

The results of the public consultation on the draft protocol for a sunscreen risk-benefit assessment

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Introduction

The development of a protocol detailing the strategy for a sunscreen risk-benefit assessment was initiated as a VKM self-task. A web-based public consultation was open from 02 July to 15 September 2018. Overall, VKM received three comments. This document presents the outcome of the public consultation.

The result of the public consultation

Contributor	Country	Section	Comments	Answer to the comments
The Norwegian Cancer Society, Mona Stensrud	Norway	General comment	The Norwegian Cancer Society find this risk-benefit assessment of sunscreen interesting and important. We have no comments on the draft protocol.	
Norwegian Radiation Protection Authority, Lill Tove Nilsen	Norway	General comment	The Norwegian Radiation Protection Authority (NRPA) is very pleased to see this risk assessment on sunscreens being carried out. Working with UV radiation related to skin cancer and preventive actions, NRPA regularly faces questions regarding risks of using sunscreen. Many people fear possible negative effects from sunscreen ingredients, and therefore avoid using sunscreen and instead experience severe sunburns. For Public Health work it is essential to Reach out with evidence based information. NRPA has no specific comments to the protocol. In general, it seems to cover the important aspects and follow established procedures for such an assessment.	
Private, Tor Gunnar Steen		General comment	It is very good that the "sunscreen issue" is raised. Did we have so much skin cancer before we got sunscreen? No. Has skin cancer and use of sunscreen both increased? Yes. But discussing the issue without addressing that sunscreen is reducing vitamin D production dramatically is no less than a crime! It has to be addressed in the study, if not the value of the study will be very low, since the big health issue is not skin cancer, but the effect low vitamin D levels have on the increase in a number of diseases, especially because low vitamin D levels reduces the effect of the immune system.	Any influence of UV-filters on vitamin D status is already included in the protocol and is covered in the hazard section, Table 3.1-1.

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		Page: 11 Row: 240	If I understand this correctly, you will not even try to find out possible bad cocktail effects of the different ingredients in the sunscreen. People do not put on ingredients one by one. They put on the sunscreen with all ingredients. If you do not check the possible bad cocktail effects, how can you say anything about sunscreen safety? Combinations of ingredients should absolutely be checked.	Since there is a large variety of sunscreens on the Norwegian market and the products contain different mixtures of ingredients, the total number of both single ingredients and mixtures will be too high to include in the present risk assessment. The ingredients included in the risk assessment will be based of the frequency of use in the sunscreen products on the Norwegian market. Thus, VKM will not assess risk or benefit of the combination of the ingredients as such. However, the risk and benefit of the selected ingredients will all be included in an overall burden of disease analysis.
		Page: 14 Row: 277	<p>The study is centered towards the ingredients in sunscreen and it seems that it is accepted that sunscreen is a good thing – doing good used in the right way.</p> <p>What if that is not the case? I would suggest taking one step back and ask two simpl/e questions:</p> <ol style="list-style-type: none"> 1) When did the rise in skin cancer start, and when did the use of sunscreen start? 2) How does the increase of use of sunscreen correlate with the increase of skin cancer? <p>If UV radiation gives skin cancer and sunscreen protect against UV radiation, increased use of sunscreen should reduce skin cancer. But both increase – the</p>	

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			<p>use of sunscreen and skin cancer. Could then the increased use of sunscreen be the cause of the increase in skin cancer?</p> <p>Until about 10 years ago, only UVB was filtered away by sunscreens. Then also 1/3 of UVA was filtered away. UVB is according to Statens Strålevern, about 2% of the UV radiation from the sun. 98% is UVA. Then combine this information with the information that it is dangerous to get sunburn, it gives cancer. So what happens when people use sunscreen and do not get sunburn? They think they are safe, right? But 10 years ago, they still got 98% of the radiation with sunscreen. With today's sunscreen they get about 66% of the radiation. It means that with today's sunscreen, if you can stay 30 minutes in the sun before getting sunburn without sunscreen, you should not stay in the sun more than 45 minutes with sunscreen to get the same radiation dose. But people stay in the sun for 3 to 4 hours. Feeling safe because they do not get sunburned.</p> <p>If you see the sunburn as a warning system for the body: "Now you have been too long in the sun – get into the shadow or put on clothes". This warning system is shut down by the sunscreen, people stay much longer in the sun since they feel safe, get a larger dose of radiation and get more skin cancer.</p> <p>This aspect should absolutely be a part of the risk - benefit assessment. And the information is easy to find, just ask the producers when they got into the market with different products and their production and sales of those products. It is a simple task to conduct. Then see how it correlates with skin cancer increase.</p> <p>The body has adapted to the sun for millions of years, sunscreen showed up recently. Skin cancer has increased dramatically recently. Maybe going back, drop</p>	<p>VKM has not performed the risk-benefit assessment yet and has no opinion on the outcome, whether the risk of using sunscreen outweighs the benefits or vice versa. The risk-benefit assessment will take these questions into consideration.</p>

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			<p>sunscreen, listening to the body and sunbath on the premises of the body will reduce skin cancer again? It would not surprise me...</p> <p>By the way, this effect of use of sunscreen is also mentioned in the VKM report 2007:37 "Risk assessment related to solar radiation and the use of sun protection products".</p> <p>In the report "Føflekkreft – forekomst, årsaker og forebyggende tiltak" from 2015, last paragraph of «Årsaker» page 12 it says:</p> <p>«Det er mye som tyder på at økningen i føflekkreft skyldes økt eksponering for sollys, og nærmere bestemt den delen av sollyset som er i det ultrafiolette området. Mye av denne konklusjonen er basert på svak dokumentasjon og ekstrapolering fra undersøkelser innen korte tidsperioder. Det er ikke mulig å fastslå med sikkerhet hvor stor del av økningen som skyldes økt soleksponering, og det er grunn til å ha øynene oppe for andre miljøfaktorer som kan være med å forklare økningen i kreftforekomst» First it states that the increase in skin cancer most likely is linked to increase in sun exposure. But then it says that the evidence for such conclusion is very weak, and it is needed to look elsewhere to try to find the cause of the increase.</p> <p>This reports also seem to accept that we are more in the sun than before and get more UV exposure. Is it really so? Being 60 years, I remember my young days playing out every day in the sun with my friends. Now most activity is moved indoors. Both the organized sports and the unorganized activities like playing games on PC and alike. What has changes is how we sunbath. In the old days people got the sun from the spring and the skin got a natural sun protection trough UVB melanin production. The skin was therefore relatively good protected when summer came with higher sun intensity. Today we stay indoors until we go</p>	

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			<p>on holiday and get a lot of sun exposure in a short period. And in addition, we put on large amounts of sunscreen, hindering also the vitamin D production.</p>	<p>Thank you for sharing your thoughts. Again, the proposed assessment will aim to answer whether the risk of using sunscreen outweighs the benefits or vice versa. It is outside the scope of the present risk assessment to assess all possible reasons for the increase in skin cancers.</p>
		<p>Page: 15 Row: 288</p>	<p>The listed databases do not cover vitamin D well. You need to find other databases covering that issue. Look at this study https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3356951/ This study is listed in the PubMed database. Another good place to find Vitamin D studies is https://vitamindwiki.com/VitaminDWiki As we speak, there are 96 studies on vitamin D and skin cancer. All these studies are published in different publications and listed here.</p>	<p>Thank you for the suggestions. VKM will consider the best suited databases for the purpose, and the literature search and inclusion/exclusion criteria for the literature will be described in the final opinion.</p>

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		Page: 27 Row: 432	<p>Here you seem to try to find benefits by the sunscreen itself. In line 173 you mentioned vitamin D as a positive effect of UVB radiation. That means that it is beneficial not too use sunscreen, to be able to produce vitamin D. That aspect is not covered. Not producing vitamin D could also be seen as a hazard using sunscreen. Where you put it is up to you, but not going into this very important aspect/effect of using sunscreen is not acceptable in a report like this. There are also studies finding that having good vitamin D blood levels reduces the mortality rate in skin cancer and other cancers.</p> <p>If vitamin D is not a part of this study, the main objective in line 216 must also be limited since you cannot fill that objective if reduced vitamin D production is not part of your study. It is an overwhelming number of studies showing that a lot of diseases increase with the distance from equator. All autoimmune diseases, cancer and Diabetes 1. Vitamin D is so important for so many diseases, therefore it is impossible to make a Hazard evaluation of sunscreen without addressing its effect on reduced vitamin D production and the effect which is a disease increase in all lifestyle diseases.</p>	Any hazards related to the use of the selected sunscreen ingredients will be covered, please see Table 3.1-1.