set limits based on the ALARA approach (expressed as both BMLs and MLs). These are not safety-based thresholds but are commonly mis-interpreted as such by stakeholders, including enforcement bodies.

The basis upon which a limit is set

Concentration limits can be calculated from a health protection goal with the objective of meeting that goal (safety-based), or they can be set from the pragmatic perspective of the concentration for a given category of food that is currently achievable at market (ALARA). Table 1 below illustrates these principles.

Table 1: the basis upon which concentration limits may be set

Limit	Risk management objective	Type of limit	How the limit is derived
Safety-based	Prevent harm: Exposure that meets the health protection goal	Static limit	Derived from safety data: 1- Identify the health protection goal (e.g., health-based guidance value or margin of exposure) 2- translate into concentration per foodstuff
ALARA	Minimize exposure: Exposure reduction to the minimum achievable	Limit is continuously reviewed	Derived from current market practice: 1- Identify categories of foods 2- collect concentration data for these categories 3- evaluate the distribution of data per category 4- select an upper percentile concentration as the limit
ALARA + Safety-based	Minimize exposure to prevent harm: Exposure reduction to achieve health protection goal	Limit is continuously reviewed to both prioritize mitigation efforts and check progress towards a health protection goal	Derived from safety data & current market practice: 1- Identify the health protection goal 2- Set ALARA-based limits as above 3- Review exposure to determine if health protection goal has been met or progress made towards it, and identify main sources of exposure for focused risk mitigation 4- Establish either static limits or continue with ALARA while factoring exposure prioritization

SAFETY-BASED

Setting limits based on safety criteria (safety-based) is complicated by the need to evaluate prospectively the change in exposure that would result from a limit being applied to a food product (*i.e.*, what limit is appropriate to meet the health protection goal). This approach is especially complicated when the exposure results from multiple foods and where the contaminant of concern shows variable concentrations depending on different factors (*e.g.*, cooking temperature, moisture, raw materials). As such, pro-active safety-based limits are normally restricted to situations where exposure is well defined and originates from a single or limited number of sources. Furthermore, the setting of safety-based limits presupposes that there is good control over the concentration of the substance within the food, which is often not the case with acrylamide.

AS LOW AS REASONABLY ACHIEVABLE (ALARA)

Limits can be set based on ALARA (as low as reasonably achievable) which is a pragmatic approach to understand what concentration is currently possible to achieve for a given group of similar foods, then setting the limit on that basis. ALARA-based limits are set using data collected on food categories of interest. Concentration data for each food category are analysed to determine its distribution with a high percentile selected as the appropriate limit; in practice, this is understood to vary from the 80th to 95th upper percentile of the data distribution for a food category. Clearly, there are influential aspects such as the number of data points available and how representative they may be of the overall group of foods. The ALARA approach is consistent with a hazard-based policy objective of reducing certain types of substances, such as those considered as contaminants, to as low as can be achieved. The ultimate objective is to achieve the lowest concentration in every food that can be controlled by regulation, so not more than the lowest level that can be quantified in approved methods, *i.e.*, Limit of Quantification (LOQ). However, for acrylamide the level that is currently as low as reasonably achievable in most products is many times the LOQ.

There are some recognized disadvantages with the ALARA approach. A major concern is the loss of a link between the limit that is set and the purpose of the limit; *i.e.*, the protection of consumer health through exposure reduction. When a potential safety concern is identified related to the scale of exposure to a substance, and a limit is set based on the ALARA approach, the limit subsequently becomes disconnected from the health concern it is attempting to control. This is because the ALARA approach means that limits are regularly reviewed to further lower them, without necessarily considering the degree to which the public health concern is mitigated or indeed whether or not it is resolved. Such a procedure inhibits the understanding of key sources of exposure or how limits should be adjusted in the future to best mitigate consumer risk.

As mentioned above, another particular concern is how food categories for which limits are established are defined, because such categories may not follow established food categorization norms. In general, the classification of specific food products is problematic due to a wide diversity of food ingredients, recipes, compositions and processing reflecting the rich diversity of foods available in developed markets. The granularity of the category structure is important; in some cases, a food category may have a limit established despite there being a wide variety of different types of products within that

category. This may lead to difficulties for a distinct type of food in meeting the assigned limit compared to other types of food within the same category that typically contain lower acrylamide concentrations. It should be noted that from a compliance and enforcement perspective there are difficulties in the interpretation of whether a given food falls within a food category if that category is poorly defined. Guidelines for food classification made available by the EC should be improved. It should also be possible to rapidly update food categories when new foods are introduced to market or when mitigation methods can be differentially applied to foods within a given category. An extra complication not so far considered is that there are differences in absorption of acrylamide in the human body depending on the type of food being consumed and present within the gastrointestinal tract (Palus, *Nutrients* 2024, 16, 2032).

ALARA + SAFETY BASED

This approach combines the advantages of both the ALARA and Safety-based approaches whilst negating some of the disadvantages. For example, the difficulty with purely safety-based limits in extrapolating an exposure target for the whole diet to individual foods. The approach first applies an ALARA-type approach of pragmatically setting limits based on current achievability, but then also formally reviews the impact of such limits on progress towards the health protection goal to inform on the prioritization of future limit adjustment.

So far, such an approach has not been widely applied. There is a general misperception that regulatory limits are safety-based and protect consumers. The combination of ALARA and a safety-based approach to limit setting, wherein the effectiveness of the limit in meeting the protection goal is periodically reviewed, would make it obvious that ALARA-based control limits are not safety-based and that a health protection goal may not be met despite their application. Whether or not there is a safety threshold recognized for a substance, it would be logical for the ALARA + Safety-based approach to be applied. Even in situations where there is no recognized safety threshold, the approach would enable more focused risk mitigation to enhance consumer protection.

The consequence of exceeding the set limit

Several requirements can be linked to concentration limits, but there are two principal approaches. 'Indicative levels' or BMLs are treated as aspirational targets, the exceedance of which is linked to a requirement to demonstrate mitigation action on the design and production of the food, such that the acrylamide concentration is optimized and preferably reduced below the BML. This contrasts with MLs which define market acceptability, with exceedance designating the foodstuff that has been tested as non-compliant.

As discussed, MLs based on ALARA are commonly misunderstood by stakeholders as being safety-based limits, the exceedance of which means that there is an unacceptable risk to consumers. In reality, such limits reflect the ALARA principle upon which they are determined and are not necessarily linked to risk. It should be noted that most food safety risks, including those due to acrylamide in the diet, are expressed on a chronic timescale related to cumulative long-term exposure. Notwithstanding, even

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moderate exceedance of a limit is treated by enforcement bodies as a food safety incident requiring market action. Critical aspects such as the frequency and degree of exceedance could be at the discretion of individual enforcement bodies in the different Member States, creating disharmony across the EU. Table 2 illustrates advantages and disadvantages with BMLs and MLs. Currently, it is not certain whether MLs for acrylamide would provide mitigation and consumer protection greater than BMLs, however MLs would be easier to enforce and would provide strong motivation for acrylamide controls across the wider food industry.

Table 2: Advantages and Disadvantages of the enforcement actions associated with BMLs and MLs.

	Aspirational Targets (Benchmark Levels (BMLs))	Market Acceptability Limits (Maximum Levels (MLs))
Advantages	<ul style="list-style-type: none"> ➤ Important for products that were established at market before legal requirements ➤ Enable flexibility to account for acrylamide variability within individual products ➤ May be proportionate to the understanding of risk 	<ul style="list-style-type: none"> ➤ Easy to enforce (enforcement agents simply test product at market) ➤ Strong driver for compliance across the wider industry
Disadvantages	<ul style="list-style-type: none"> ➤ Significant effort required by enforcement bodies (<i>i.e.</i>, require detailed audit to review food operator data and controls). This disadvantage is significant and can lead to low enforcement ➤ Resulting lack of enforcement does not incentivise compliance across the wider industry ➤ Uncertainty on how much acrylamide in a product is considered too much. BMLs do not provide any limit of market acceptability, and therefore may result in differences between enforcement agencies, for example the use of multiples of the BML as a <i>de facto</i> ML. 	<ul style="list-style-type: none"> ➤ Does not provide flexibility to account for unpredictable variability of acrylamide within products, (even within specific products variability can be large and sporadic despite control on ingredients and processing) ➤ Causes a focusing of compliance effort on the topic, as opposed to other food safety topics that may be a greater health concern ➤ Can cause significant market disruption and costs to all stakeholders, despite unclear consumer benefit (the benefit to risk reduction of the market action) ➤ The time it takes for analysis can cause supply chain disruption, particularly for short shelf-life products like fermented cereal-based products such as sour-dough.

Views of the ACRYRED Community

Well-functioning regulatory systems establish a tangible link between the objective of reducing consumer risk and the control measure applied. In the case of potentially carcinogenic small reactive dietary substances, the concern is risk associated with chronic exposure resulting both from long term systematic exposure from many foods, which is relatively stable, and intermittent spikes of exposure. These spikes arise from the consumption of specific foods that, when added to background exposure may briefly overwhelm detoxification mechanisms, leading to potential interaction with genetic material. Therefore, it is logical to reduce general background dietary exposure while focusing on those foods that contain higher concentrations of acrylamide and may be eaten at a frequency and quantity that tangibly increases acrylamide exposure compared to background, thereby driving internal dose significantly beyond other dietary sources. The differential contribution of foods to acrylamide exposure should be clarified and periodically reviewed (presumably by EFSA).

Background exposure is determined by the foods commonly eaten that together result in a relative steady state of exposure. Managing background exposure requires all the foods to be mitigated without focus on any specific food. Within a diet, if there is a food that is a predominant exposure source, which when eaten causes transient spikes of acrylamide internal dose, this food should be considered as meriting special attention. We believe that in this situation the application of MLs could be useful in providing more focused acrylamide management.

Although there is uncertainty regarding the carcinogenic effect of acrylamide at dietary exposure levels, the ACRYRED community believes that the established approach based on BMLs remains appropriate to mitigate 'background' dietary exposure. Some control agencies from Member States and food business representatives presented data in the ACRYRED Brussels conference, 2024, confirming that BMLs were effective as a part of acrylamide mitigation for many, but not all, foodstuffs (*Breitling-Utzmann, ACRYRED Conference 2024, and see [here](#)*)

We believe that there is a complementary role for MLs and BMLs in managing different aspects of acrylamide exposure, based on effectiveness in risk mitigation, as follows:

1. When establishing regulatory controls, the systematic application of BMLs is an effective approach to manage acrylamide concentrations in types of foods that form the background exposure. In contrast, MLs should not be applied systematically but rather used to enable focused attention for exposure mitigation when there is exposure beyond the background.
2. When reviewing the effectiveness of regulatory controls, if there is a specific food that consistently does not meet the assigned BML, and it is determined that the food contributes significantly to overall exposure, a ML should be considered. Note, if the food is not in itself contributing significantly to overall exposure it should be considered how to better account for the food within the BML system, either through modification of the category BML or the establishment of a separate BML for the particular type of food.

As per point 2 above, under the existing regulatory system in the EU, limits are established for broad categories of foods within which there are many different types of foods with wide variation in

composition and production methods and therefore acrylamide concentration. If there are specific types of foods within a category that may lead to significant exposure spikes (above background exposure) it would be logical to manage them separately, also depending on the differences in absorption in the human body. We propose that MLs could be relevant for these foods.

Although it is the understanding of the ACRYRED Community that EU regulation on acrylamide seeks to avoid the prohibition of any types of foods, the application of MLs to some food categories requires care to prevent the effective prohibition of specific types of foods. Wholemeal wheat products are of specific concern: on one hand, such products are proven to be beneficial for gut and heart health and preventing some cancers, in addition to micronutrient intake, but, on the other hand, they are generally higher in acrylamide than their refined counterparts, principally due to the natural presence of free asparagine within the bran fraction. Further exacerbating this issue is that in the case of 'organic' products, it is not possible to utilise the tool of asparaginase in processing and therefore acrylamide mitigation options are limited. Risk-benefit assessment is needed to better inform risk management and wider society. The possibility that specific types of foods can bring a higher risk of acrylamide exposure, strengthens the need to enable consumers to be more informed, so that they can make knowledgeable choices. For this reason, the ACRYRED Community supports the launch of information campaigns directed at doctors, nutritionists, chefs, consumers and collective canteens, with particular attention to those serving children.

Available data indicate that BMLs applied over the past years have been successful in managing acrylamide concentrations in foods. Such data have been made available by some individual trade associations representing categories of foods, such as potato snacks (as presented by the snacks sector at the ACRYRED Conference, 2024). However, in general, data on mitigation against BMLs are not easily accessible for stakeholders such as enforcement bodies, as it is generated and held within food businesses. To facilitate meeting the requirement of existing regulation in the EU such data should be easily accessible for enforcement bodies. For this reason, we recommend that a standard template be developed and used by food operators to capture and report as requested the data and mitigation efforts undertaken. It would be helpful for the food industry to maintain a database beyond individual, sector-specific trade associations.

Given the logic and advantages of BMLs in controlling substances such as acrylamide that are highly variable within individual products, we believe that they should remain the principal method by which background exposure to acrylamide via multiple sources in the diet is managed. We believe that MLs should only be used when there is logic for a more focused mitigation related to exposure that is beyond background. The application of MLs is also logical in the case of products specifically intended for consumers who are likely to be most sensitive to the adverse effects; i.e. infants and young children.

Conclusions

The ACRYRED community believes the following:

- There is need for improvement in the capturing and communication of uncertainty around the current understanding of risks in the food chain (such as the likelihood that acrylamide is a human carcinogen at dietary exposure levels and actual human absorption). Such information is pivotal for risk managers to inform their decision-making against the criteria of the precautionary principle, to provide an appropriate basis to prioritise risk management action.
- As acrylamide concentrations in the diet are currently considered an unacceptable risk for consumer safety, it is important that consumers are adequately informed on the risk and appropriate risk management measures they may take. It is our understanding that consumers are not yet properly aware of acrylamide-related risk and mitigation, especially with aspects related to thermal processing of foods that are consumed daily.
- To improve risk mitigation, the setting and reviewing of limits should follow the 'ALARA + Safety-based' approach, which enables an initial pragmatic setting of limits followed by a more targeted prioritisation based on those foods that are most influential in exposure. The effectiveness of regulatory measures in achieving exposure and therefore risk reduction needs to be reviewed periodically. Such an approach enables a current understanding of how control measures are contributing towards a health protection goal.
- To improve acrylamide mitigation and compliance with regulated limits, it is advisable to establish subcategories within those food groups where the type of product formulation and/or processing is clearly associated with different acrylamide formation potential. This would allow for more precise monitoring of products in relation to the establishment of limits and compliance.
- Risk to consumers may result from long-term background exposure from the whole diet, and spikes of increased exposure above background due to specific foods. As acrylamide is variable within individual products, BMLs provide flexibility to manage acrylamide variability and have been shown to be effective in providing mitigation targets. However, more data are required to better qualify the effectiveness of BMLs for all food categories.
- To best mitigate consumer exposure and prevent undue market disruption with limited benefit to consumer protection, BMLs should remain the approach for products that form background exposure (the majority of products), while for foods that are identified as presenting exposure above background, there may be a justification for MLs to enable a more focused enforcement action linked to tangible reduction in overall consumer exposure.
- Since MLs result in food loss and market disruption, and prioritise the limited available resources of both food businesses and enforcement agencies, their application to foods should be restricted to those products that are not adequately controlled using BMLs and in themselves contribute significantly to exposure above background. The application of MLs is also logical in the case of

products specifically intended for consumers who are likely to be most sensitive to the adverse effects; i.e. infants and young children.

- Although BMLs have been codified for some time, they appear to have been subject to limited enforcement to date and it is not clear the degree to which the wider food industry (beyond the larger operators) is prepared for more stringent measures to be applied for acrylamide control. In particular, it is likely that the wider industry has limited experience of extrapolating regulatory limits to 'operational limits'. The consequences of acrylamide variability within a product resulting in transgression of a limit are clearly more serious if the limit is linked to market action. Greater understanding is needed of how enforcement authorities have monitored and controlled against BMLs to prepare for the application of MLs where needed.
- The application of MLs should be justified based on scientific and/or monitoring data related to consumer exposure and not on ease of enforcement (compared to BMLs). Greater transparency is needed from food operators on how products meet BMLs such that information is readily available for enforcement bodies. On the other hand, transparency in the process of limit setting is needed from current regulatory systems.