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Benefit and Risk Assessment of Breastmilk for Infant Health in Norway

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Authors' contributions

The authors have prepared the draft opinion. The report from the project group has been evaluated and approved by the panel on nutrition, dietetic products, novel food and allergy, the panel on contaminants and by the Scientific Steering Committee of VKM.

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Grey Literature

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ABSTRACT

The present benefit and risk assessment of breastmilk and contaminants in breastmilk was initiated by the Norwegian Scientific Committee for Food Safety (VKM). The overall objective is to provide a balanced assessment of the benefits of breastmilk against the possible risks from exposure to contaminants in breastmilk with focus on Norwegian conditions. The aim is to contribute to a foundation for decision-makers when providing recommendations on the length of exclusive and partial breastfeeding.

The composition of breastmilk is tailored for the needs of the newborn. Provided that the nutritional needs of the mother are met during pregnancy and breastfeeding, breastmilk covers all the nutritional requirements of the infant the first months of life, with the exception of vitamin D. Breastmilk also contains a number of specialised components, including growth factors, factors with anti-microbial and anti-inflammatory properties and selected immunological components which

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boost the maturation of the infant's immune system. Infant formula fulfils the infant's established nutritional needs, but does not provide the specific protective factors which are present only in breastmilk.

However, studies over the last four decades have shown that polluting chemicals have accumulated in the environment, biomagnified in the food chain, are in our bodies, and consequently in breastmilk. The levels of lipid-soluble persistent contaminants in the foetus, the newborn child and in breastmilk largely reflect the amount of these in the mother's body.

Thus, breastmilk contains nutrients and protective immunological factors which have a positive effect on infant health, but may also contain contaminants. Particularly lipid-soluble and persistent contaminants accumulate in the infant during breastfeeding. This has contributed to a debate among experts agreeing that breastfeeding is beneficial, but discussing the advisable length of breastfeeding.

Breastfeeding in Norway

Breastfeeding prevalence is higher in Norway than in most European countries. 80% of the infants are breastfed at 6 months of age and 46% at 12 months. Mean breastfeeding duration is about 10 months.

Norwegian health authorities recommend that infants are exclusively breastfed for 6 months with a total duration of at least 12 months. However, only a minority of Norwegian mothers breastfeed exclusively for the recommended 6 months. The prevalence of exclusive breastfeeding declines rapidly from 3 months onwards with only 9% being exclusively breastfed at 6 months.

Mean breastmilk consumption in exclusively breastfed infants increases from approximately 700 ml/day at age 1 month to 850 ml/day at age 6 months. The amount of breastmilk provided to the child is not very different between the partially and exclusively breastfed infants during the first 4 months. From 7 months, breastmilk consumption in partially breastfed infants may be about 500 ml/day.

There are a few conditions where breastfeeding is contraindicated. Among these are some metabolic disorders, infections and use of certain pharmaceuticals.

Nutrients and Immunological Components in Breastmilk

The positive health effects of breastmilk relates to nutritious as well as immunological properties.

An infant who is exclusively breastfed for the first 6 months of life has, provided adequate nutrition of the mother, all the nutritional needs covered with the exception of vitamin D. Therefore, worldwide, the recommended daily intake of nutrients for infants is derived from the nutrient concentrations in breastmilk multiplied with the average intake of breastmilk.

The composition of nutrients in breastmilk varies by stage of lactation, the time of day and during a given feeding. The concentration of some nutrients also varies according to the mother's diet. The energy content of breastmilk varies, but has been estimated to be about 700 kcal/L. The content of proteins and carbohydrates is relatively stable, while the fat content has large variations. The fatty acid composition and concentrations of most vitamins reflect the maternal intake, while the concentrations of most minerals are not affected by the maternal diet, except for selenium and iodine.

Breastmilk has protective properties. It contains a number of specialised components, including factors with anti-microbial and anti-inflammatory properties as well as constituents boosting the maturation of the infant's immune system. This benefits health in childhood and most likely also later in life. The milk antibodies are targeted against potential pathogens and other antigens to which the mother has been exposed. Moreover, maturation of the infant's immune system is

influenced by contact with the immune-modulating factors in breastmilk as well as dietary and microbial constituents in the infant's gut. Different components in breastmilk facilitate the establishment of a beneficial intestinal microbiota, which is important for induction of a balanced mucosal immune system. Through all these mechanisms, breastfeeding represents an ingenious immunologic integration of mother and child.

Nutrients in Infant Formula

If breastfeeding is not possible or if there is a need for more milk in addition to breastmilk, infant formula is recommended until the child is 12 months of age.

Infant formula fulfills the infant´s established nutritional needs, but does not provide maternal antibodies and innate defence factors or immunity-promoting components. The majority of the infant formulas on the Norwegian market are cow's milk-based.

Data from a national dietary survey among infants (Spedkost, 2006) showed that at 6 months of age, 43% of the infants in Norway had been introduced to infant formula, and 36% used it regularly. At 1 year of age, 43% of the infants received infant formula regularly.

Infant formulas in Norway are subject to EU regulations that cover the composition, labelling, marketing and distribution of the product. The regulations give minimum and maximum limits for nutrients for infant formulas and include some of the provisions of the WHO Code[1].

Contaminants and Microbiological Organisms in Breastmilk and Infant Formula

Breastmilk, as a reflection of the mother's body, contains low concentrations of a mixture of different contaminants. Only the most prevalent contaminants in breastmilk have been determined chemically and even fewer have been studied in humans with regard to impact on early life health.

The main focus of the present benefit and risk assessment of breastmilk are contaminants which are included in the Stockholm convention on Persistent Organic Pollutants (POPs)[2]. They can be divided into the three main groups; pesticides (DDT and HCB), other halogenated organic pollutants (dioxins and dioxin-like PCBs, non-dioxin-like PCBs, brominated flame retardants (PBDE), perfluorinated compounds (PFOS/PFOA)) and heavy metals (lead, mercury and cadmium).

In the identification and characterisation of negative health effects, combined exposures to multiple contaminants[3] from breastmilk have to some extent been taken into consideration, as several of the cohorts have been investigating the impact on health outcomes of PCBs and dioxins in combination with DDT or HCB and some in combination with mercury. Additionally, it should be noted that the contaminants studied may be considered as markers for the combined exposure of multiple contaminants, since their occurrences are often correlated.

Metal concentrations in both breastmilk and infant formula (e.g. mercury and lead) are generally low and not at levels associated with concern.

Due to national and international restrictions and bans on use, the levels of dioxins, PCBs, and pesticides (like DDTs and HCB) have declined substantially (more than 60%) in the environment and in humans the last three decades. Compared to DDTs, HCB, dioxins and PCBs, the concentration of PBDEs in breastmilk in Norway increased until approximately year 2000, after which a decline has been observed. The fluorinated surfactants PFOS and PFOA have shown a similar time trend as the PBDEs.

[1] *International Code of marketing of Breast-Milk substitutes.*
[2] *The Stockholm Convention (SC) on Persistent Organic Pollutants (POPs) is a global treaty administered by the United Nations Environment Programme (UNEP) to protect human health and the environment from chemicals, and first entered into force in 2004 (Stockholm Convention on POPs 2004 http://www.chm.pops.int). The criteria for being included in SC are persistence, bioaccumulation, potential for long-range transport, and adverse effects.*
[3] *In popular terms often referred to as the "cocktail effect".*

There are limited Norwegian data on levels of persistent organic pollutants in infant formula, but the levels reported are generally much lower than in breastmilk.

Some contaminants which do not accumulate in the food chain may also be relevant in both breastmilk and infant formula. Substances from food packaging materials, e.g. phthalates, may be present in both breastmilk and infant formula, as well as process-generated substances such as acrylamide, PAHs, furan and 3-MDCP. The hormone active substance bisphenol A (BPA) used in plastic has recently been banned in infant feeding bottles in EU and Norway. Occurrence data in breastmilk and infant formula for these substances in Norway are scarce.

The main difference between the contaminants in breastmilk and those provided by infant formula or bottle-feeding is that breastmilk generally contains higher levels of persistent organic pollutants, while most of the unwanted substances imposed by infant formula and bottle-feeding have a shorter half-life.

Infant formula may contain microbial contamination of concern, which may lead to diarrhea and in severe cases bacteraemia and meningitis. *Cronobacter* spp. (formerly *Enterobacter sakazakii*) is a rare cause of invasive infection with high death rates in newborn infants. Possible outbreak from microbiological hazards in infant formula itself or due to contaminated water is an issue in developing countries, but no such outbreaks have been registered in Norway.

Methodological Approach to this Benefits and Risk Assessment

The *benefit* assessment is based on positive health effects reported in systematic reviews and meta-analyses published within the last 10 years. This implies that VKM has not conducted its own specific literature search to reveal the epidemiological studies that have examined positive health effects of breastmilk, but summarises and discusses the health outcomes described in the included systematic reviews and meta-analyses[4].

In addition, some other reviews or single studies of high quality have been included if recent publications of relevance to the benefit assessment have appeared, or the above described reviews and meta-analyses have not commented on diseases/conditions of interest. In the VKM conclusions, most emphasis has been put on two recent systematic reviews; one from Nordic Nutrition Recommendations (2013) and one from WHO (2013).

As a basis for the *risk* assessment to identify and characterise possible negative effects of contaminants in breastmilk, a full scale systematic literature search for single studies investigating such effects associated with exposure to contaminants in breastmilk was conducted.

It was set as an absolute inclusion criterion that the studies should provide good breastfeeding data and be able to differentiate effects of postnatal exposure from prenatal exposure.

The systematic literature search resulted in 46 studies which were rated for quality (A-B-C) according to a predefined set of criteria. Of these, no studies were categorised as A, while 24 studies qualified for category B. The category C-studies were not considered further. The negative health effects of contaminants in breastmilk in this report are thus based on 24 papers from 10 cohorts conducted in seven different countries (USA, Canada, Faroe Isles, Spain, Germany, the Netherlands and Slovakia). No such data on impact on infant and child health of exposure to contaminants via breastmilk was available from Norway. Only the contaminants PCBs, dioxins, DDT/DDE, HCB and mercury were investigated in the included studies.

[4]*The included systematic reviews and meta-analyses are: Breast-feeding: A Commentary by the ESPGHAN Committee on Nutrition (including a previous WHO-report from 2007, and two other systematic reviews from 2005 and 2007). The influence of maternal, fetal and child nutrition on the development of chronic disease in later life from the Scientific Advisory Committee on Nutrition in UK from 2011. Breastfeeding, introduction of other foods and effects on health: A systematic literature review for the 5th Nordic Nutrition Recommendations from 2013. Long-term effects of breastfeeding: A systematic review from WHO also from 2013.*

Grading

There are several methods in use for grading evidence in systematic literature reviews. The grading of evidence used in this benefit and risk assessment is similar to the grading system used by the World Cancer Research Fund (WCRF) in the report Food, Nutrition, Physical Activity and the prevention of Cancer: a global perspective from 2007.

In short, the grades for the evidence are[5]:

- Convincing
- Probable
- Limited – suggestive
- Limited – no conclusion

When grading the evidence of the literature on positive health effects associated with breastmilk, VKM has graded the sum of the work by others, some of whom have not graded their results and some using grading, but various grading systems. An element of "best judgement" is thus unavoidable from our side, as there to our knowledge are no international guidelines for grading on the basis of reviews and meta-analyses.

Breastfeeding Data in Meta-analyses and Reviews for Positive Health Effects

Few of the meta-analyses, reviews or single studies used as a basis for the benefit assessment enabled differentiation of health benefits of breastmilk in a long-term dose-dependent manner. Although some of the studies support conclusions that prolonged and exclusive breastfeeding up to 6 months of age stimulates protective effects better than shorter duration, the optimal length of exclusive and total duration of breastfeeding remains to be settled.

Norwegian Contaminant Exposure Estimates and Tolerable Intake Levels

Exposure estimates for Norwegian infants were done for PCB-153, DDE, HCB, dioxins and dl-PCBs. These compounds were the only contaminants where sufficient occurrence data in Norwegian breastmilk were available. Furthermore, these compounds were investigated in the included studies on possible negative health effects associated with contaminants in breastmilk.

The cumulative amounts pr kg body weight were estimated by combining contaminant concentrations in breastmilk from Norwegian women with mean consumption of breastmilk, mean fat concentration in breastmilk and the mean body weight in children.

In general, the risks from exposure to contaminants have been assessed by international risk assessment bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or European Food Safety Authority (EFSA). Tolerable intakes have been set for some contaminants (e.g. dioxins and dl-PCBs (dioxin-like PCBs)), DDE, HCB and some fluorinated compounds).

For other contaminants, EFSA could not establish tolerable intakes due to lack of data (e.g. PBDEs and ndl-PCBs (non dioxin-like PCBs)). However, VKM has previously used a guidance value and used this for sum of six ndl-PCBs.

As long as the exposure from breastmilk is below tolerable intakes, exposure in infants is considered not to be of concern. It is important to note that tolerable intake values are values presumed to be safe. They are not equivalent to levels above which negative health effects are likely to occur. Safety margins are incorporated in the values, and exceeding the tolerable intake merely results in a reduced safety margin.

The exposure estimates indicate that the DDE and HCB exposure via breastmilk to infants is lower than the tolerable daily intakes (TDIs). The guidance value for ndl-PCBs is based on maternal

[5]*More detailed criteria given in section 10.1.*

exposure in cohorts were the infants were breastfed. Exposure estimations in Norwegian women indicate that at least 95% of Norwegian infants are exposed to ndl-PCBs below a level which can be considered tolerable.

Exceeding the tolerable intake in infants does not necessarily imply that the concentration in the infant body reaches a level of concern, and therefore the tolerable intakes of dioxins and dl-PCBs are not directly applicable for infants. The tolerable intake of dioxins and dl-PCBs has been set to ensure that the contaminant concentration in the mother (the maternal whole body concentration, expressed per kg body weight) is below the highest concentration that is considered safe to the foetus. This is the body concentration associated with intake similar to the tolerable intake. Due to the rapid growth of the infant a dilution of contaminants takes place with a slower increase in body concentration.

The dietary intake of dioxins and dl-PCBs, as recently estimated in the Norwegian MoBa cohort, was below the tolerable weekly intake (TWI[6]) for more than 97% of the participating pregnant women. This indicates a low risk associated with prenatal exposure among infants in Norway.

Contaminant Exposure in Norwegian Infants in Comparison with Infants in Included Cohorts Addressing Negative Health Effects

The Norwegian levels of PCB-153 and DDE in breastmilk are substantially lower than in most of the cohorts included in the risk part of the assessment. However, Norwegian mothers continue partial breastfeeding longer than women in most of the studies addressing negative health effects. Even when being breastfed for 2 years, the accumulated amount of contaminants in Norwegian children will not reach the maximum levels of the included cohorts. Furthermore, the highest body concentration in Norwegian infants is reached later in infancy in comparison with the included cohorts.

Additional Considerations

The present benefit and risk assessment has included studies that have separated measures of pre- and postnatal exposure and associations with the health outcomes. Effects from prenatal exposure can be assessed by e.g. investigating association between infant and/or maternal exposure levels at birth and health outcomes later in life. However, if postnatal exposure is also of importance, it may influence the associations with prenatal exposure. Further, associations between postnatal exposure and health outcome may also be influenced by prenatal exposure. Although such influence can be adjusted for in statistical analyses, residual influence cannot be ruled out. Focusing on studies separating associations with pre-and postnatal exposure was in view of VKM the best approach available for this benefit and risk assessment.

Many of the studies on negative effects on neurodevelopment included in the present assessment found an association between *prenatal* contaminant exposure[7] and increased risk – an effect not observed by postnatal exposure. Hence, assuming equal sensitivity in the pre- and postnatal period is probably a conservative approach which most likely overestimates the risk when the highest body concentration is reached as late in infancy as 12 months, as in Norway.

Benefit and Risk Assessment by Health Outcome

The literature grading forms the basis of the benefit and risk assessment. Furthermore, the evaluation of the benefits and possible risks related to breastmilk is based on Norwegian data on prevalence of breastfeeding and concentrations of persistent organic pollutants in breastmilk.

The health outcomes described in the included papers for positive and negative health effects are related to the following diseases or conditions:

[6]*The TWI for dioxins and dl-PCBs is 14 pg TEQ/kg body weight/week.*
[7]*Mostly twice or more than current Norwegian exposure.*

- Neurodevelopment
- Immune response-associated diseases including infections, asthma/wheezing and allergy, coeliac disease, inflammatory bowel disease (Crohn's disease and ulcerative colitis) and type 1 diabetes.
- Growth, overweight and obesity
- Outcomes related to the metabolic syndrome such as blood-pressure, serum-cholesterol, type 2 diabetes and cardiovascular disease
- Malignant diseases (cancer)
- Sudden infant death syndrome
- Thyroid parameters
- Sexual maturation

The VKM conclusions are organised according to health outcomes, starting with those outcomes that have been studied from both a benefit and risk point of view.

Neurodevelopment - IQ and Cognitive Development

Based on systematic reviews and meta-analyses published within the last 10 years, VKM finds that the evidence is *convincing* for an enhancing effect of breastmilk on neurodevelopment. The optimal length of exclusive and partial breastfeeding which stimulates the positive effect remains to be settled.

The grading of the scientific evidence for negative health effects from persistent organic pollutants in breastmilk on neurodevelopment is based on seven cohorts, with findings of increased risk in three cohorts (Dutch, German and Canadian cohorts). The findings were transient in the Dutch and German cohorts, whereas no follow up study from the Canadian cohort was available.

The evidence is *limited suggestive* for a negative effect from persistent organic pollutants in breastmilk on neurodevelopment at exposure levels in these cohorts. The length of exclusive and partial breastfeeding associated with the transient negative effects in some studies remains to be settled. As to mercury, this compound was only investigated in one cohort and VKM concludes that the evidence for an effect of exposure from breastmilk is *limited and no conclusion* can be drawn.

A specific confounder challenge for interpretation of studies on neurodevelopment was the lack of HOME score measurements. HOME score measurements were used in 7 of the 14 papers investigating associations between POP's in breastmilk and neurodevelopment, including the two papers which reported transient findings.

The estimated cumulative amounts per kg body weight of contaminants in infants in the Dutch, German and Canadian cohorts were higher than currently in Norway, both prenatally, early postnatally and at 1 year of age. Even with a breastfeeding duration of 2 years, the cumulative amounts of contaminants in Norwegian infants will not reach similar peak levels as the infants in the included cohorts. Furthermore, the highest cumulative amount received by present-day Norwegian infants is reached later in infancy than in infants in the included cohorts. Taking the methodological challenges and the additional considerations into account, the following conclusion is drawn:

> VKM Concludes that the Benefits of Breastmilk Clearly Outweigh the Possible Risk of Impaired Neurodevelopment from Contaminants in Breastmilk.

Immune Response-associated Diseases

Based on recent systematic reviews and meta-analyses, VKM finds that the grading of the evidence on the benefit side is *convincing* for a protective effect of breastmilk on infections, at least as long as the child is breastfed.

The evidence is *limited and no conclusion* can be drawn for a possible protective effect of breastmilk on asthma and wheezing, allergies and atopic dermatitis.

The grading of the scientific evidence for negative health effects from persistent organic pollutants in breastmilk on immune response-associated diseases is based on four cohorts, with findings of increased risk in three cohorts (Faroe Island 3, Dutch and Slovakian cohorts). The evidence is considered *limited and no conclusion* can be drawn for a negative effect from persistent organic pollutants in breastmilk on thymus weight, vaccine antibody titre, respiratory infections, asthma and wheezing. VKM notes that although the evidence is limited and inconclusive, this is mainly due to the scarcity of studies and disparate endpoint measurements. All studies investigating immunological endpoints reported some effect.

In the risk assessment of immune response-associated diseases other than infections, a major challenge was the heterogeneity within each main group of outcomes, e.g. immune response- or allergy-related diseases, where all five papers included in reality measured widely different outcomes, and different parameters of similar outcomes.

The Faroe 3 cohort had approximately 9-fold higher concentrations of PCBs than the present-day Norwegian levels. The Slovakian and Dutch cohorts had about 3 to 4 times higher mean breastmilk levels than the present levels in Norway. In the INMA (Menorca) cohort DDE was addressed, and the mean levels were 100-fold higher than in Norway.

The estimated cumulative amount per kg body weight of contaminants in infants in the Faroese, Slovakian and Dutch cohorts were higher than current Norwegian levels, both prenatally, early postnatally and at 1 year of age. Even with a breastfeeding duration of 2 years, the cumulative amounts of contaminants in Norwegian infants will not reach similar peak levels as the infants in the included cohorts. Furthermore, the highest cumulative level in present-day Norwegian infants is reached later in infancy than in infants in the included cohorts.

Four of the five studies investigating association between persistent organic pollutants in breastmilk and immunological parameters also found an association between *prenatal* contaminant exposure and immune response-associated diseases. The nervous- and immune systems undergo substantial development after birth, and have been assumed to be sensitive to chemical exposures also in the postnatal period. In the absence of knowledge, a conservative approach would be to assume that the infant is as sensitive as the foetus.

Taking the methodological challenges and the additional considerations into account, the following conclusion is drawn:

> VKM concludes that the benefits of breastmilk in terms of defence against infections clearly outweigh the possible risk of reduced resistance to infections from contaminants in breastmilk, at least as long as the child is breastfed.
>
> No conclusion can be drawn on other immune response-associated diseases due to inconclusive results on the benefit side and few and disperse studies on the risk side.

Growth, Overweight and Obesity

Based on recent systematic reviews and meta-analyses, VKM finds that the evidence is *convincing* for a protective effect of breastmilk on risk of overweight and obesity in childhood. The optimal length of exclusive and partial breastfeeding associated with the reduction in risk remains to be settled.

Grading the evidence on the risk side, VKM concludes that the evidence is *limited and no conclusion* can be drawn for a possible association between persistent organic pollutants in breastmilk and impaired growth in children. The grading of the scientific evidence for negative health effects from persistent organic pollutants in breastmilk on growth was based on three

cohorts, with negative findings in one, pointing towards reduced (and not increased) weight with increasing PCB exposure (Faroe Island 2). Infants in the Faroese cohorts have historically had substantially higher levels of contaminants in blood both at birth as well as early and late in the nursing period in comparison with Norwegian infants.

Taking the methodological challenges and the additional considerations into account, the following conclusion is drawn:

> VKM concludes that the reduced risk of overweight and obesity associated with breastfeeding clearly outweighs the possible risk presented by contaminants in breastmilk.

Thyroid Parameters

VKM concludes that the evidence for association between postnatal exposure to contaminants and parameters related to thyroid hormones is very *limited and no conclusion* can be drawn.

Type 1 and 2 Diabetes, High Blood Pressure, Crohn's Disease, Ulcerative Colitis, Coeliac Disease, Childhood Cancer and Sudden Infant Death Syndrome

VKM concludes that the evidence is *probable* for a protective effect of breastmilk on later risk of type 1 diabetes, type 2 diabetes and high blood pressure. The optimal length of exclusive or partial breastfeeding which protects remains to be settled.

VKM concludes that the evidence is *limited suggestive* for a protective effect of breastmilk on the risk of Crohn's disease, ulcerative colitis, coeliac disease, childhood cancer and sudden infant death syndrome.

No studies investigating these health outcomes in relation to contaminants in breastmilk were identified.

Overall Conclusions on Benefit and Risk Assessment of Breastmilk to Infant Health in Norway

Taking the present-day levels of contaminants in breastmilk and the long duration of breastfeeding (12 months) in Norway into account, VKM concludes that:

- The benefits of breastmilk clearly outweigh the possible risk of impaired neurodevelopment from contaminants in breastmilk.
- The benefits of breastmilk in terms of defence against infections clearly outweigh the possible risk of reduced resistance to infections from contaminants in breastmilk, at least as long as the child is breastfed.
- The reduced risk of overweight and obesity associated with breastfeeding clearly outweighs the possible risk presented by contaminants in breastmilk.
- As regards the beneficial effects of breastmilk on risk of type 1 and type 2 diabetes and high blood pressure, the evidence suggests a *probable* beneficial effect later in life. There are no studies investigating these health outcomes in relation to contaminants in breastmilk.
- No conclusion can be drawn on other immune response-associated diseases due to inconclusive results on the benefit side and few and disperse studies on the risk side.

Following a comprehensive assessment of scientific literature on the positive health effects of breastmilk and concentrations in breastmilk of compounds representing possible health hazards, and given current knowledge about concentrations of contaminants in Norwegian breastmilk and breastfeeding duration in Norway, VKM concludes that the benefits associated with breastmilk clearly outweigh the risk presented by current levels of contaminants in breastmilk. This conclusion is not affected by whether a child is exclusively or partially breastfed up to the age of 6 months and partially breastfed up to 12 months of age.

Keywords: Breastmilk; benefit risk assessment; infant; health; VKM; Norwegian Scientific Committee for Food Safety.

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