

Prof. Dr. Werner Bergholz
Werner.bergholz@isc-team.eu

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Risk analysis Implementation of rapid Covid-19 tests and through PCR tests

Revision level 4

Table of Contents

1.	summary	Page 2
2	Introduction and structure of the analysis	page 4
3	Risk and hazard analysis	page 5
4	Discussion of the analysis results in the context of	page 14
	social reality	
5	Conclusions / recommendations for action	page 16
	revision history	page 17

1. Summary

- I) The rapid antigen tests contain gold nanoparticles and in at least one case a chemical that has not been approved in Europe and has now received an exemption. All of these substances are harmful to health and the environment. All package inserts for rapid tests that have been examined to date contain chemicals that are hazardous to health. A spit test is based on carbon nanotubes, also a nanomaterial that is fundamentally subject to the European REACH chemicals regulation.
- II) According to scientific studies, it can be assumed that the swabs for both the rapid antigen tests and the PCR tests from ethylene oxide (EO) sterilization contain 50 times as much EO on the surfaces as the daily permitted amount for occupationally exposed persons. Food must not contain any EO at all, as it is

extremely carcinogenic and mutagenic. Sterilization with gamma rays (R), which is sometimes indicated on the packaging, would be harmless, but sterilization of several million pieces a day seems unrealistic due to the high costs and limited radiation capacities and therefore implausible without a certificate confirming the radiation.

- III) Additional damage is caused by the abrasive swabs, as they injure the mucous membranes, often lead to nosebleeds, leave foreign bodies on the mucous membranes and, in extreme cases, have led to the escape of brain water from nasal swabs.
- IV) The protective measures required in the package inserts because of the hazardous substances are inconsistent, ranging from no information to around 80% of the protective measures that actually need to be mentioned. Package inserts for lay use often completely omit important information about hazardous substances and protective measures and usually do not contain any detailed information about the chemicals at all.
- V) Conducting the tests by laypersons in a home environment or in classrooms violates general safety regulations for the handling harmful chemicals and in at least one case against the provisions of the European chemicals regulation REACH and was therefore illegal before the granting of an exemption.
- VI) The mass use of rapid antigen tests and PCR tests is pointless because, realistically speaking, they cannot have any positive effect on the course of infection. This applies in particular to the use in schoolchildren, for whom the risk of hospitalization (i.e. a severe course) is negligible, and schoolchildren also do not pose a significant risk of infection for other age groups. However, this also applies to everyday working life, since the risk for those under sixty is also very small, comparable to the risk of a medium-sized flu.
- https://www.bundestag.de/resource/blob/843532/1aca5ffd3465fef8dd7f1e5a4628b00d/19_14_0337-16_Prof-Dr-Werner-Bergholz_IfSG-data.pdf)
- VII) It is recommended that the rapid antigen tests should only be used by qualified personnel in laboratories equipped for this purpose and only in the case of symptomatic people.

2. Introduction

If the plans of the federal government and the states to introduce regular compulsory tests in schools, companies, shops and other institutions where many people come together are implemented across the board, then this will lead to many millions of quick tests every day, contingents of 16 million Tests per week are planned and appear realistic. The random PCR tests instead of rapid antigen tests prescribed in some federal states will also lead to an increase in weekly PCR tests by well over a million tests per week, which will reach the limits of laboratory capacity. In addition to the predictable flood of false positives and because of the relatively bad ones

Sensitivity between 20 and 50% "overlooked" really infected people in the rapid antigen tests, there is a much bigger problem that has not been present in the public discussion until now:

AllThe antigen test kits considered so far contain several hazardous substances and therefore the implementation is inevitably associated with risks for the health of the users and for their surroundings and the environment. The question is how likely it is that there are health hazards in a test. It is explained in the next section that even with the greatest care, without proper protective measures (which are often omitted in the package inserts for lay use) there will be a rate of contamination / contact with skin etc. in many cases.

This is confirmed in a preprint of a scientific publication (medRxiv preprint doi:<https://doi.org/10.1101/2020.12.05.20244673>; this version posted December 7, 2020.): 4 tests were examined. Six criteria were used for the evaluation, including the risk of contamination with the chemicals during use. For all four tests considered, the risk of contamination was found to be the worst of all six evaluation criteria considered.

In view of the large number of tests carried out every day, even a very small probability of errors in the performance of the antigen rapid tests by laypersons, which lead to the release or incorporation of the hazardous substances, is unacceptable. Everyone has had the experience that when gluing things together with, for example, the owl, you occasionally get glue on your fingers. It seems just as likely that after "fiddling around" with the test kits you unnoticed have reagents on your fingers.

In order to gain more clarity here, a risk analysis is carried out in three steps in Section 3:

1. List of hazardous substances
2. Damage that can be caused by the hazardous substances
3. Assumed effectiveness of protective measures

In section 4, the results of the analysis are discussed and put into context, in section 5 conclusions and recommendations are presented.

3. Risk and hazard analysis

3.1. Health hazard from swabs

Probably the greatest health hazard comes from the smear sticks. This applies to both the antigen rapid tests and the PCR tests.

The sticks are exposed to the sterilizing gas ethylene oxide in the foil packaging. This gas penetrates through the foil packaging and slowly outgass again after the treatment, but not completely because of the adsorption on the surfaces. The problem is: This gas is extremely carcinogenic. Lt. the safety data sheet from Linde (https://products.linde-gas.at/sdb_konformant/C2H4O_10021703DE.pdf) the following health risks exist:

- Acute Toxicity (Ingestion) Category 3 H301: Toxic if swallowed.
- Acute Toxicity (Inhalation - Gas) Category 3 H331: Toxic if inhaled.
- Skin corrosion Category 1A H314: Causes severe skin burns and □ eye damage.
- Serious eye damage Category 1 H318: Causes serious eye damage.
- Germ Cell Mutagenicity Category 1B H340: May cause genetic defects.
- **Carcinogenicity Category 1B H350: May cause cancer.**
- Toxic for reproduction Category 1B H360Fd: May damage fertility. Suspected of damaging the unborn child.
- Specific Target Organ Toxicity - Single Exposure
- Category 3 H336: May cause drowsiness or dizziness □ H335 May cause respiratory irritation.
- Specific target organ toxicity - repeated exposure
- Category 11. H372: Causes damage to organs

Reliable information as to whether and how much of the gas is still left in the Swab remains, according to a publication from 2004 (AD

Lucas et al, "Damage of Office Supply, Personal Use Items, and Over-the-Counter Medical Devices after Sterilization by Ethylene Oxide Gas, Electron Beam, and Gamma Radiation", Management and Technology 38, page 476ff, November/December 2004):

Prof. Dr. Werner Bergholz, risk analysis for conducting Covid-19 tests

After that, there are still 149 µg / g ethylene oxide on Q-tips (which are roughly comparable to swabs) months after fumigation. This is a quantity of substance that is by no means negligible, considering that this substance comes into intensive contact with the mucous membranes of the nose.

According to a document from the Federal Institute, however, no ethylene oxide is permitted in food at all and, depending on body weight, the daily intake of persons exposed occupationally is limited to 2 - 3 µg, i.e. one fiftieth of the amount on the test sticks (Figure 1a)! A statement by the German legal authorities

Accident insurance that there are no EO residues on the sticks is questionable without evidence, eg through a measurement in an accredited laboratory, in view of the scientific work cited above (Figure 1b).



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Bundesinstitut für Risikobewertung

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Gesundheitliche Bewertung von Ethylenoxid-Rückständen in Sesamsamen

Aktualisierte Stellungnahme Nr. 024/2021 des BfR vom 20. Juli 2021*

... Diese „Aufnahmemenge geringer Besorgnis“ hat das BfR für Ethylenoxid mit 0,037 Mikrogramm je Kilogramm Körpergewicht und Tag (µg/kg KG/Tag) berechnet. In Übereinstimmung mit der EFSA verwendet das BfR diesen Ansatz jedoch nicht zur Entscheidung über die Zulassungsfähigkeit von Pflanzenschutzmitteln, die Festsetzung von Rückstandshöchstgehalten oder die Genehmigungsfähigkeit von Pflanzenschutzmittelwirkstoffen. Der Ansatz sollte keinesfalls weder als Grundlage zur Feststellung der Verkehrsfähigkeit von Lebensmitteln mit Ethylenoxid-Rückständen durch die Länderbehörden herangezogen werden, noch zu einer generellen Abkehr vom Minimierungsgebot für genotoxische Kanzerogene ohne Schwellenwert führen.

Figure 1a: Permissible amount of ethylene oxide per kg of body weight for occupationally exposed persons according to a document from the Federal Institute for Risk Assessment

komm mit mensch
Sicher. Gesund. Miteinander.

Stellungnahme des Koordinierungskreises für Biologische Arbeitsstoffe (KOBAS) und des Koordinierungskreises für gefährliche Arbeitsstoffe (KOGAS)

Mögliche gesundheitliche Gefährdungen durch die Anwendung von SARS-CoV-2-Schnelltests

11.05.2021

... Die Sterilisation erfolgt üblicherweise in vollautomatisch programmgesteuerten Gassterilisatoren. Das Verfahren ist streng reguliert (u.a. Gefahrstoffverordnung, TRGS 513, Medizinproduktegesetz, Medizinproduktebetriebsverordnung) und stellt mit programmgesteuerten Desorptionsphasen sicher, dass nach der Sterilisation kein Ethylenoxid auf dem Sterilgut verbleibt. Sorgen, dass möglicherweise bei Importware Ethylenoxid auf dem Sterilgut wegen nicht sachgerechter Sterilisation vorhanden ist, sind unbegründet. In Hinblick

MANAGEMENT & TECHNOLOGY

Damage of Office Supply, Personal Use Items, and Over-the-Counter Medical Devices After Sterilization by Ethylene Oxide Gas, Electron Beam, and Gamma Radiation

Anne D. Lucas, PhD; Katharine Merritt, PhD; Victoria M. Hitchins, PhD

Table 2. EO* residual concentration for items sterilized in the spring. ND indicates not detected. The limits of detection were approximately 5 µg/ml for EO.

Item	Notes	EO µg/g
Cotton swabs, Q-tips		148.83

November/December 2004

Figure 1b: Statement by the DGUV that no ethylene oxide remains on the test strips (left) contrasts with the investigation of EO residues on everyday objects after EO sterilization cited above (right). Without metrological evidence of the statement of the DGUV, this is to be considered dubious.

The hazard potential of ethylene oxide is increased by the fact that the swabs are not comparable to cotton swabs because they are "prickly" on the outside because they are intended to scrape cells from the nasal mucosa. In other words, the sticks act like sandpaper and injure the mucous membrane or worse, individual spikes can break off and then remain in the nose. It cannot be ruled out that they then act in a similar way to asbestos fibers, in conjunction with the carcinogenic ethylene oxide residues.

Finding 1:

The test sticks pose an immediate health risk due to EO residues, injuries to the mucous membranes and material residues remaining on the mucous membranes.

3.2. Hazardous substances in rapid antigen tests

According to the package insert from a well-known manufacturer (distributor Roche, production by an external company Biosensor in Korea), the following substances are included:

“Reagents

- *Mab anti-COVID-19 antibodies*
- *Mab anti-Chicken-IgY*
- *Mab anti-COVID-19 Antibody-Gold Conjugate*
- *Purified chicken-IgY-Gold conjugate”*

The gold conjugate is gold nanoparticles with a diameter of approx. 50 nm /Ref. 1/.

The list of warnings is remarkable:

Vorsichtsmaßnahmen und Warnhinweise
Die Packung enthält Bestandteile, die gemäß der Verordnung (EG) Nr. 1272/2008 wie folgt klassifiziert sind:

Warnung:

H317 Kann allergische Hautreaktionen verursachen.
H319 Verursacht schwere Augenreizung.
H412 Schädlich für Wasserorganismen, mit langfristiger Wirkung.

Prävention:

P261 Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden.
P273 Freisetzung in die Umwelt vermeiden.
P280 Schutzhandschuhe/Augenschutz/Gesichtsschutz tragen.

Reaktion:

P333 + P313 Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
P337 + P313 Bei anhaltender Augenreizung: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.
P362 + P364 Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

Für Kunden im Europäischen Wirtschaftsraum: Enthält einen besonders besorgniserregenden Stoff (SVHC): Octyl-/Nonylphenoethoxylate. Nur zur Verwendung als Teil einer IVD-Methode und unter kontrollierten Bedingungen – gem. Art. 56.3 und 3.23 der REACH-Verordnung.
Nicht in die Umwelt, Kanalisation oder Gewässer gelangen lassen.

Figure 2: Warnings in the package insert for the Roche Rapid Antigen Test

It therefore contains substances that can cause considerable discomfort and damage to health, which therefore requires the wearing of protective gloves and eye/face protection. The substances must not be released into the environment and there is a reference to a "substance of very high concern: octyl/nonylphenol ethoxylate, only to be used as part of an IVD method under controlled conditions according to Art. 56.3 and 3.23 of the REACH regulation."

The wording of the listed articles of the EU REACH regulation, which regulates the safety of chemicals in the EU area, is as follows:

REACH Art. 3.23 Scientific research and development: scientific experiments, analyzes or carried out under controlled conditions

Research work involving chemical substances in quantities of less than 1 ton per year

REACH Art. 56.3 Paragraphs 1 and 2 do not apply to the use of substances in the context of scientific research and development. Annex XIV specifies whether paragraphs 1 and 2 apply to product and process-oriented research and development and to which maximum quantities the exemption applies

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R1907R%2801%29>)

This means that these are obviously hazardous substances whose use poses significant risks to health and the environment.

For the reasons given, the Hanseatic City of Hamburg has replaced the test used millions of times by the company Biosensor, Korea, distributed by Roche, with another rapid antigen test that still contains gold nanoparticles. In the case of the chemicals in the buffer solution, these are now substances that are approved in the EU, but a safety data sheet also provides hazard warnings here.

In the meantime, there is apparently an exemption from the EU, which is absolutely incomprehensible.

The test kits from Siemens Healthineers and Boson Biotech also contain gold nanoparticles and other chemicals classified as dangerous. When testing by Boson Biotech, it is noticeable that there is not even a CE mark on the packaging.

According to the current state of knowledge, all tests are only provisionally approved, and the approvals will expire in a short time. This date is indicated on the respective packages, it is recommended to reject tests on which the date of provisional approval has expired.

Finding 2:

In particular, it should be noted that according to the European legal framework "REACH", the use of the Roche test is only permitted under controlled conditions (i.e. in a suitably equipped laboratory), which are available for scientific experiments, with expert personnel. All tests are originally intended for use by laboratories performed by knowledgeable personnel as they contain gold nanoparticles and hazardous chemicals. All other nasal swab tests researched so far also contain gold nanoparticles, and all tests contain chemicals in the buffer solution that are approved in the EU, but there is a safety data sheet for all these chemicals with safety information to be observed.

In the further part of this section (only relevant for the antigen rapid tests) - without striving for scientific rigor - it should be explained and illustrated how one should imagine the damage caused by the hazardous substances contained.

For a consideration of the damage that can emanate from the gold nanoparticles, documents that were developed within the framework of the Technical Committee ISO TC 229, Working Group 3 "Health, Safety and Environmental Aspects of Nanotechnologies" are "the" source. Documents that are available in German are listed on the DIN website in Berlin (which is significantly involved in the work on ISO TC 229):

<https://www.din.de/de/mitmachen/normenausschuesse/nmp/nationale-bodies/72366/wdc-grem:din21:123722135!search-grem-details?masking=true>

It is already evident from the list that intensive work is being done on these topics and that inhalation and incorporation by various routes appear to pose significant risks. A fundamental damage mechanism is cell damage caused by nanoparticles, which can penetrate cells due to their small size and can also overcome the blood-brain barrier. This was demonstrated directly on fish for the carbon nanotubes contained in a spit test.

A nanoparticle in a cell can lead to cell death or DNA damage.

Another relevant standard was developed by the International Electrotechnical Commission IEC, Geneva in IEC TC 113.

(https://www.iec.ch/dyn/www/f?p=103:29:1231529051683:::FSP_ORG_ID,FSP_LAN_G_ID:1315,25#3) (<https://webstore.iec.ch/publication/27780>).

The other reagents are surfactants and/or surface-active substances ("surfactants"), which cause irritation when they come into contact with the eyes or mucous membranes (besides the entry of the gold nanoparticles). Anyone who has ever gotten shampoo in their eyes knows such irritation. This effect is annoying but not permanently damaging, in contrast to the following damage path:

The effect of octyl/nonylphenol ethoxylates on the reproductive capacity of fish is another mechanism of damage from which it can be assumed that damage in this direction is also possible for people who come into contact with it or ingest the substances.

Finding 2:

The substances contained in the rapid test can, in addition to the immediate effects that impair well-being (e.g. skin or eye irritation), also cause long-term harmful effects.

In section 3.3. the protective measures are analyzed in terms of how reliably they can prevent damage and which substances require analogous protective measures.

3.3 Effectiveness of Safeguards

When using the rapid antigen test, there are therefore risks that require protective measures. The table below compares the safety instructions for 2 products with the safety measures when using low-level radioactive reagents in research and medicine:

	safety notice Package leaflet Roche	Safety instructions in the Handout of Lower Saxony Ministry of Education (Was standing 9.4.2021) Test: Boson Biotech, Xiamen, China *)	Safety measures for liquid radioactive substances (Source: mutatis mutandis from the training documents for Radiation Protection Officer Nuclear Research Center Karlsruhe, /Ref 2/)
1	Avoid inhaling .../aerosols	–	avoid incorporation
2	Wear protective gloves/eye protection/face protection	–	Wear protective gloves/eye protection/face protection
4	In the event of spills, ensure thorough cleaning with a suitable disinfectant.		In case of accidental contamination thorough cleaning with a suitable cleaning agent
5	–	Line tables with a paper towel on which tests are performed	Cover work surfaces with an absorbent pad, handle in a flat bowl, which is also equipped with an absorbent pad
6	–	The test materials can then be disposed of together in the folded paper towel	Dispose of the folded ones Documents and materials in one Radioactive waste containers
7	–	–	Take off the protective gloves in such a way that no contamination of the skin is possible through the surfaces of the gloves
	Take off contaminated clothing and wash before reuse	After the test, the tables are to be wiped down with a cleaning agent containing surfactants. Washing or disinfecting hands with soap.	After finishing the work washing the Hands and checking clothes up Contamination, if necessary wash / decontaminate contaminated clothing
7	Avoid release to the environment	Care must be taken not to spill test liquids	After completion of the work: check on spills with one contamination detector on the work surfaces, on clothing/shoes or skin. If contamination is detected, cleaning until no more radioactive substance can be detected

8th	If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention	Nor are they allowed to extraction liquid nor the get test liquid in your eyes. Should this happen, however, the eyes should be rinsed out thoroughly with running water. If symptoms or pain occur, you should immediately consult your family doctor or ophthalmologist	In the case of complaints or proven superficial contamination or Incorporations Consult doctor
9	Observe the usual precautionary measures when handling laboratory reagents. Disposal of all waste should be in accordance with local guidelines.	The test person disposes of the test kits in a rubbish bin with a tear-resistant rubbish bag, if possible. The rubbish bags are then tied tightly. The package insert for the distributed test kit states: "The test kit can be disposed of with normal household waste in compliance with local regulations".	Dispose of all contaminated materials and equipment in special Collection tanks for solid or liquid radioactive substances

*)The test kit, which is distributed to schools by the Lower Saxony Ministry of Education, contains NO safety information and has limited approval for self-use until May 24th, 2021

The comparison shows that there are clear parallels between the safety measures for low-level radioactive substances and those for the antigen rapid test kits. The safety concept for radioactive substances has been tried and tested and has been proven to work (determination also based on the author's many years of practice when working with radioactive substances).

Since the hazardous substances contained (gold nanoparticles, carbon nanotubes and tensides/surfactants) have a risk potential, which mainly consists of long-term effects from physical contact, incorporation and release into the environment, the greatest caution and care is required because the damage only occurs over the long term.

It is noticeable that the security measures for the Roche product and for the products provided by the NDS Ministry of Education each have gaps, so the security concepts are not consistent. The following points are particularly critical:

- i. **None**Safety instructions in the package insert for the Boson Biotech product that is used in Lower Saxony. This also applies to the other 3 newly analyzed rapid tests.
- ii. **None**Protective equipment prescribed for use in schools in Lower Saxony
- iii. **No way**Detect small amounts of liquid spills (in the case of radioactive substances this can be done with a Geiger counter, so the situation related to the rapid tests is more dangerous because of the lower detectability)
- iv. **No regulation**that users must have proven specialist knowledge
- v. **No controlled environment** (like in a laboratory), in kitchens possible transmission to food

- vi. **Disposal in household waste** is unacceptable in terms of impacts on water bodies and living beings. With 16 million tests per week and an estimated 100 µl of liquid, that's 1600 liters of pollutants per week!

Finding 3:

The information on safety measures is in no way sufficient, safe use can only be carried out by trained persons. One

Use by children and young people must be ruled out! Disposal in normal household waste causes serious environmental damage, since, according to a rough estimate, more than 1000 liters of environmentally harmful liquid are produced in 16 million quick tests. It is generally noticeable that the instructions for use for laypersons contain fewer or no indications of health hazards or precautionary measures compared to the instructions for use by professionals.

4. discussion the analysis results in the context of social reality

Section 3 demonstrated that the materials contained in the test kits pose significant safety risks and that there are serious gaps in the information on safety measures.

When evaluating and discussing these findings, three questions arise:

1) Is the mass and regular use of rapid antigen tests in the intended manner responsible for the safety deficiencies identified?

Based on the available facts, the answer can only be an unequivocal no. These tests must be performed by trained professionals, in an appropriate controlled environment, with appropriate protective equipment and responsible disposal.

Implementation by laypersons or children leads to significant health risks for health and the environment and is at least questionable.

In addition, before an exemption was granted, there was at least one violation of the EU REACH regulation, which must be legally evaluated and, if necessary, prosecuted.

The Roche test described above, which contains the chemical that is not approved in Europe and for which the exemption in the REACH regulation does not apply to laypersons, has now been withdrawn by the city of Hamburg.

2) Is it necessary for laypersons to carry out the tests on a large scale despite the risks to the environment and health of the users due to the infection process?

The question implicitly assumes that the strategy of frequent testing with antigen tests can serve the purpose of reducing infections. But this is NOT the case, because

- With the current prevalence of Covid-19, a calculator provided by the Robert Koch Institute shows that, under realistic assumptions, 19 of 20 positive tests with the best test kits are false positives. Initial experiences in schools in Bremen roughly confirm these calculations. Out of 40,000 tests, 120 positive antigen tests were found, of which only 15, i.e. 12.5%, were confirmed by PCR. (Source: Weserkurier from March 28th, 2021)

In my statement to the Health Committee of the Bundestag (Hearing on May 17th, 2021), with the help of the data from the Robert Koch Institute and results from the Statistics Institute of the LMU Munich, I pointed out that the risk of infection for and from students is so small that the tests are pointless and should be stopped immediately because they (as outlined here) pose significant health risks.

(<https://www.bundestag.de/ausschuesse/a14/anhoerung#url=L2F1c3NjaHVlc3NIL2ExNC9hbmhvZXJ1bmdlbi84NDA3OTItODQwNzky&mod=mod795762>)

- Due to the relatively poor sensitivity, according to studies by the Cochrane Institute, 20 to 60% of real infections are assessed as negative, i.e. the "slip" of this test is far too large for an effective reduction in infections in schools (which is very rare anyway are, see for example the study Codaq 11 of the Ludwig Maximilian University of Munich) can be expected.

https://www.covid19.statistics.uni-muenchen.de/pdfs/codag_bericht_11.pdf

Taking into account that asymptomatic people cannot infect anyone, and that symptomatic people with the current "State of alarm" will certainly stay at home, the number of missed infections is very likely to be negligible.

- **The use of the antigen rapid tests is "off label"**, meaning these tests are only validated for people with Covid-19 symptoms and are only approved for this group of people.

- According to the requirements of REACH for chemicals, use of the Roche test is only permitted for research purposes in a controlled laboratory environment. The application for mass tests in an uncontrolled laboratory environment and without scientific support is not permitted according to the REACH specification, i.e. it represents an illegal act! This is all the more the case if such an act is ordered by the authorities without obviously having carried out a risk analysis or an investigation into legality beforehand. With regard to this critical legal situation, an extremely questionable permit was apparently granted.

5. Conclusions / recommendations for action

For both the rapid antigen tests and the PCR tests, swabs sterilized with ethylene oxide pose an unacceptable health risk if NO ethylene oxide residues are permitted in food at the same time (therefore there is no limit value for food!).

Due to the health and environmental hazards presented in connection with the antigen rapid tests, it is absolutely unacceptable to give the antigen rapid tests into the hands of laypersons or even children. The use in mass tests represented a violation of the EU chemicals regulation REACH for at least one of the tests and was therefore illegal before the exemption was granted.

Mass tests do not lead to more security, but only increase the false positive PCR tests and mean that the infection process can not be tracked better, but worse.

The recommended course of action can therefore only be:

The use of mass antigen tests by laypeople is not useful and harmful and should therefore be stopped. Tests are only to be carried out by qualified personnel in medical laboratories where it makes sense, e.g. for quick clarification when symptoms are present.

For both rapid antigen tests and PCR tests, testing non-symptomatic people is pointless because a study of 10 million people in Wuhan at the end of 2020 found that this group of people does NOT cause infections.

The Covid-19 infection risks for students, and the risks posed by students, are so small that the requirement for rapid tests in schools is pointless. (see also https://www.bundestag.de/resource/blob/843532/1aca5ffd3465fef8dd7f1e5a4628b00d/19_14_0337-16-_Prof-Dr-Werner-Bergholz_IfSG-data.pdf)

Further source references:

Reference 1: Personal communication from Dr. U. Reschgenger, Federal Institute for Materials Testing BAM, Berlin, April 12, 2021

reference 2: 62nd Course on Radiation Protection, 7.1. – 18.1. 1974, Nuclear Research Center Karlsruhe, School for Nuclear Technology.

Revision history:

rev No. and Date	What has been changed	Remarks
1 from 16.4. .20 21	Creation of the document	-
2 from 26.4. .20 21	<p>1) About the</p> <p>2) chemicals in the</p> <p>3) Siemens Healthineers test kits</p> <p>4) Information that Hamburg has withdrawn the test kit distributed there</p> <p>Information on an additional risk potential from the test sticks</p> <p>Addressed the fact that the instructions for use for laypersons</p>	<p>Topic 4) is mentioned, but a legal assessment is expressly not the subject of this document, this should be reserved for lawyers and other legal experts.</p> <p>The content of this document has been created to the best of our knowledge, but no guarantee can be given for its correctness.</p>

	<p>ns leave some of the safety aspects unmentioned</p>	
<p>3 from m 22.5 . 20 21</p>	<p>1) Information about 2) on about 3) the "spikes" 4) on test sticks Information about further test kits About a spit test that contains carbon nanotubes instead of gold nanoparticles Link to my opinion at the Committee on Health of the Bundestag in the hearing on May 17, 2021: No significant risk for students and by students, quick</p>	<p>(https://www.bundestag.de/ausschuesse/a14/anhoungen?url=L2F1c3NjaHVlc3NIL2ExNC9hbmhvZXJ1bmdlbi84NDA3OTItODQwNzky&mod=mod795762)</p>

	<p>tests pointless and dangero us</p>	
<p>4fr o m th e 12. 11 .20 21</p>	<p>1) Addition al informat ion on ethylen oxide, in particul ar with regard to a docume nt from the Federal Institute for Risk Assess ment dated July 20, 2021</p> <p>Measure ments of ethylene oxide residues on the Everyda y objects, especiall y on Q- Tips</p>	<p>"Health Assessment of ethylene oxide residues in Sesame seeds" Updated Opinion No. 024/2021 of the BfR of July 20th 2021*</p> <p>A. Lucas et al, "Damage of Office Supply, Human Resources</p>
	<p>3) Informat ion on hazardo us substan ces for ethylen e oxide</p>	<p>Damage of Office Supply, Personal Use Items, and Over-the-Counter Medical Devices after Sterilization by Ethylene Oxide Gas, Electron Beam, and gamma radiation"</p> <p>Linde Safety Data Sheet</p> <p>"Possible health hazards from the Application of SARS-CoV-2 rapid tests", document of 11.5.2021.</p>

	4) Statement by Kobas from the German statutory accident insurance	
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