



VKM Protocol

Protocol: Food and chemical substances relevant for monitoring

The Scientific Steering Committee of the Norwegian Scientific Committee for Food and Environment

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Protocol: Food and chemical substances relevant for monitoring

Preparation of the protocol

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft the protocol. The Scientific Steering Committee assessed and approved the final protocol.

Authors of the protocol

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM. The principles reflect the collaborative nature of the work, and the authors have contributed as members of the project group and/or the VKM Scientific Steering Committee.

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Competence of VKM experts

Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third-party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Definitions used for the purpose of this report

Control plans

Control plans specifically target suspect products or the most at-risk companies with regard to the presence of undesirable substances that may pose a health risk in the food chain or a given production sector.

Food

In the Commission Regulation (EC) No 1831/2003 (2003), the following definition is given: *'Food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.* For the purpose of this report, food supplements are also considered to be food.

Food supplement/dietary supplement

Food containing concentrated amounts of nutrients or other substances that are intended to supplement the normal diet (EFSA, 2021).

Monitoring

Food monitoring is a system of repeated examination, measurement and evaluation of levels of undesirable substances, such as plant protection products, heavy metals and other contaminants.

Official controls

For the purposes of this report; "official controls" means activities performed by the competent authorities to verify compliance with regulations.

Undesirable substances in food

For the purpose of this report, undesirable substances are defined as chemical substances in food that may constitute a potential health risk, and are limited to unauthorized use levels of food additives, unauthorized substances, contaminants, natural toxins, processing contaminants and substances migrating from food contact materials.

Background as provided by the Norwegian Food Safety Authority

Food shall not contain levels of undesirable substances that can be of health concern. An extensive overview of the occurrence of substances in foods contributes to ensure consumer safety and can be obtained by monitoring. To prioritize which substances to include in the monitoring of substances, the Norwegian Food Safety Authority (NFSA) asked the Norwegian Scientific Committee for Food and Environment (VKM) in spring 2019 to provide a knowledge-based ranking of substances that may pose a potential health risk to the Norwegian consumers. The assignment was divided into three parts. Part 1; To provide an overview of undesirable substances in foods, drinks and dietary supplements that may potentially pose a health risk. Part 2; To assess and rank the substances identified in part 1, according to potential health risks. Part 3; For each of the substances identified in part 1, to describe a) which foods, drinks and/or dietary supplements are most relevant for monitoring and b) what is adequate sampling and number of samples to ensure monitoring that is representative for the occurrence in foods consumed by the Norwegian population.

NFSA received the report from VKM 16th September 2019. Part 1 and 2 were comprehensively answered. Due to time restrictions given by NFSA, part 3 was answered by expert judgment, and a systematic literature search was not performed. NFSA is now in need of a more comprehensive knowledgebase regarding the foods that are relevant for monitoring with respect to the contaminants identified and ranked by VKM. In addition, NFSA requests more knowledge regarding sampling and number of samples. The new official controls regulation (EU2017/625) obligate NFSA to submit and follow national control plans for contaminants in foods from 2023. NFSA therefore asks VKM to revisit and expand part 3 of the previous assignment.

Terms of reference as provided by the Norwegian Food Safety Authority

Assignment:

- a) For the substances identified in VKMs report “Ranking of substances for monitoring in foods, drinks and dietary supplements - based on risk and knowledge gaps (2019)”, the NFSA asks VKM to give an overview of the food/part of the food (e.g. fat versus muscle), drinks and/or food supplements consumed by the Norwegian population (e.g. based on national dietary surveys), that are relevant for monitoring.
- b) For each combination of substance and food/drink/food supplement in a), describe how sampling should be performed to
 - Obtain sufficient data on occurrence, levels, and status in Norway.
 - Be useful and relevant for exposure assessments of the Norwegian population (including vulnerable groups).

Factors that may be included in VKMs assessment of sampling (not exhaustive list):

- Number of samples (representativity)
- Aggregate samples versus single samples
- Frequency of sampling
- Season/season variations
- Geographical aspects
- Country of origin
- Preparations
- When relevant, other issues related to sampling*

*National authorities perform official controls according to regulation Forskrift om prøvetaking og analyse for offentlig kontroll av visse forurensende stoffer i næringsmidler covering the sampling, number of samples, and frequency of sampling for certain contaminants in foods. The purpose is to ensure that the foods are in compliance with the current regulations, i.e. that the in foods do not exceed the existing maximum limits. The official controls do not, however, encompass sampling to ensure that data are representative for the occurrence of substances in the foods. Most data for official controls are not representative as they are taken risk based, i.e. samples are taken where the risk of finding an exceedance of the maximum levels is high (to identify non-compliance).

1 Introduction

The data obtained from monitoring, should give a representative description of the presence of undesirable chemical substances in food. In addition, the data should be useful for the assessment of potential risks associated with chronic exposure to undesirable chemical substances in food. For the purpose of this report, undesirable substances are defined as chemical substances in food that may constitute a potential health risk, and are limited to unauthorized use levels of food additives, unauthorized substances, contaminants, natural toxins, processing contaminants and substances migrating from food contact materials.

VKM will identify food groups and food items consumed by the Norwegian population that are relevant for monitoring with regard to content of one or more undesirable chemical substances. A report useful for prioritisation and pinpointing the monitoring of chemical substances of potential health risk to the most relevant food groups and food items will be prepared. NFSA will use the report as a knowledgebase in the preparation of control plans and in the planning of other mapping and monitoring plans. An overview is given in Figure 1-1.

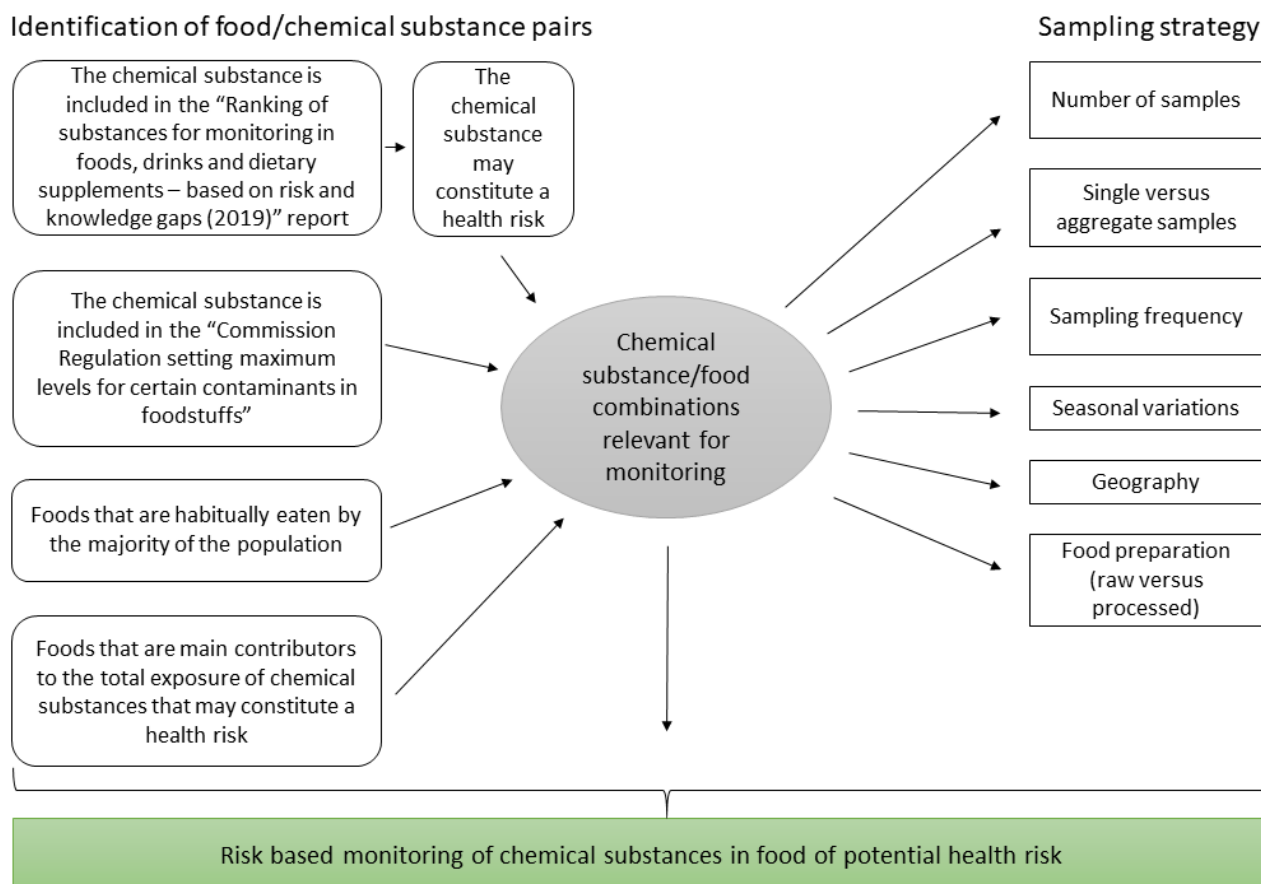


Figure 1-1. An overview of the content of the report to be prepared by VKM and the planned use areas for the NFSA (in green).

1.1 Aim and objectives

The overall aim is to establish a comprehensive knowledge base consisting of foods relevant for monitoring with respect to undesirable chemical substances that might pose a health risk, and to describe parameters important for the best sampling strategy.

The objectives:

- Develop criteria for inclusion of chemical substances
- Develop criteria for inclusion of food
- Prepare an overview of chemical substances fulfilling the inclusion criteria
- Prepare an overview of the food/chemical substance pairs
- Pinpoint sampling information considered relevant/important

2 Chemical substances

The chemical substances included in the report will be limited to:

- Contaminants included in the Commission Regulation setting maximum levels for certain contaminants in foodstuffs (Commission Regulation (EC) No 1881/2006, 2021).
Justification: NFSA need to consider these substances for the control plans.
OR
- Chemical substances/substance groups identified and ranked by VKM (VKM et al., 2019), with a combined score for toxicity and exposure of 4 or higher.
Justification: these substances might have a higher risk of causing negative health effects than the substances with lower scores.

Due to the limited time available to prepare the report, other chemical substances will not be considered for inclusion.

When substances in food cannot be identified with currently available analytical methods because the level of quantification (LOQ) is higher than the concentrations of the substance in food, a remark will be given in the report.

3 Food

Foods eaten by the Norwegian population that are relevant for monitoring of the included chemical substances (Section 2) will be identified using the national dietary surveys Spedkost 3 (Paulsen et al., 2020), Småbarnskost 3 (Astrup et al., 2020), Ungkost 3 (Hansen et al., 2015) and Norkost 3 (Totland et al., 2012), and data obtained from other dietary assessments. The habitual diet will be identified for different age groups based on the national dietary surveys. Food supplements will be evaluated separately.

Occurrence data will be obtained mainly from reports, risk assessments, and existing data bases. Depending on the available knowledge on the occurrence of a chemical substance in food, one of three approaches for the evaluation of relevance for monitoring will be applied for each substance:

- Approach 1 will be applied for the included chemical substances where occurrence data for food groups and food items that contribute to the total exposure are available.
- Approach 2 will be applied for the included chemical substances where occurrence data for food groups or food items that contribute to the total exposure are limited.
- Approach 3 will be applied for the included chemical substances where knowledge on occurrence in food are missing.

Approach 1. Occurrence data for a chemical substance in food are available and enable exposure estimation

Criteria for inclusion of food groups or food items:

- Occurrence data for a given chemical substance are available. The data could be at a detailed level such as "bread" or at a more aggregated level, such as "cereal products".
AND
- The food group or food item must have been reported to be eaten by one or more age groups covered by the national dietary surveys or other relevant dietary assessments.
AND
- The food group or food item contributes considerably to the total exposure to the chemical substance. What is considered to be a considerable contribution will be assessed for each chemical substance, based on available data, by expert judgement.

Justification: An overview of food groups and food items that contribute to the total exposure of the chemical substance, and the level of contribution, will be prepared.

Approach 2. Occurrence data for a chemical substance in food are limited, which hinders exposure estimations or introduces a high level of uncertainty in the estimations.

Criteria for inclusion of food groups or food items will be a combination of approach 1 and 3.

For the food groups or food items where occurrence data for a chemical substance are available (approach 1), the criteria for inclusion are:

- The food group or food item is considered likely to contain the chemical substance, based on available occurrence data and known occurrence in related foods.
AND
- The food group or food item must have been reported to be eaten by one or more age groups covered by the national dietary surveys or other relevant dietary assessments.
AND
- The food group or food item is likely to contribute considerably to the total exposure to the chemical substance. What is considered to be a considerable contribution will be assessed for each chemical substance, based on available data, by expert judgement.

For the food groups or food items where occurrence data for a chemical substance are not available (approach 3), the criteria for inclusion are:

- The food group or food item are habitually eaten by one or more age groups covered by the national dietary surveys and other relevant dietary assessments.
AND
- The food groups or food items combined contribute with approximately 90% of total mean dietary intake (in g/day) or approximately 90% of total mean energy intake (in kJ/day).
AND
- Information on the properties of the substance, such as e.g. solubility, will be used to pinpoint food group or food items likely to contain the chemical substance.

An overall evaluation for which food groups and food items that are relevant for monitoring will be assessed by expert judgement.

Justification: An overview of food groups or food items considered to be a contributor to the exposure of the chemical substance will be obtained, combined with an overview of food groups or food items habitually eaten that contribute to a large share of the total dietary intake in the age groups covered by the national dietary surveys.

Approach 3. Occurrence data for a chemical substance in food are not available, and exposure estimations cannot be performed

Criteria for inclusion of food groups or food items:

- The food group or food item are habitually eaten by one or more age groups covered by the national dietary surveys and other relevant dietary assessments.
AND

- The food groups or food items combined contribute with approximately 90% of total dietary intake (in g/day) or approximately 90% of total energy intake (in kJ/day).
AND
- Information on the properties of the substance, such as e.g. solubility, will be used to pinpoint food group or food items likely to contain the chemical substance.

An overall evaluation for which food groups and food items that are relevant for monitoring will be assessed by expert judgement.

Justification: An overview of food groups or food items habitually eaten that might contain the chemical substance will be obtained.

4 Sampling strategy

To provide guidance for the number of samples and sampling frequency for each chemical substance/food pair, the following points will be assessed:

- Seasonal variations
- Geography/area of production
- Degree of contribution to the total exposure to a chemical substance
- Potential health risk
- Lack of occurrence data for the chemical substance in the food groups or food items
- Whether the substance is regulated or not
- Whether the substance is approved for use in food in Norway/EU (on a positive list)

Remarks will be made about single versus aggregated samples, which part of the food that should be sampled, and sampling of raw versus ready-to-eat will be provided where relevant.

Guidelines for the sampling strategy for the different food groups or food items will be given. These guidelines will be generic, e.g. sample one of five of the most eaten bread types.

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