

Joint statement issued by the Federal Institute for Risk Assessment (BfR), Federal Office of Consumer Protection and Food safety (BVL), Robert Koch Institute (RKI)

Conclusions

1. BfR, BVL and RKI jointly conclude that the current general recommendation to abstain from eating cucumbers, tomatoes, lettuce in northern parts of Germany does not need to be upheld.
2. In addition to adherence to good hygiene practices, BfR, BVL and RKI recommend abstaining from eating raw sprouts. Households and gastronomic businesses should dispose of any sprouts currently in stock as well as any food items that might have come in contact with these.
3. BfR, BVL and RKI recommend in addition that all food products originating from a distinct producer in Lower Saxony be taken from the market.
4. BfR, BVL and RKI recommend strict adherence to good hygienic practices when handling food or caring for patients.

This notice replaces earlier recommendations issued by BfR and RKI regarding the consumption of cucumbers, tomatoes and lettuce.

State of knowledge regarding human infections

Current situation

Data from several surveillance systems established at the Robert Koch Institute confirm a decline in the number of new EHEC infections. The sentinel surveillance system established in hospital emergency departments shows that the daily number of patients presenting with bloody diarrhoea – as the first indication of a possible EHEC infection – as well as the proportion of female cases is declining. Mathematical modelling of statutory notification data taking into account the notification delay also confirms that the number of reported cases in the affected areas is continually decreasing, both using the date of symptom onset as well as the date of hospitalization. The observed decline may be due to changes in the dietary consumption of cucumbers, tomatoes and lettuce (which may indirectly have led to a reduced consumption of sprouts) or to a gradual disappearance of the source of infection.

Earlier epidemiological studies

Since May, 20, 2011 RKI together with other federal and state authorities for health and food safety has been investigating an outbreak of hemolytic uremic syndrome (HUS) in northern Germany. The cause of the outbreak could be progressively narrowed down through the analysis of several consecutive epidemiological studies that built upon one another.

For methodological reasons, the first two case-control studies were limited to exposures that were hypothesized – based on extensive exploratory interviews – to potentially explain a large proportion of cases. Epidemiological analysis of these studies showed that cases consumed raw tomatoes, cucumbers and lettuce significantly more often than healthy study participants. These findings were complemented by results of another case-control study conducted among affected customers of a canteen that revealed a strong association between the consumption of foods from the salad bar and EHEC infection. As neither the results of these studies nor available information from investigations of the food safety authorities permitted a more precise identification of the source of infections, RKI initiated further studies.

„Recipe-based restaurant cohort study“

With a high probability, the results of the „recipe-based restaurant cohort study“ finally permit narrowing down the source of the infection to the consumption of sprouts. It was possible to apply this methodological approach only after a sufficient number of restaurant customers could be identified to ensure adequate statistical power of this analysis.

To ascertain the consumption of raw fruit and vegetables by patients and controls more objectively and less dependently on memory, RKI used the following approach in the “recipe-based restaurant cohort study”: Five groups (travel groups, clubs, etc) that comprised a total of 112 participants and included 19 individuals who acquired EHEC infection were questioned regarding the foods they consumed after eating in a common restaurant. Additionally, the menus ordered by the participants were identified by means of order lists and meal receipts. The restaurant kitchen was questioned in detail regarding the preparation and the type and quantity of ingredients in each menu ordered by any of the study participants. Furthermore, available photographs taken by travel group members were analysed to confirm which food items, including toppings, were seen on the plates. The data thus gathered was analysed in a cohort approach that permits the retrospective estimation of the relative risk of infection for the restaurant customers. Results of this analysis showed that customers who ate sprouts had an 8.6-fold increased risk (95% confidence interval (CI) 1.5- ∞) of EHEC/HUS illness compared to those who did not. This study also revealed that 100% of those who contracted the illness had eaten sprouts.

Insights from case-control-studies regarding the consumption of sprouts

Patients were questioned on the consumption of a large number of animal and plant origin food products, including sprouts, in the initial intensive exploratory interviews in Hamburg on May 20 and 21. In these, only 3 of 12 patients reported having eaten sprouts. Moreover, a relevant under-ascertainment of sprout consumption seemed unlikely since the participants of this survey demonstrated an exceptionally high dietary awareness. Methodological standards in outbreak investigations call for inclusion of those exposures in the standardized questionnaires that can potentially explain a high proportion of outbreak cases. The inclusion of too many potential exposures may lead to false positive associations. For these reasons, sprouts were not included in the questionnaires of the initial case control studies. Later, more extensive interviews subsequently conducted by RKI again included the consumption of sprouts. Overall, 16 (30%) of 54 patients who could answer questions on the consumption of sprouts in the context of these extensive interviews stated having eaten sprouts within the time frame consistent with the period of acquisition of the infection.

An additional case-control-study with the goal of further differentiating among plant food products was initiated on May 29, 2011 in Lübeck, Bremerhaven and Bremen using three healthy controls matched according to age, sex and place of residence to each of 26 HUS patients. In this study, 6 (25%) of 24 cases stated having eaten sprouts in the incriminated period of infection, compared to 7 (9%) of 80 healthy controls. This association was statistically significant in univariate (odds ratio: 4.35, 95% CI 1.05-18), but not in multivariate analysis, thus limiting the explanatory power of this result. Compared to controls, cases included in this study reported eating vegetables such as tomatoes, cucumbers and lettuce more frequently, a finding in accordance with the earlier case-control-studies. However, these associations were not statistically significant. Overall, these findings are thus consistent with the results of the two previously published case-control-studies and show these vegetables to be frequently eaten together.

State of Knowledge regarding the food supply chain

So far, the EHEC pathogen O104:H4 was not detected in any food product from the retail market. A definitive point of entry of the EHEC pathogen O104:H4 into the food supply chain has not been identified despite intensive efforts of all authorities involved in the affected federal states as well as RKI, BfR, and BVL.

According to current knowledge, distribution chains suggest that the spread of the EHEC infections may have emanated from an agricultural business in Lower Saxony and are in accordance with the geographical distribution of many of the case clusters.

To support the investigation of this outbreak affecting several federal states, the federal and state level decided to establish a task force at BVL consisting of experts from several states,

BVL, BfR and RKI, and supported by experts of the European Food Safety Authority (EFSA) as well as the European Commission.

The mission of this Task Force is to analyse the available epidemiological results on individual outbreak clusters in conjunction with information on related food supply chains available from food safety authorities across federal states. Clusters consist of persons who contracted the disease after a common exposure, such as eating in the same hotel, restaurant or canteen.

Distribution supply chains of sprouts originating from the Lower Saxony producer can explain 26 of 55 EHEC O104:H4 disease clusters or isolated cases in 5 German states. Lower Saxony has provided extensive information from food control activities. At present, human introduction of the EHEC pathogen into the agricultural business cannot be excluded. However, water, preceding suppliers or seeds are also possible sources. These possibilities are currently under investigation through investigations of supply chains and laboratory analyses.

Other sources of contamination into this specific agricultural production cannot be excluded at present. The authorities in Lower Saxony and BfR have taken extensive samples in this business in the past few days, the investigation of which has not been entirely completed. Even if the outbreak pathogen has not been detected in any samples thus far, the accumulated evidence strongly points to this producer as the source of the outbreak. The federal and state authorities will perform further investigations and analyses of supply and distribution chains to investigate whether contaminated seed for sprout production may be present in other companies or could reach the market.

Because the seed used for the production of sprouts may also be the source of the pathogen, other sprout producing businesses could potentially be contributing to the spread of EHEC O104:H4 as well.

The ability to survive and grow on sprouts makes a wide distribution of EHEC through the supply chains of the producers to the consumer possible.

Therefore, RKI, BVL and BfR recommend not eating uncooked sprouts until this potential source of the contamination has been thoroughly investigated.

This information replaces the earlier warning of RKI and BfR against the consumption of cucumbers, tomatoes and lettuce. According to the current state of knowledge, products from the agricultural business in Lower Saxony are the most likely source of the EHEC infections.

Further information:

www.bfr.bund.de

www.bvl.bund.de

www.rki.de