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To the Inspector-General of the Netherlands Food and Consumer Product Safety Authority

Advisory Report of the Director of the Office for Risk Assessment and Research concerning

Risks in the Potato Production Chain

Ware potatoes are a staple food in the Netherlands and are consumed not only as table potatoes but also in the form of industrially processed products such as chips, crisps and chilled products. In addition, the Netherlands produces and processes large quantities of potatoes and is a major player in the global market for potatoes and potato products (Bremmer et al., 2019). The Office for Risk Assessment & Research (BuRO) has assessed the risks for plant health and food safety in the potato production chain (hereinafter: potato chain), and based on these assessments, has identified the most important findings and drawn up certain recommendations. Other risks to human health and to nature and the environment resulting from the production (cultivation, processing) of potatoes and potato products are only referred to in brief, without any detailed risk assessment being carried out for these risks.
The potato chain risk assessment is part of a larger programme that develops systematic and periodic overviews and insights relating to the risks to people, animals, plants and nature that can occur in the production chains for food and consumer products.

Introduction to the potato chain

The Netherlands has a large potato processing industry that processes more potatoes than are actually produced in the country. About 30% of the fresh potatoes consumed or processed in the Netherlands are imported from EU Member States and countries outside the EU (StatLine, 2019). Of the potato products (mainly pre-fried chips) produced in the Netherlands, 85% are exported (StatLine, 2019). Some potato cultivars are grown specifically for processing into potato starch, which forms the basis for many industrial applications.
The Netherlands is the world's largest exporter of seed potatoes, with a market share of 60% (EZ, 2017). Over 2016-2018, the Netherlands exported, on average, approximately 800,000 tons of seed potatoes annually to over 100 countries (NAO, 2020). Potato breeding in the Netherlands is an activity that is closely related to the production of seed potatoes. In 2015, approximately 450 Dutch cultivars were registered, of which over 40% were developed specifically for the export of seed potatoes, with properties tailored to the production conditions in the destination countries (van Loon, 2019).

A detailed description of the potato chain, substantiation for the risk assessment and the sources used can be found in the Annexes.

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Research question

BuRO has formulated the following research questions for its assessment of the risks in the potato chain:

What are the biggest risks in the potato chain for plant health and food safety? What other risks to public health, nature and the environment are associated with the production of potatoes?

Scope

Potato production chain

For this risk assessment, the potato chain has been subdivided into five stages and the scope has been demarcated as activities of food business operators dealing in potato or potato products (Table 1 and Figure 1).

Table 1 Stages of the potato production chain

Stage		Phase
1	Breeding and selection of new cultivars	Plants for planting
2	Production of seed potatoes	
3A	Production of ware potatoes	Primary (Farm)
3B	Production of starch potatoes	
4A	Handling and processing of ware potatoes	Secondary (industry, unit packaging companies, sorting companies)
4B	Processing of starch potatoes	
5	Distribution of potatoes and potato products to food handlers (consumer, mass caterer [1]) and the preparation of potatoes and potato products	Tertiary (Distribution and Consumption)

The risk assessment takes into account the influence of the preparation method of potatoes and potato products on the food safety risks that may have arisen in the above-mentioned stages of the chain. Food safety risks relating to potatoes and potato products that are introduced in the kitchen through the actions of the food handler have not been taken into account in the risk assessment. In order to assess the food safety risks, the stages of the chain involved in the production of potatoes and potato products intended for consumers have been divided into the primary (farm, Stages 3A and 3B), secondary (industry, Stages 4A and 4B) and tertiary phases (distribution and consumption (preparation), Stage 5). The division into phases is in line with the terminology used in the supervisory and enforcement activities carried out with respect to food business operators.

[1] Mass caterers: any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer.
As defined in: Regulation (EC) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

Import (both from EU Member States and from third countries) of potatoes and potato products in all the stages of the potato chain are included in this risk assessment.

The storage and transport of potatoes and potato products in all stages of the potato chain within the Netherlands, including transport of certified lots for export to countries outside the EU up to the external borders of the Netherlands, have been taken into account in the risk assessment.

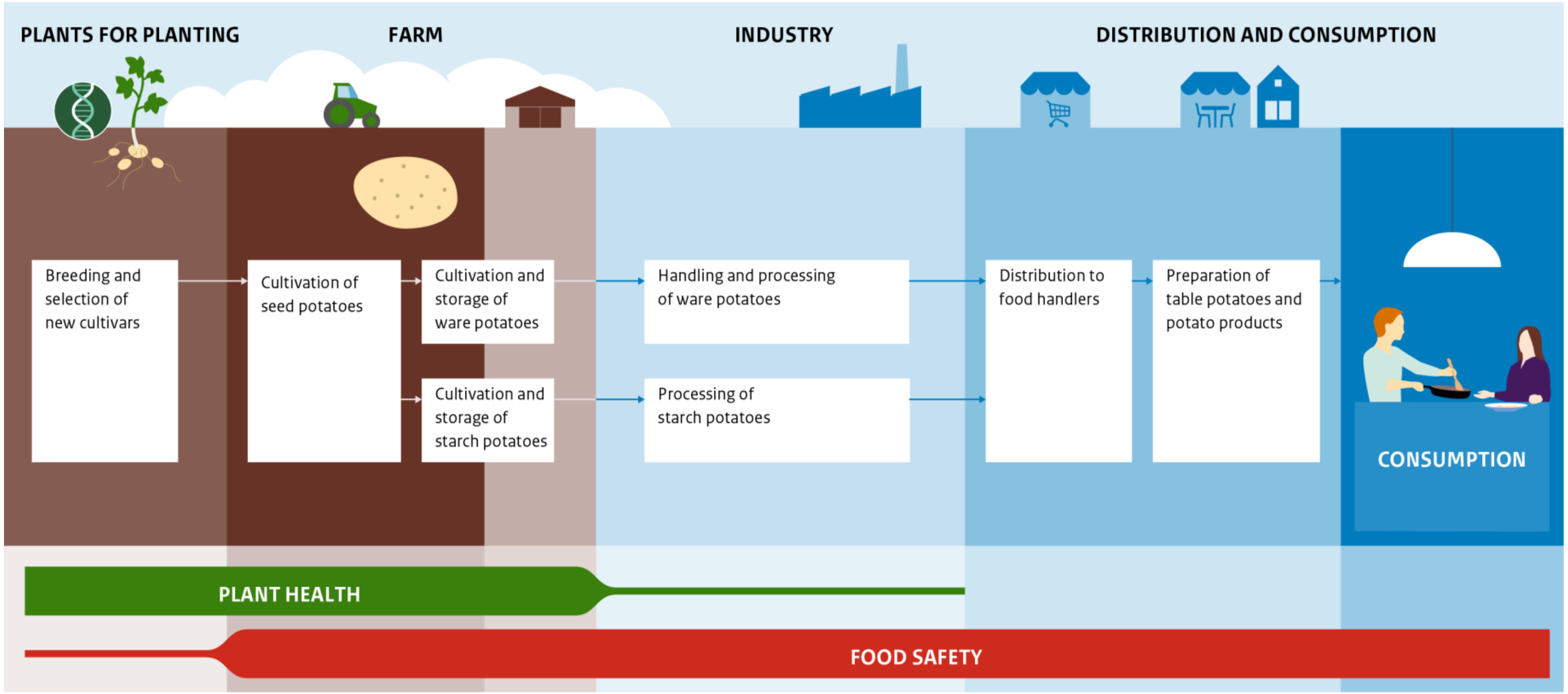

Figure 1. Five stages of the potato production chain (see Table 1).

Plant health
The risks to plant health caused by harmful organisms have been assessed. These organisms include viroids, viruses, bacteria, fungi, pseudofungi, insects, mites, nematodes, snails and plants that may affect or displace the existing plants (weeds). The adverse effect caused may lead to a reduction in the quantity and/or quality of plants or harvested products. For plant health in the potato chain, the risks of harmful organisms that have quarantine status in the European Union (Union Quarantine Pest, UQP) or which potentially qualify for this status (new harmful organisms and potential UQPs) based on the EU Plant Health Regulation[2] (see Table 2), have been assessed. A UQP is defined in the Plant Health Regulation as a pest that:

- Has an established identity
- Is not present or present only to a limited extent in the EU
- Is capable of becoming established in the EU and has an unacceptable impact after entry
- Can be countered using available feasible and effective measures, and
- Is listed in Annex II of the Implementing Regulation (EU) 2019/2072[3] (Article 4 of the Plant Health Regulation)

Priority Pests are a special group within the UQPs for which additional requirements apply. In the current risk assessment, besides the pests listed in the above-mentioned Annex II, organisms subject to temporary measures pursuant to an implementing act (Article 30 of the Plant Health Regulation) are also considered as UQPs. In fact, these pests are also subject to a European control obligation.

A ‘new harmful organism’ is defined here as one that is not yet present or present only to a limited extent in the EU and that is not designated as a UQP. If the organism is already present in the EU (in limited numbers), it is usually one that did not originally occur in the EU and was therefore introduced from outside the EU. A ‘potential UQP’ is a new harmful organism that meets all the criteria of a UQP. Therefore, potential UQPs are harmful organisms that may be granted European quarantine status in the future. The Plant Health Regulation (Article 29) also provides that, if a Member State encounters a new harmful organism that meets the criteria of a UQP on the basis of a preliminary risk assessment, the Member State is obliged to take measures to eradicate the organism. In the Netherlands, these organisms are designated as NL-provisional Q-pests. Organisms can also be assigned the NL-provisional Q-pest status in the Netherlands following an application by a company or institution for the import of the organism for research purposes.
The following categories of organisms are excluded from the scope (see also Table 2):

- Protected Zone Quarantine Pests (PZQP), i.e. pests that are regulated only in certain areas of the EU. Since the Netherlands has no PZQPs, this category will not be discussed further here.
- Union Regulated Non-Quarantine Pests (RNQP)

[2] Regulation (EU) 2016/2031 of the European Parliament and of The Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC.
[3] Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 laying down uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and of the Council, as regards protective measures against pests of plants, and repealing of Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019

- Pests with quarantine status in a third country but not in the EU (third-country QP)
- All other organisms

Table 2. Categories of harmful organisms that are in/out of scope (see the text below and Annex 4 for complete definitions).

Category	Abbreviation	Short definition	In scope?
Union Quarantine Pest	UQP	Pest listed in Annex II of Implementing Regulation (EU) 2019/2072	Yes
Priority Pest	Priority UQP	UQP with additional requirements based on Article 6 of Regulation (EU) 2016/2031	Yes
Provisional Union Quarantine Pest	UQP[1]	Pest subject to temporary EU measures via an implementing act	Yes
Protected Zone Quarantine Pest	PZQP	Pest with quarantine status for certain areas within the EU	No
Union Regulated Non-Quarantine Pest	RNQP	Pest that is regulated only with respect to certain planting material	No
New harmful organism	-	Harmful organism not present or present only to a limited extent in the EU	Yes[2]
Potential Union Quarantine Pest	Potential UQP	New harmful organism that meets all criteria of a UQP	Yes
NL-provisional Q-pest	-	Potential UQP subject to official measures in the Netherlands	Yes
Third-country quarantine pest	Third-country QP	Pest with a quarantine status in a third country	No
Other organisms	-	Organisms not covered by any of the above definitions	No

[1] NB According to Regulation (EU) 2016/2031, only the pests listed in Annex II of Implementing Regulation (EU) 2019/2072 are Union Quarantine Pests.
[2] To assess whether the pest meets the criteria of a UQP (see potential UQP).

The presence of harmful organisms in a plant production chain can lead to reductions in yield, higher plant protection costs and reduced market opportunities. These aspects have been taken into account during the assessment of UQPs and potential UQPs. However, the impact of a possible tightening of EU phytosanitary legislation and regulations on trade and export has not been assessed. The finding of a UQP or potential UQP can have a major impact on a company, landowner and/or other parties involved because of the costs of the measures involved to contain or eradicate the pest. No estimate has been made of the actual amount of these costs.

Food safety
For food safety in the potato chain, an assessment has been made of the risks relating to microbiological, chemical and physical hazards that may be introduced during production, processing and packaging of ware potatoes and starch potatoes and that have the potential to damage human health.

Damage caused to potatoes or potato products due to rotting, loss of quality or decay[4] falls outside the scope of this risk assessment because the microorganisms involved in these processes do not cause disease in humans.
With respect to plant protection products, this study is limited to the risks of the active substances in plant protection products and biocides; it has not considered the possible risks of adjuvants[5] and basic substances[6]. Biostimulants[7] have also not been taken into consideration in the assessment.

Other risks to public health, the environment and nature
Plant protection measures taken during the cultivation of potatoes can give rise to risks for public health (other than food safety), the environment and nature. Risks to users of plant protection products in the potato chain (occupational risks) have been referred to but not dealt with in detail because the supervision of these risks is the responsibility of the Social Affairs and Employment Inspectorate (*Inspectie Sociale Zaken en Werkgelegenheid*) and not that of the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit, NVWA*). Incorrect application of plant protection products can lead to exceedances of environmental standards. The NVWA does not perform measurements on surface water and groundwater, but it supervises the correct agricultural application of plant protection products. These environmental risks are only briefly discussed, since policy-making in this area is not the responsibility of the NVWA's commissioning ministries but that of the Ministry of Infrastructure and Water Management.

Out of scope
The following fall outside the scope of the potato chain:
- Introduction of hazards due to actions of the food handler
- Production of composite products: products in which, in addition to potatoes, ingredients from production chains other than the potato chain have been used, with the exception of added salt, herbs and spices
- Use of potato starch in composite foods and industrial non-food products
- By-products created within the potato chain and processed within other production chains and waste products (the risks of using potato processing by-products in animal feed have been assessed elsewhere (NVWA, 2019))

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[5] An adjuvant is added to a plant protection product, for example, to improve its effectiveness. Adjuvants must be officially registered; detailed legislation for the assessment of these substances is pending.
[6] A basic substance is one that is already on the market for use for another purpose (for example, in cosmetics or food). Any risks have therefore already been identified. Basic substances may be used for plant protection, but they cannot be sold as plant protection products. There is an official list of authorised basic substances.
[7] Biostimulants encourage the natural nutritional processes of plants but are not actual nutrients. They are not considered plant protection products.

- Use of biocides for rodent control in potato storage facilities and sheds for storing tools and machinery used in potato cultivation

Approach

BuRO commissioned Wageningen Food & Biobased Research and RIKILT[8] to conduct the necessary research to obtain insight into the food safety risks in the potato chain. Additional sources of data and other information and literature were also used and regular consultations were held with supervisory directorates of the NVWA to obtain factual information on operational processes in the potato chain. Representatives of sector organisations were asked to review the draft assessment (without findings and recommendations) for factual inaccuracies.

BuRO presented the preliminary findings and recommendations of the risk assessment to the Inspector General and the directorates of the NVWA so that they could formulate a management response. Subsequently, the findings and recommendations were presented to the relevant policy departments of the Ministry of Agriculture, Nature and Food Quality and Ministry of Health, Welfare and Sport.

The method used for the risk assessment of the potato chain is largely based on that followed by the Codex Alimentarius and the working method of the European Food Safety Authority (EFSA). This method is in line with the systematic risk assessment approach referred to in the General Food Law Regulation (GFL)[4]. Although the approach followed in this Regulation is specifically intended for assessing food safety risks, it is essentially comparable to the international methods used for assessing risks to plant health[9] (EFSA Scientific Committee, 2012).

The risk assessment method consists of four steps:

- Hazard identification: identification of the hazards[10] (threats) to plant health and food safety in the potato chain as described in various sources, including scientific literature and research reports.
- Hazard characterisation: assessment of the relevance of the hazards to plant health and food safety in the Dutch potato chain. In case of plant health, this involves an estimation of the potential consequences, due to the presence of harmful organisms in the Netherlands, for the yield and/or quality of potatoes and for the trade and export of potatoes and other plants. In case of food safety, this is an estimation of the extent to which microbiological, chemical and physical hazards arising out of the consumption of potatoes and potato products contribute to the burden of disease or negative long-term effects on human health.
- Exposure assessment: the probability of the occurrence of these hazards. For plant health, this is an assessment of the likelihood of a harmful organism entering and establishing in the Netherlands and the extent to which it can spread in the Netherlands. For food safety, this involves an assessment of the degree to which the consumer is effectively exposed to the microbiological, chemical and physical hazards present in potatoes and potato products.

[8] RIKILT: as of 2019, known as Wageningen Food Safety Research.
[9] International Plant Protection Convention (IPPC): International Standards for Phytosanitary Measures No 2 and No 11. Available at https://www.ippc.int/en/core-activities/standards-setting/ispms/.
[10] A hazard is a biological, chemical or physical agent with potential adverse effects on plant health, nature, the environment, public and animal health (based on the definition in the General Food Law Regulation (Regulation (EC) No 178/2002).

- Risk characterisation: overall assessment of the nature and severity of each hazard, and the likelihood or prevalence thereof in the Netherlands (conclusion of the risk assessment).

In the comprehensive risk assessments (Annexes 4 to 10), these four steps have been followed for each of the identified hazards. Below we first discuss the findings, conclusions and recommendations, followed by the main risks emerging from the comprehensive risk assessments. The following topics will be dealt with in turn: A) Plant health, B) Food safety, subdivided into B1) Microbiological risks, B2) Chemical risks, B3) Physical risks and C) Other risks to public health, the environment and nature.

Findings

Risks to plant health

Established Union Quarantine Pests (UQP)

1
Six UQPs have been identified that are relevant to potatoes and established in the Netherlands: the nematodes *Globodera pallida, G. rostochiensis, Meloidogyne chitwoodi* and *M. fallax,* the bacterium *Ralstonia solanacearum* and the fungus *Synchytrium endobioticum*. These pests can cause yield losses and pose a threat to the trade and export of potatoes because of their UQP status and because they are regulated in many third countries.

2
Frequency of cultivation and the use of resistant varieties play an important role in the control of *Globodera pallida* and *G. rostochiensis* (potato cyst nematodes). In the Netherlands, it is not allowed to grow potatoes on the same plot more than once every three years. An exception to this rule is made for the northeastern sandy soil and reclaimed peatland areas, where there is no restriction on the frequency of cultivation of starch and ware potatoes. Particularly in case of a high cultivation frequency, the availability of resistant varieties is important for preventing damage, but at the same time the frequent cultivation of these varieties favours the development of new virulent populations of potato cyst nematodes. New virulent populations of *G. pallida* were identified in the northeastern sandy soil and reclaimed peatland areas in 2015. The risk of the development of new virulent populations of both nematode species was assessed as high for areas with high potato cultivation frequencies.

3
Meloidogyne chitwoodi and *M. fallax* are probably more widely distributed than is officially known. The spread is difficult to prevent because both nematode species can affect several plant species. Infested propagating material, soil and soil tare can lead to plot infestation. Because of their quarantine status, *M. chitwoodi* and *M. fallax* pose a threat to the trade and export of seed potatoes. In practice, damage in ware potatoes and starch potatoes is limited due to the voluntary measures taken.

4
Ralstonia solanacearum (brown rot bacterium) occurs in surface water in parts of the Netherlands and is the main source of crop infestation. The current ban on the use of surface water for the cultivation of potatoes reduces the risk of infestation. However, there is still a risk of infestation via infested surface water, for example, during storms and floods.

5
The use of resistant potato varieties plays an important role in the control of the fungus *Synchytrium endobioticum* (potato wart disease). In addition to the use of these resistant varieties, preventing the spread of the disease via the soil is an important control measure.

6
Nematodes, *Synchytrium endobioticum* and other soil-borne pests can be spread and introduced into the Netherlands via soil tare. For potato soil tare, regulations have only been laid down in relation to *Globodera pallida* and *G. rostochiensis*. Soil-borne pests can also be spread via soil tare of other root crops. For *Synchytrium endobioticum*, deep burial and non-agricultural disposal are currently the only options for neutralising infested soil.

Transient UQPs

7
One UQP - the ring rot bacteria *Clavibacter sepedonicus* - has been identified that can affect potatoes and that is transient in the Netherlands. The organism is mainly transmitted through mechanical activities and via seed potatoes. Measures taken in recent years to reduce the risk of infestations with this bacterium appear to be effective. No further infestations have been found since 2014.

Absent UQPs

8
From the UQPs, 16 pests and groups of pests have been identified that can affect potatoes but that do not yet occur in the Netherlands. However, there is a likelihood of introduction and the potential impact can be substantial. From among these pests or pest groups, the level of risk is assessed as relatively high for the potato psyllid *Bactericera cockerelli* in combination with the bacterium '*Candidatus* Liberibacter solanacearum' and the flea beetles *Epitrix cucumeris* and *E. papa.*

9
The bacterium '*Candidatus* Liberibacter solanacearum' can cause major yield losses and damage to the quality of the potatoes. But although the bacterium occurs in Europe, it currently poses only a minor risk to potatoes due to the absence of an efficient vector for its spread in this crop. The introduction of the vector species *Bactericera cockerelli* (potato psyllid) will greatly increase the level of risk. The most likely pathway of introduction of this vector species is the import of Solanaceae fruits from third countries. The EU requirements imposed since 1 September 2019 are considered insufficient to practically nullify the likelihood of introduction via fruits.

10
The flea beetles *Epitrix cucumeris* and *E. papa* mainly cause cosmetic damage on the potato tuber and form a particular hazard for the trade and export of potatoes. The likelihood of introduction of these pests has been assessed as relatively high due to their presence in the EU (Spain and Portugal). There is uncertainty as to whether the current EU regulations can prevent the spread of these pests within the EU.

11
The EU ban on imports of potato tubers and plants for planting of Solanaceae from most third countries considerably reduces the likelihood of introduction of UQPs or potential UQPs harmful to potatoes. However, potatoes have been found in passenger baggage during checks at Schiphol Airport; this kind of intentional or unintentional illegal import of potatoes can result in the introduction of UQPs or potential UQPs in the Netherlands. Internet commerce also poses a risk. The NVWA works together with the customs authorities and courier services to reduce the phytosanitary risks from passenger baggage and parcel post.

Risks to food safety

Microbiological risks

12
The microorganisms that pose the greatest risk to human health worldwide, through the consumption of potatoes and potato products, are *Bacillus cereus* and *Clostridium botulinum*. However, botulism is rare in the Netherlands and potatoes have never been reported as a cause. The burden of disease of *B. cereus* caused by potatoes is estimated to be very low for the Dutch population. *Listeria monocytogenes* and *Salmonella* are also considered relevant hazards for the potato chain. However, cases of listeriosis and salmonellosis caused by potato products are rare. As a result, it can be concluded that there is hardly an impact of potatoes on the food-related microbiological burden of disease in the Netherlands.

13
The main route of contamination of potatoes is via the soil *(B. cereus*, *C. botulinum* and *L. monocytogenes*) during cultivation, followed by post-process contamination *(Salmonella*, *L. monocytogenes*) in later stages of the chain. Outbreaks and cases of illness caused by potatoes and potato products worldwide are almost always related to food handling practices during food preparation.

14
B. cereus and *C. botulinum* are spore-forming bacteria that can survive the applied heat treatments during the processing of potatoes and therefore may also occur in potato products.
L. monocytogenes is present on fresh potatoes, which means that this bacterium is continuously present in the potato processing industry. In the processing environment, *L. monocytogenes* can survive quite easily and hence this pathogen poses a particular threat as a result of the post-process contamination of chilled ready-to-eat products.
Salmonella is sometimes isolated from ready-to-eat potato products, such as potato crisps. The source is post-process contamination through additives (herbs or herb mixes).

The risk of these bacteria is controlled through measures that prevent post-process contamination and/or growth (and toxin formation) in the product, such as post-packaging pasteurisation and the storage of chilled products at a maximum of 7°C.

Chemical risks

15
The food safety risks of most substances in the potato chain have been assessed as negligible. For a number of substance groups, it is not possible to assess the risks. For three substance groups, there is a potential risk for potatoes and potato products.
The most important of these are acrylamides that are formed when potatoes are heated (deep-frying or frying). Deep-fried potatoes and crisps are the largest contributors to acrylamide intake via food.

16
Glycoalkaloids (a group of plant toxins) pose a potential acute food safety risk when large servings of prepared potatoes, whether in peeled or unpeeled form, are consumed. The applied limit for glycoalkaloids in potatoes is not legally defined.
For both lead and cadmium, the total intake via food is higher than the health-based limit value. Therefore, potatoes are an important contributor (5-20%).

17
The risks of cleaning agents and disinfectants, hydraulic oils and processing aids cannot be assessed because there is insufficient knowledge about which of these are used in the potato chain. The risks of substances from packaging materials cannot be assessed because it is not known which ones are relevant to potato products. In the meantime, research studies have been initiated on the use of cleaning agents and disinfectants as well as substances in packaging materials.

18
Preparation (washing, peeling and cooking, frying or deep-frying) of potatoes substantially reduces the levels of plant toxins (such as calystegines), nitrate, environmental contaminants, plant protection products and sprout inhibitors. However, when potatoes are heated (boiled, fried, deep-fried), new substances can be formed, such as acrylamides, furans and methylfurans and AGEs (advanced glycation end products). Special attention is paid to the occurrence of acrylamides: in the Netherlands, their presence in chips is monitored and benchmark levels have been set in a European context. For furans and methylfurans and AGEs, more information on the occurrence in potato products is needed to assess the risk.

19
Active substances of plant protection products are regularly analysed using multi-residue methods. However, a number of substances authorised in the Netherlands are overlooked by these methods, including maleic hydrazide and 1,4-dimethylnaphthalene. Products based on these substances are considered to be an alternative to chlorpropham-based sprout inhibitors (banned since 31 July 2020). For both these active substances, the risk to the food safety of potatoes cannot be determined because little or no information is available about their levels in or on potatoes.

20
A number of plant protection products and disinfectants are only authorised for use for seed potatoes. Residues of these substances constitute a potential risk when these seed potatoes are used as ware potatoes.

Physical risks

21
Introduction of foreign objects, such as stones, animal and plant remains and metal parts, into the chain mainly takes place during the cultivation phase. These objects must be removed after the harvest. This is most difficult for objects with a specific weight similar to that of potatoes, such as golf balls and crown roots of maize plants, which can only be effectively removed by hand.

22
The risks to consumers from foreign objects in the potato chain are negligible because of the strict controls carried out. The number of official reports of foreign objects in potatoes and potato products is very limited given the volume of potatoes produced.

Other findings

23
Voluntary certification schemes can help supplement legislation and regulations, so that the risks in the potato chain can be controlled.

24
Plant pathogens and pests are a threat to plant health and the market opportunities of potatoes. Plant protection products are used in the various stages of the chain to control diseases and pests. The use of these products can lead to risks for human health, nature and the environment, particularly in the aquatic environment.

Conclusions

There are six UQPs established in the Netherlands that pose a risk to plant health in the potato chain. Since elimination of these pests is no longer an option, measures should be aimed at minimising the risk of infestation of the potato production chain. There are several ways to do this. Frequency of cultivation and the use of resistant varieties play an important role in the control of *Globodera pallida* and *G. rostochiensis*. A high frequency of cultivation of resistant varieties favours the development of new virulent populations of the nematodes *Globodera pallida* and *G. rostochiensis*. Reducing the frequency of cultivation can help reduce the risk to the potato chain. In addition, infestation of potato plots with *S. endobioticum*, *G. pallida, G. rostochiensis* and the nematodes *Meloidogyne chitwoodi* and *M. fallax* may occur if soil tare from potatoes or other root crops grown on infested plots is used.
The threat to the potato chain posed by the bacterium *Ralstonia solanacearum* is mainly due to the use of infested surface water. Due to regularly occurring dry spells and water scarcities, there can be a high temptation to use surface water.

This can increase the likelihood of infestation of the chain and resulting harmful effects.
The risk posed by the potato psyllid *Bactericera cockerelli*, which is not present in the EU, depends largely on the likelihood of its introduction into the Netherlands from countries where this pest is present. In particular, fruits of Solanaceae from certain countries may be infested. Therefore, the risk of introduction of the potato psyllid can be considerably reduced by preventing or limiting the introduction of these potentially infested fruits. The damage to potato production is not caused by the potato psyllid itself but by the bacterium '*Candidatus* Liberibacter solanacearum' spread by *B. cockerelli*. *Epitrix cucumeris* and *E. papa* are flea beetles that occur in Europe (but not in the Netherlands) and that can cause damage; this makes them a particular risk in relation to the potato trade. There is a likelihood of introduction of UQPs and potential UQPs via the illegal import of potato tubers in passenger baggage and via Internet commerce. The extent of these risks is uncertain due to the lack of information on the number of tubers/lots entering in this way.
The risk of infestations with *Clavibacter sepedonicus* has been greatly reduced in recent years through the adequate implementation of hygiene measures. Thanks to these measures, the likelihood of large-scale effects is very limited. But if the implementation of the measures is slackened, the level of risk may increase sharply.

Physical hazards for food safety can be introduced in the different phases of the potato chain, but the cultivation phase is the most important in this respect. No safe limit of exposure has been established. Control measures are implemented within the chain to prevent consumers from being exposed to these hazards. It has been estimated that such physical hazards pose a negligible risk to food safety.

Of the microorganisms associated with the food safety of potatoes and potato products, *B. cereus* is the one that causes relatively the highest number of outbreaks. Outbreaks and cases of illness caused by *C. botulinum* are rare and reports of salmonellosis and listeriosis caused by potato products are scarce. It has been assessed that only *B. cereus* slightly contributes to the burden of disease in the Netherlands. Based on consumption data, a rough estimation is 0.1 DALY per year. Potato is estimated as contributing 0.003% (0.1 DALY) to the total burden of foodborne disease (4,245 DALYs). This represents 0.03% (203 cases) of a total of 652,500 foodborne disease cases. Given the very limited amount of data, it is concluded that there is a large degree of uncertainty about the attribution of the burden of disease to potato consumption. Based on these available data, it is assessed that potatoes have little or no contribution to the microbiological burden of foodborne disease in the Netherlands.

Among chemical substances, acrylamides that are formed during the heating (deep-frying, frying) of potatoes pose the greatest risk to the food safety of potatoes and potato products. In addition, glycoalkaloids (a group of plant toxins) pose a potential acute food safety risk when large servings of prepared potatoes, whether in peeled or unpeeled form, are consumed. Potatoes can contribute to the intake of lead and cadmium from food. With frequent consumption of large quantities of potatoes, there is a chronic intake of nitrate as well as of

chlorpropham, the active substance in most sprout inhibitors[11]. However, washing, peeling and preparing (boiling, frying, deep-frying) potatoes substantially reduce the amounts of nitrate and chlorpropham present, making an exceedance of the health-based limit value unlikely.
For a number of chemical hazards, the risk cannot yet be assessed because there is insufficient or no data available on the occurrence of these substances in potatoes and potato products. This applies to calystegines (a group of plant toxins), sulphite (additive), furans and methylfurans. Not all chemical hazards are included in this chain risk assessment because it is not known which individual substances from these substance groups are relevant to the potato chain. Furthermore, it is not known which cleaning agents and disinfectants, processing aids, hydraulic oils and lubricants are exactly used in the potato chain and which substances from packaging materials and other food contact materials are relevant. There is also insufficient knowledge about other substances (such as AGEs) that are formed, besides acrylamide, when potatoes and potato products are heated. Persistent organic compounds, the heavy metals arsenic and mercury, mycotoxins, radioactive substances and refrigerants (agents used in cooling systems) and MCPD in potato products such as crisps and chips do not pose a risk to the food safety of potatoes because they are either present in very low concentrations or are even absent from potatoes and potato products. The same conclusion can be drawn for plant protection products: their use in potato cultivation does not constitute a risk to the food safety of potatoes. However, there are three caveats to this. Firstly, not all plant protection products authorised for use in potato cultivation are regularly analysed. As a result, it may have been wrongly assumed that these substances are not found in potatoes. Secondly, a number of products are only authorised for use with seed potatoes but not with ware potatoes. If seed potatoes are used as ware potatoes - as is often the case with oversized seed potatoes - they could contain substances that are not authorised for ware potatoes Thirdly, the simultaneous exposure to these substances from other foods or the simultaneous exposure to different substances is not taken into account.

Compared to other arable crops, a relatively large amount of plant protection products is used in potato cultivation. This may give rise to public health risks other than the risks to food safety, the environment and nature.
The measured exposure to plant protection products of people living in the vicinity of agricultural fields is below the health-based limit values. In the potato chain, occupational exposure to plant protection products occurs during the pre-treatment of the tubers, the spraying of the plots containing the potato crop and the storage period. Growers and the government continue to pay insufficient attention to the occupational risks of working with plant protection products. A number of azole-based products have been authorised for use in potato cultivation, but it is not known to what extent the use of these products contributes to the development of resistance of *Aspergillus fumigatus* towards azoles used in the area of health care.
Despite the requirements imposed on the use of plant protection products, emissions to surface water cause, by far, the greatest environmental impact. As far as the cultivation of ware potatoes and seed potatoes is concerned, the environmental impact has decreased since 2009 and 2011, respectively. For

[11] In the Netherlands, products based on the active substance chlorpropham have a grace period for use until 31 July 2020.

starch potatoes, a decrease was observed from 2008 onwards, but this was followed by an increased impact in the period 2012–2014.

Recommendations

Plant health

1
Urge policymakers to investigate the advantages and disadvantages of a longer rotation period for the cultivation of potatoes throughout the Netherlands, with the highest priority given to northeastern sandy soil and reclaimed peatland areas.

2
Maintain current prohibitions on the use of surface water to reduce the likelihood of *Ralstonia solanacearum* infestations.

3
Urge policymakers to establish general measures for the safe processing of soil tare from root crops based on a phytosanitary perspective and additional requirements for soil tare originating from areas where *Synchytrium endobioticum* occurs.

4
Continue to encourage private hygiene measures to minimise the risk of *Clavibacter sepedonicus* infestations.

5
Introduce more intensive inspections of Solanaceae fruits from countries where *Bactericera cockerelli*, the vector of '*Candidatus* Liberibacter solanacearum', is known to occur and urge policymakers to prohibit, if intercepted, the import of Solanaceae fruits from infested areas.

6
Monitor developments regarding the spread of *Epitrix cucumeris* and *E. papa* within the EU and urge policymakers to tighten current requirements for the intra-Community supply of potatoes from infested areas if they appear to be insufficient.

7
Continue to carry out checks on parcel post and passenger baggage in cooperation with customs authorities and courier services.

Food safety

8
Continue to carry out and support ongoing studies on the food safety risks of substances generated by heating potato products, in particular AGEs.

9
Initiate an evaluation, based on the food safety risk, of the limit value for glycoalkaloids in potatoes applicable in the Netherlands.

10
Initiate research on the toxicity of calystegines (a group of plant toxins).

11
Regularly adapt chemical multi-residue methods based on newly implemented active substances of plant protection products, in particular sprout inhibitors.

12
Ensure that further insight is gained into the frequency and extent of the use of seed potatoes as ware potatoes.

Other

13
Share this advice with the Human Environment and Transport Inspectorate (*Inspectie Leefomgeving en Transport*) and the Social Affairs and Employment Inspectorate.

Yours sincerely,

Office for Risk Assessment & Research
Prof. Dr Antoon Opperhuizen

A. Plant health risk assessment

Hazards

All organisms, viroids, viruses, bacteria, fungi and pseudo-fungi, nematodes, insects, mites, snails and plants that are harmful to plants are hazards to plant health. Based on the prevailing laws and regulations, harmful organisms can be divided into several categories (Table 2). As previously indicated (see Scope) this risk assessment is restricted to UQPs and new harmful organisms that fulfil or potentially fulfil the criteria of a UQP. There are about 180 UQPs (species and groups of pests). From these, the pests and pest groups relevant to potato cultivation were selected. These are pests that affect potatoes or the occurrence of which can lead to trade restrictions for potatoes. In addition, based on a literature search and consultation of NVWA experts, a brief inventory was made of new harmful organisms that affect potatoes and an initial assessment was drawn up of the risk posed by these organisms.

Risks to potato cultivation

Most of the UQPs relevant to potatoes do not yet occur in the Netherlands but may enter the country in various ways, particularly via import of plants and plant products including import from other EU Member States. The current import flows through which harmful organisms can enter the Netherlands have been taken into account in assessing the risk of UQPs. If a UQP is found, the Netherlands must take measures to eliminate the pest, and if it is too late for that, it must take measures to prevent the spread. These measures may involve the destruction of lots and a prohibition on the use of plots for certain crops for an extended period of time. The measures must be taken consistently at all times, regardless of the risk of the pest for plant health in the Netherlands. As a result, the detection of a UQP that potentially causes little direct damage to the Netherlands may nevertheless have a substantial impact, locally or otherwise, because of the mandatory measures. This risk assessment therefore focuses mainly on UQPs with a relatively high likelihood of causing infestation in the potato chain and UQPs with a high risk (likelihood x consequence) for Dutch potato cultivation.

Current phytosanitary legislation and regulations have been taken into account while assessing the risks of UQPs (see Annexes 2 and 4). This legislation is aimed at preventing the introduction and spread of these pests. For example, special rules apply to the import of several plants and products to prevent certain UQPs from entering the EU with these plant products. Furthermore, all consignments of plants and plant products, with the exception of five tropical and subtropical fruits, must be accompanied by a phytosanitary certificate. Imports of all consignments of plants and certain products must also be inspected for the absence of UQPs or potential UQPs[12]. In addition, a number of import bans and general requirements apply to the import of specific plants and products. As regards the cultivation of potatoes the following bans are especially relevant: a ban on imports of potato tubers and a ban on imports of plants for planting, other than seeds, of the family Solanaceae, to which potato also belongs. The import of true potato seeds is also prohibited. The import bans apply to all third countries with the exception of certain countries designated in the regulations (Implementing Regulation 2019/2072, Annex VI, points 15-18). Certain areas in some countries have been

[12] For a number of product-origin combinations, a system of reduced checks apply, which means that only a certain percentage of the consignments must be inspected. See: https://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/less_frequent_checks_en

temporarily exempted from the ban on the import of potato tubers for use either as seed potatoes or as ware and starch potatoes, by means of derogations. Some of the established UQPs are subject to specific EU rules, laid down in European directives, which are aimed at identifying the distribution of the pests within the EU and preventing their further spread. In addition, Member States are generally obliged to carry out surveys on the occurrence of UQPs in their territory. To help them do this, EFSA, commissioned by the European Commission, has drawn up general guidelines for conducting risk-based surveys (EFSA et al., 2020).

In the risk assessment (Annexes 4 and 5), a distinction is made between UQPs that already occur in the Netherlands (are established here) and non-established UQPs. This is because the likelihood of infestation with an established UQP is generally much higher than that by a non-established UQP. In view of the relatively high likelihood of infestation, the risks of all established UQPs relevant to potatoes have been discussed below. All non-established UQPs relevant to potatoes have been mentioned, but only those pests associated with a relatively high likelihood of infestation or relatively high level of risk are discussed in more detail. Then, the main pathways of UQPs and potential UQPs relevant to potatoes are discussed in general terms. No new harmful organisms with a relatively high risk for potatoes have been identified and are therefore not mentioned here. Details concerning the legislation, methodology and risk assessments can be found in Annexes 4 and 5.

Established UQPs
Six UQPs are established in the Netherlands that are considered relevant to potatoes:

- *Globodera pallida* (white potato cyst nematode)
- *Globodera rostochiensis* (yellow potato cyst nematode)
- *Meloidogyne chitwoodi* (Columbia root-knot nematode)
- *Meloidogyne fallax* (false Columbia root-knot nematode)
- *Ralstonia solanacearum* (brown rot of potato)
- *Synchytrium endobioticum* (potato wart disease)

These pests are all harmful to potatoes, but in case of an infestation, direct damage to the crop (loss of yield) is generally limited, partly due to the official and voluntary measures in place. Due to their quarantine status, detection of these pests means that infested lots must be destroyed, or depending on the particular pest involved, these lots may be sold under certain conditions as ware or starch potatoes. Detection of some of these pests implies that restrictions will apply for one or more years to the plot found to be infested (as well as adjacent and possibly infested plots) or even the entire production site. All six are soil pathogens, and in principle, infestation can be prevented by starting the cultivation with clean seed potatoes on a pest-free plot. In addition, a *Ralstonia solanacearum* infestation can be avoided by using non-infested surface water for irrigation. However, some of the pests are already quite widespread, which can make it difficult to find a pest-free plot. These species therefore constitute a particular risk for the trade and export of potatoes because, due to their quarantine status in the EU as well as in many third countries, an infestation leads to the automatic rejection of a lot. The main routes of infestation of each of the six pests are briefly discussed below as well as the effectiveness of current regulations, and where relevant, the risks of the emergence of new variants (pathotypes) of the pests. Since soil tare, i.e. adhering soil released during the post-harvest processing of potatoes, can be a source of infestation for each of these UQPs, the risk of soil tare is discussed separately. Detailed information about the pests can be found in Annex 5.

Globodera pallida and *G. rostochiensis* cause the potato cyst nematode disease. These nematodes attack the roots of the potato plant, slowing down its growth and decreasing the yield. The main source of infestation of these nematodes is infested soil that can be spread via potatoes as well as via other plant species and with machinery, etc. Based on the EU control directive for potato cyst nematodes,[13] seed potatoes may only be grown on a plot that has been found free of these nematodes after an official investigation. In the Netherlands, it is not allowed to grow potatoes on the same plot more than once every three years. These measures are aimed at preventing the development of *Globodera* spp. populations. The cultivation of starch and ware potatoes in the northeastern sandy soil and reclaimed peatland areas is exempt from this rule. A cultivation frequency of 1:3 in itself is not sufficient to control potato cyst nematodes; a much lower cultivation frequency of once every six to eight years on average would be necessary for this (Molendijk, 2018). Another important measure for preventing damage due to *G. pallida* and *G. rostochiensis* is, therefore, the use of varieties with a high degree of resistance. Each year, the NVWA draws up a list of potato varieties with their corresponding resistance levels, in accordance with the EU control directive for potato cyst nematodes[13] (NVWA, 2020a). Without these high-resistance varieties, there would be much more damage, especially in the northeastern sandy soil and reclaimed peatland areas where a lot of starch potatoes are grown in close rotations. In 2015, new virulent populations of *G. pallida* were identified in the northeast of the Netherlands. These virulent populations multiply more strongly on certain varieties than would be expected based on the known resistance level. New and more virulent populations of *G. rostochiensis* also seem to be developing (NVWA, 2018a). Therefore, the development of these new virulent populations, particularly in areas with close rotations, has been assessed as the primary risk with regard to *G. pallida* and *G. rostochiensis*.

Meloidogyne chitwoodi and *M. fallax* lead to the formation of galls on the potato tubers that can make ware potatoes unsuitable for processing (chips producer) and for sale as fresh potatoes (table potatoes). The main sources of infestation in the Netherlands are infested soil and infested propagating material. Both nematodes can affect a large number of plant species besides potatoes. Specific EU rules apply to seed potatoes but not to the propagating material of other plant species. In the Netherlands, seed potatoes originating from a plot on which a previous infestation has been found must be tested in the laboratory. In addition, an area with a radius of 1 km is demarcated around each new site of occurrence for the next year of cultivation and all seed potato lots from plots located wholly or partly within this area are tested. After one year, the demarcated area is limited to the 'Topographic Plot'[14] where the pests were originally detected. Each new detection leads to the demarcation of a new 1 km-wide area. A declaration of infestation of a Topographic Plot may be withdrawn if the nematodes have not been detected over two consecutive seed potato crops on the infested plot. Outside the demarcated areas, some of the seed potato lots are tested at an average of one lot per grower per year (NVWA, 2020b). Other plant species are

[13] Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC.
[14] Topographic Plot: area of land enclosed by topographic, permanent or temporary boundaries such as roads, water, hedgerows, fences and buildings.

only visually inspected, but these inspections are of limited effectiveness because many plant species show no or few symptoms after infestation. The nematodes are probably more widespread than is officially known.

Ralstonia solanacearum causes brown rot in potato. This bacterium is present in surface water in the Netherlands, which is probably the most important source of infestation. It is subject to specific EU regulations aimed at preventing its spread in potato cultivation (Directive 1998/57/EC). The use of surface water for the cultivation of ware and starch potatoes is prohibited in large parts of the Netherlands. The use of surface water for the cultivation of seed potatoes is prohibited throughout the Netherlands. In addition, all seed potato lots are sampled and tested for the presence of this bacterium. Partly due to these measures, brown rot infestations only occur incidentally in potato cultivation. Incidental infestations caused, for example, due to the flooding of plots with infested surface water, are difficult to prevent.

Synchytrium endobioticum causes potato wart disease. The fungus is found in certain areas in the southeast and northeast of the Netherlands. The main sources of infestation are infested soil and infested plant waste. The resting spores of this fungus survive composting and can survive in the soil for many years. National measures to be taken in case of detection are based on European Directive 69/464/EEC. If this fungus is detected on a plant, no potatoes may be cultivated on the plot in question for at least 20 years. Measures also apply to the surroundings of the plot and the production site. Under certain conditions and depending on the detected pathotype (taxonomic unit within a fungal species indistinguishable based on morphological characteristics), this 20-year period can be reduced. Resistant varieties and hygiene measures to prevent the transfer of infested soil are important tools for controlling the disease. It is also possible that a longer rotation period will help control of the fungus. Different pathotypes[15] have been distinguished and potato varieties may be resistant to one pathotype, yet susceptible to another. Each year the NVWA draws up list of the names of potato varieties that are resistant to the pathotypes occurring in the Netherlands (NVWA, 2020c). Of the pathotypes known in the Netherlands, pathotype 18(T1) is particularly dangerous because only a few potato varieties are available with a proven high level of resistance to this pathotype. In addition, new and more virulent populations may arise through a process of selection. New pathotypes may also be introduced from other countries. For certain areas in the southeast, northeast and east of the Netherlands (known as the ‘Prevention Areas’), the condition is that only starch potatoes and other potatoes may be grown that offer a minimum level of partial resistance to the pathotypes of the fungus occurring in these areas. For pathotype 18(T1), this requirement only applies to smaller ‘Core Areas’ and only to starch potatoes. It is a matter of international debate as to whether the cultivation of partially resistant varieties is a good strategy to control the pathogen since this may promote the development of new virulent pathotypes.

Soil tare

As far as soil tare is concerned, regulations have been laid down only for *Globodera pallida* and *G. rostochiensis*: soil tare from potatoes grown on infested

[15] Unit within a species (mainly used for fungi) that is indistinguishable based on morphological characteristics but which can be distinguished based on pathogenicity on a set of plant varieties of one or more host plant species (according to Bos et al., 1985).

plots must be treated or disposed of in such a way so as to prevent the spread of these pests (NVWA, 2020d). This measure is based on the EU control directive for potato cyst nematodes[13]. An effective treatment against *G. pallida* and *G. rostochiensis,* as well as against *Meloidogyne chitwoodi* and possibly *M. fallax,* is soil inundation. For this to be effective, the soil must remain inundated for long enough and temperatures must be sufficiently high. However, *Synchytrium endobioticum* is much more difficult to eliminate because the resting spores of this fungus are very persistent. Currently, deep burial and non-agricultural disposal are the only options for neutralising soil infested with *S. endobioticum*. Restricting soil tare measures solely to the officially infested plots is only partially effective. It is likely that more plots are infested with *S. endobioticum* and the four above-mentioned nematodes than is officially known. These pathogens can also be spread with soil tare from other products of plant origin. It should be noted however that companies in the Netherlands, that are authorised to process potatoes harvested from plots infested with *G. pallida* and *G. rostochiensis*, are obliged to process all soil tare in the same way. In addition, more measures are being taken on a voluntary basis to combat the spread of soil-borne pathogens via soil tare. For example, the standard practice is to treat and dispose (outside the agricultural sector) of soil tare originating from the Dutch potato starch industry in such a way so as to prevent the spread of soil-borne pathogens to agricultural plots. However, there is no EU legislation that imposes requirements for soil tare other than those mentioned above for potatoes in relation to *G. pallida* and *G. rostochiensis*. Therefore, even if all soil tare in the Netherlands were to be treated and disposed of in a phytosanitary manner, the introduction and spread of pests could still occur via soil tare imported from other EU Member States. Recently, *S. endobioticum* was found in a lot of soil tare from another EU Member State. Import of soil from third countries is prohibited.

Transient UQPs

One UQP - the ring rot bacteria *Clavibacter sepedonicus* - has been identified which may affect potatoes and which is transient (present but not leading to established populations) in the Netherlands. Infested seed potatoes and mechanical transmissions (via contact) are the main pathways of introduction and spread of this bacterium. Discovery of ring rot in seed potatoes in 2010 prompted a ban on the cutting of seed potatoes[16], with the exception of a number of situations in which there is only a small chance of a rapid spread of ring rot due to the cutting of seed potatoes (NVWA, 2018b). This ban has been in place since 2014. The cutting ban, communication about the risk posed by the pest and the hygiene measures to be taken by the sector have probably contributed greatly to mitigating the risk of *C. sepedonicus*. A number of infestations have been identified over the past decade, but the last finding dates back to 2013. The intra-Community acquisition of potatoes from countries where *C. sepedonicus* occurs (on a large scale) appears to be the main route by which *C. sepedonicus* can be introduced into the potato chain (NVWA, 2018a).

Absent UQPs

From the UQPs, 16 pests and pest groups have been identified that can affect potatoes and that are absent from the Netherlands (Table 3). In case of one of the identified UQPs - *Ralstonia syzygii* subsp. *celebesensis* - it is not known whether it can affect potatoes. For most of these pests, the import of potato tubers is the

[16] When cutting seed potatoes, a tuber is cut in half to increase the amount of plant reproductive material: a potato plant can grow from each part.

most important pathway of introduction into the Netherlands and the EU. In addition, plants for planting of Solanaceae, other than seeds, are also considered an important pathway. Some potato viruses and viroids are also known to be seed transmissible. However, there is a ban on imports of potato tubers, true potato seeds and plants for planting of Solanaceae, other than seeds (this exception does not include true potato seeds), from most third countries. Switzerland is exempted from the import ban on seed potatoes and true potato seeds. In addition, a number of Southern European Member States have a derogation for the import of seed potatoes from certain provinces in Canada. Specifically mentioned countries and territories on the European continent and in the Mediterranean region are exempted from the import ban on the remaining types of potato tubers and plants for planting of Solanaceae, other than seeds (Implementing Regulation 2019/2072, Annex VI, points 15-18). In addition, there are derogations for certain areas of Cuba and Lebanon. Most of the 16 UQPs and groups of UQPs are (as far as known) not present in Europe, the Mediterranean region and Cuba (Table 3), and the likelihood of introduction for most of these pests therefore appears to be low or very low. For two of the 16 above-mentioned pests and pest groups, the probability of infestation or introduction was assessed as relatively high. These are *Epitrix cucumeris* and *E. papa*, which are present in the EU*.* These pests and *Bactericera cockerelli* are briefly discussed below. In fact, the potential impact of *Bactericera cockerelli,* in combination with the bacterium '*Candidatus* Liberibacter solanacearum', has been assessed as very high and this pest can enter with fruits of Solanaceae, the import of which is not prohibited.

Bactericera cockerelli (potato psyllid) is the main vector of the Zebra chip disease in potatoes, which is caused by the bacterium '*Candidatus* Liberibacter solanacearum'. The bacterium causes various above-ground symptoms, such as leaf discoloration, wilting and stunting, leading to loss of yield. In addition, infected potato tubers develop stripes, usually when the potatoes are deep-fried (Zebra chip disease). This makes the tubers unsaleable as ware potatoes. '*Candidatus* Liberibacter solanacearum' is already present in the EU, with most infestations found in Apiaceae (carrot and celery). Infestations have also been found in potatoes but only on an incidental basis (in Spain and Finland). There is currently no known vector species in Europe that efficiently transfers the bacterium between potato plants, and without an efficient vector, the risk posed by the bacterium to potatoes is low. If the vector *B. cockerelli* is introduced, the risk of the bacterium for potatoes will increase considerably. Several variants known as haplotypes can be distinguished within this bacterial species. The haplotypes found in Europe are different from those found in America and that have caused the Zebra chip disease there. For the time being, the European haplotypes are also suspected as being harmful to the potato because Zebra chip disease symptoms have been demonstrated in infested potatoes in Spain. Currently, the main pathway of introduction of the vector, *B. cockerelli*, seems to be the import of fruits of Solanaceae (including bell peppers, chili peppers and tomatoes). Since 1 September 2019, special requirements apply to imports of Solanaceae fruits from Australia, North and South America and New Zealand, although imports from infested areas are still permitted. Within the requirements, one of the measures (Option c) is that the fruits should come from a production site where inspections and treatments have been performed during the last three months before export to guarantee the absence of the pest[3]. This option is considered insufficient to guarantee the absence of the pest. However, keeping a production site free in an area where the pest occurs seems to be very difficult. The species can be carried and spread over long distances by wind and may be present in various stages in specific places, for example, under sepals on fruits, where they are difficult to detect and control. The risk of *B. cockerelli* is therefore assessed as high. According to EPPO (2012), the only effective option for fruits of Solanaceae is 'country freedom'. In addition, two alternative options are offered (one of which is for tomatoes only) but only as part of a bilateral arrangement. Countries can be very large and pests do not care about national borders. 'Area freedom' is therefore technically a better option than country freedom. In general, the effectiveness of the various special provisions in the EU regulations depends to a great extent on the degree of implementation by countries (the intensity and quality of surveys and inspections, the quality of insect-repellent material, etc.). However, due to the biological characteristics of *Bactericera cockerelli*, the above-mentioned regulatory Option (c) is considered to be of limited effectiveness. The pest is on the EU Priority Pests list[17,,3], which means that Member States must have a contingency plan ready for eradicating an outbreak. However, in case of an outbreak, the chances of eliminating *B. cockerelli* are low because of the expected delay in detection and the rapid spread of the pest (EFSA, 2019).

Epitrix cucumeris and *E. papa* are flea beetles of the leaf beetle family. These pests are mainly a threat to the trade and export of potato tubers due to superficial feeding damage caused by the larvae on the potato tuber. They are present in Portugal and Spain and can be introduced into the Netherlands via import of potatoes from these countries. Specific EU requirements apply to potatoes from infested areas: these potatoes must be brushed or rinsed clean so that they are virtually free of soil. However, it is not entirely certain whether potatoes that are free of soil will always be entirely free of live larvae. Moreover, it is difficult to detect the pest in a field, and areas may therefore already be infested for some time before the pest is officially identified and measures taken. Hence, the EU requirements do not entirely eliminate the likelihood of the introduction of either *Epitrix species*. The NVWA has been carrying out inspections for several years at companies importing potatoes from Spain and Portugal. So far, the pest has not been detected.

Pathways of introduction of UQPs and potential UQPs
Potato pests can be introduced mainly via potato material (potato tubers, and to a lesser extent, true potato seeds) and plants for planting of related species. Therefore, the import of potato tubers, true potato seeds, plants for planting of other stolons or tuber-forming species of *Solanum* L. and plants for planting of Solanaceae, other than seeds, is prohibited from most third countries. Taking these regulations into account, the most likely pathways for the introduction of UQPs and potential UQPs for potatoes have been identified (see Annex 5.5 for details):

1. Import of potato tubers from EU Member States and from third countries that (via a derogation) do not fall under the import ban
2. Illegal import of potato tubers, true potato seeds and plants for planting of other Solanaceae by consumers and companies (incl. via passenger baggage and parcel post)
3. Import of fruits of Solanaceae (incl. bell pepper, chili pepper and tomato)

[17] Priority Pests are UQPs with the "most serious economic, social or environmental consequences" (Article 6, Regulation EU 2016/2031[2]). They are pests subject to special provisions, "in particular, the provision of information to the public, surveys, contingency plans, simulation exercises, action plans for eradication and co-financing of measures by the Union".

4 Use of material imported in the past for research and breeding purposes, which have been stored without testing
5 Import of plants for planting of Solanaceae, other than seed potatoes, from European and Mediterranean countries that are exempt from the import ban
6 Import of potatoes and plants for planting of *Solanum* species for research and breeding purposes[18].

NB For specific pests, other pathways may be more likely than the ones listed above. For example, 'hitchhiking with plant products' seems to be one of the most likely pathways for the introduction of the weevil *Naupactus leucoloma* (Table 3). However, the hitchhiking pathway is very difficult to control. Polyphagous organisms, such as *Ralstonia pseudosolanacearum* and *R. syzygii* subsp. *indonesiensis*, that affect plants from different families may also enter through the import of non-Solanaceae. However, these two species pose a low risk to potato cultivation in the Netherlands.

The illegal import of potatoes or other potato materials (Pathway 2 in the list above) may constitute one of the biggest risks, alongside the import of potatoes. Due to the illegal nature of the imported materials, there is no guarantee whatsoever of their phytosanitary status. For example, the introduction of the moth *Tecia solanivora* in the Canary Islands was possibly due to illegal import of potatoes from South America (EPPO, 2005). The NVWA controls passenger baggage in collaboration with the customs authorities and controls parcel post in collaboration with customs and courier services. (NVWA, 2018c). Prohibited materials of plant origin are regularly intercepted by them in passenger baggage at Schiphol. In 2016, potatoes were intercepted in passenger baggage from Peru. Various harmful organisms were found in the potatoes, including *Synchytrium endobioticum* and various quarantine viruses. In June 2018, potatoes were found in three suitcases during the passenger baggage control of a flight from Peru. The potato is native to South America and several UQPs are known to occur there (Table 3). Regulation (EU) 2016/2031, which entered into force on 14 December 2019, requires "*Member States, seaports, airports and international transport companies*" to inform travellers about the phytosanitary requirements for passenger baggage. It is not known whether passengers carry the potatoes with them out of ignorance or deliberately in order to circumvent the import ban. Whether or not it is merely sufficient to inform them about the risk of doing this will have to be proven by inspections at airports. Postal services are also subject to an information obligation. As far as is known, no potatoes or other potato material have been intercepted in parcels, but German research shows that it is easy to order seed potatoes illegally via the Internet (Kaminski et al., 2012).

[18] Commission Delegated Regulation (EU) 2019/829 of 14 March 2019 supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of official testing, scientific or educational purposes, trials, varietal selections, or breeding.

Table 3: UQPs relevant to potatoes not present in the Netherlands or with transient status, their distribution area and main potential pathways for introduction into the Netherlands (situation as on 1 March 2020).

Pest	Distribution area (EPPO Global Database)	Main existing or potential pathways for introduction/products via which the pest can enter
Bacteria		
Clavibacter sepedonicus (ring rot bacterium)	Asia, Europe, North America (transient in the Netherlands)	Potato tubers
Ralstonia pseudosolanacearum	Asia, Africa (possibly on more continents)	Plants for planting of Solanaceae[2] and ornamental plants, other than seeds
Ralstonia syzygii subsp. *indonesiensis*	Asia (Safni et al., 2018)	Plants for planting of Solanaceae[2] and ornamental plants, other than seeds
Insects and mites		
Bactericera cockerelli (potato psyllid)	Australia, New Zealand, North America, South America	Plants for planting of Solanaceae[2]; fruits of Solanaceae
Epitrix cucumeris	Europe (Portugal, Spain), North and South America	Potato tubers with adhering soil from Spain and Portugal
Epitrix papa	Portugal, Spain (probable origin: North America)	Potato tubers with adhering soil from Spain and Portugal
Epitrix subcrinita	North America, South America (Peru)	Potato tubers with adhering soil[1]
Epitrix tuberis	North America, South America (Ecuador)	Potato tubers with adhering soil[1]
Naupactus leucoloma	Europe (Azores), Africa (South Africa), Australia, New Zealand, North and South America	Hitchhiking with plant products; plants for planting (with adhering growth medium)
Premnotrypes spp. (non-European)	South America	Potato tubers[1]
Tecia solanivora	Europe (Canary Islands, Spain), North and South America	Potato tubers from Spain[3]
Nematodes		
Nacobbus aberrans	North and South America	Potato tubers[1]; plants for planting (polyphagous organism)

Pest	Distribution area (EPPO Global Database)	Main existing or potential pathways of introduction/products via which the pest can enter
Fungi and pseudo-fungi		
Puccinia pittieriana	North and South America	Leaves of potato and tomato plants[4]
Septoria malagutii	South America	Leaves of potato and other tuberous *Solanum* species[4]
Stagonosporopsis andigena	South America	Leaves of potato plants[4]
Thecaphora solani	North and South America	Potato tubers[1]
Viruses, viroids and phytoplasmas[5]		
Potato viruses, viroids and phytoplasmas such as[5]:		
Andean potato latent virus	South America	Potato tubers[1]
Andean potato mottle virus	North and South America	Potato tubers[1]
Arracacha virus B, oca strain	South America	Potato tubers[1]
Non-European isolates of the potato viruses A, M, S, V, X and Y (incl. Yo, Yn and Yc) and *Potato leafroll virus*	Multiple continents	Potato tubers[1]
Potato black ringspot virus	South America (Peru)	Potato tubers[1]
Potato virus T	South America	Potato tubers[1]

[1] There is an import ban on potato tubers from most third countries (Implementing Regulation 2019/2072, Annex VI, points 15 and 17). In the Regulation, certain specifically mentioned European and Mediterranean countries or parts thereof are exempted from this import ban; the pest is not known to occur in these countries or parts thereof.

[2] There is a ban on importing plants for planting of Solanaceae from most third countries (Implementing Regulation 2019/2072, Annex VI, point 18). In the Regulation, certain specifically mentioned European and Mediterranean countries or parts thereof are exempted from this import ban; the pest is not known to occur in these countries or parts thereof. Import of seed potatoes is prohibited from all third countries other than Switzerland (Implementing Regulation 2019/2072, Annex VI, point 15).

[3] *Tecia solanivora* was found in mainland Spain in 2015 (see the short risk assessment for this pest in Annex 5).

[4] There is no import ban on Solanaceae leaves. However, there is no known import of potato or tomato leaves or the use of these leaves for consumption purposes.

[5] The specifically named viruses or isolates thereof and all non-European viruses, viroids and phytoplasmas affecting potato are UQPs.

B. Food safety risk assessment

The NVWA supervises the safety of food. Food must not be unsafe[4], in the sense that it must not be harmful to health or unfit for human consumption.

The safety of our food is threatened by several hazards. These include microbiological, chemical and physical agents that may be present in food.

Food business operators are responsible for the safety of the food produced or managed by them. Despite all the measures taken based on food safety plans (see Annex 2.2.3) to ensure that our food is safe, there are agents (microbiological, chemical or physical) in our food that can be harmful to health.

This public health risk assessment investigates the hazards that can occur in the potato chain in the Netherlands and which ones pose a risk to consumer health (food safety).

B1. Microbiological risks

Microorganisms occur everywhere and humans can come into contact with an enormous range of such organisms. Food also contains microorganisms, sometimes in large numbers. However, only a limited group of microorganisms is capable of causing illness in humans. This group of pathogenic microorganisms is the subject of this risk assessment.

Some of these pathogenic microorganisms cause a burden of disease that is relevant to public health. Burden of disease is defined as the number of healthy life years lost in a year at the population level. This is expressed in terms of disability-adjusted life years (DALYs)[19].
The burden of disease of food-related pathogens is monitored annually by the National Institute for Public Health and the Environment (*Rijksinstituut voor volksgezondheid en milieu, RIVM*). The RIVM estimates that, in 2018, there were approximately 652,000 cases of illness caused by the consumption of food contaminated by pathogenic microorganisms. With around 20 billion servings consumed in the Netherlands per year, this amounts to around 1 in every 30,000 servings.
The burden of disease caused by pathogenic microorganisms in our food is estimated at 4300 DALYs for 2018. This involved 652,500 cases of illness, which included 76 deaths.

The assessment of the microbiological food safety risks has investigated which pathogenic microorganisms (hazards) could occur in the potato chain and which hazards pose a risk to public health in the Netherlands through the consumption of potatoes and potato products (Annex 7). For each hazard, the pathways of introduction and the factors that determine whether a hazard becomes a risk (Figure 2) have been examined. The extent to which these hazards contribute to the estimated burden of disease from food has been assessed. Finally, the options for controlling the risks have also been discussed.

[19] DALY: measure of the burden of disease. It is a summation of the total number of days of illness at the population level (taking into account the severity of the condition) and the total number of years of life lost at the population level due to premature mortality caused by a particular hazard or condition.

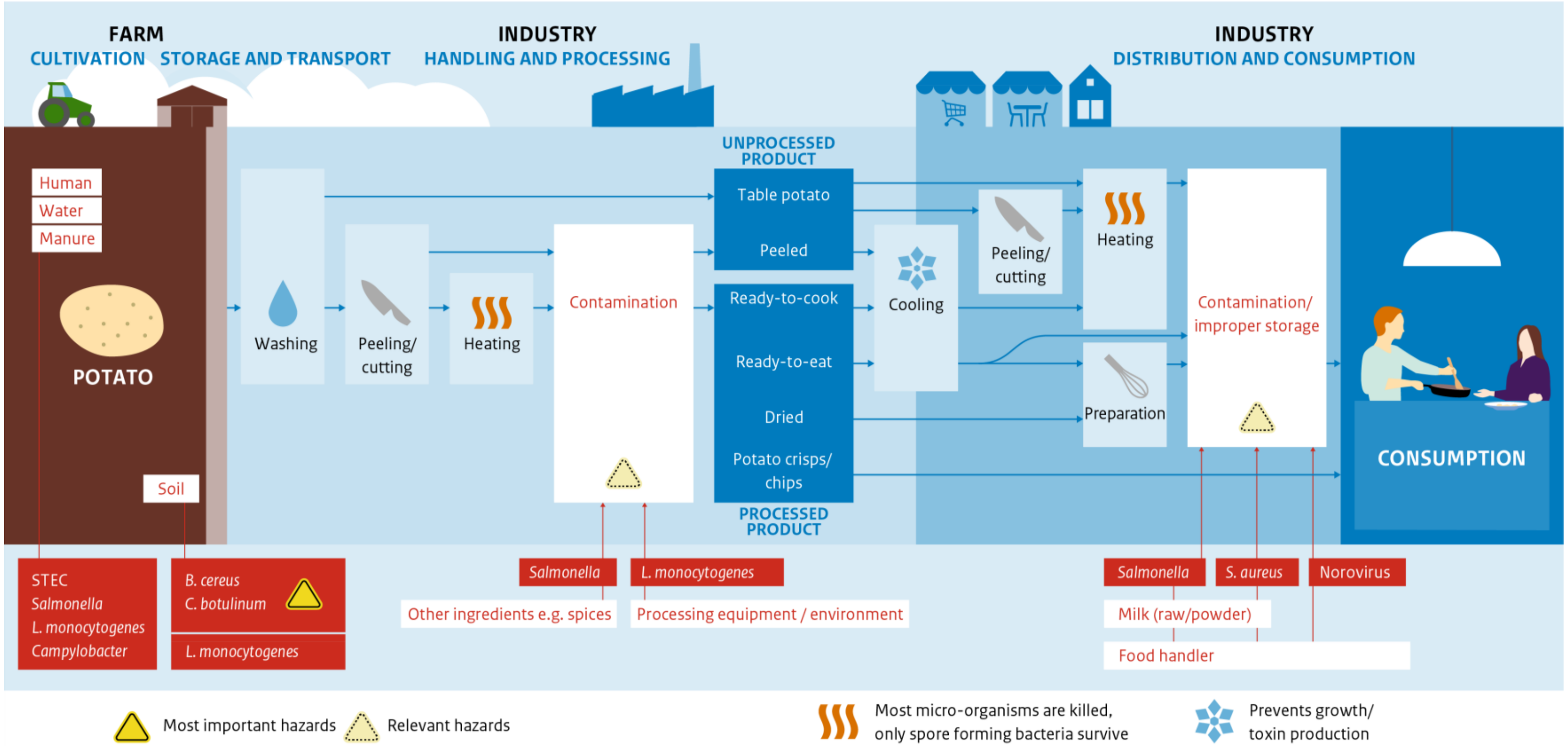

Figure 2. Microbiological hazards in the various stages of the potato production chain

Hazard identification
Various pathogenic microorganisms occur on ware potatoes and products made from them. These contaminate the product during cultivation, processing and preparation by the food handler (mass caterer[1], consumer). The substantiation provided in Annex 7 includes a risk assessment for each of these hazards. From this assessment, it appears that a number of these hazards have been associated several times with outbreaks and cases of illness caused by the consumption of potatoes or potato products and/or are naturally occurring on fresh potatoes. This concerns *B. cereus*, *C. botulinum*, *L. monocytogenes*, *Salmonella*, *S. aureus*, pathogenic *E. coli* (STEC) and norovirus (Table 4).

No data have been found on the occurrence of human pathogenic viruses or parasites on fresh potatoes and no cases of illness have been described. The exception to this is norovirus. This virus originates from humans and is introduced into the potato chain at the stage involving the food handler. *Staphylococcus aureus* was also only associated with the food preparation stage of the chain. However, this stage falls outside the scope of this study. Hence, these microorganisms have not been taken into account here.

Table 4: Overview of pathogenic microorganisms that have caused several cases of illness and/or outbreaks through the consumption of potatoes or potato products and/or that occur naturally on fresh potatoes. The phase of the chain in which the hazard was introduced as well as the pathway of introduction have been indicated. It is also indicated whether the pathogen survives the preparation process of potatoes.

Phase	Primary: Farm		Survives heating	Secondary: Industry	Tertiary: Trade and consumption
Pathogen	Soil[1]	Manure[2]		Post-process contamination[3]	Post-process contamination[3]
B. cereus	x		x	(x)[4]	
C. botulinum	x		x		
L. monocytogenes	x	x		x	
Salmonella		x		x	x
S. aureus					x
STEC		x			
Norovirus					x

[1] Soil: microorganisms naturally occurring in the soil
[2] Manure: microorganisms that migrate into the crop from the animal reservoir via fertilisation (livestock manure) or faeces of wild animals
[3] Post-process-contamination: microorganisms that contaminate the product via the production environment, through added ingredients or the food handler's actions
[4] (): less important pathway of introduction

Production of ware potatoes
Pathogenic microorganisms can be introduced into the chain during the production of potatoes via the soil, animal manure (incl. wild animals), irrigation water or humans.

Humans are assessed as a less important pathway at this stage of the chain since contact is limited (mainly during sorting) and the other pathways play a larger role. However, contamination via the human reservoir should be prevented and hygiene measures should be respected.

The pathogenic microorganisms associated with manure or with irrigation water contaminated by manure are STEC, *Campylobacter*, *Salmonella* and *L. monocytogenes*. The main source of manure-related bacteria in the Dutch potato chain is organic animal manure. This is only used in the field before or shortly after planting potatoes. As a result, the microbiological pressure at the time of harvest will not be high, since only the pathogenic microorganisms from manure that can survive for a longer period of time in soil may be transferred to the potatoes. Manure from wild animals and birds will play a lesser role since it is the underground parts of the potato plant (no direct contact with excrement) that are eaten rather than the parts of the plant above the ground.
Furthermore, irrigation water can be a source of indirect contamination via manure, as can water that flows over the fields unintentionally due to flooding (from sewers or ditches). The use of surface water as irrigation water for ware potatoes is not permitted in large parts of the Netherlands (for control of brown rot). The use of surface water is also subject to specific rules (Akkerbouw Certificeringsoverleg, 2019) and manure legislation aims to prevent the contamination of surface water with manure. As a result of these measures, irrigation water in the Netherlands is not considered to be an important pathway of introduction of pathogenic microorganisms into the potato chain.

The bacteria associated with manure or irrigation water are not commonly found on fresh potatoes. All of these are vegetative bacteria (not spore formers) that do not survive the preparation process (cooking) of potatoes. That is why two STEC outbreaks in the United Kingdom (1985 and 2011) deserve special attention: here fresh potatoes were the cause and adhering soil was considered to be the source of the STEC contamination. Cross-contamination from the soil to ready-to-eat products probably led to the above cases. These outbreaks are an exception and therefore the risk to public health is considered to be very low. For this reason, it has been concluded that manure and irrigation water are not a route of contamination (not a risk factor) for potatoes that can lead to relevant public health risks. However, potatoes, and especially table potatoes, must be properly cleaned (less adhering soil).

Pathogenic microorganisms associated with soil are bacilli *(B. cereus*), clostridia (in particular, *C. botulinum*) and *L. monocytogenes*. These bacteria are regularly found on fresh potatoes. *B. cereus* has also been found inside potatoes (endophyte). The presence of these pathogenic microorganisms on potatoes cannot be prevented. Therefore, the environment (soil) has been assessed as the main route of contamination for potatoes.

Handling and processing of ware potatoes
Fresh potatoes are only washed, which has a limited effect on the amount of bacteria present on the potato. However, as mentioned earlier, table potatoes are required to be clean.
The further handling of fresh potatoes (peeling, slicing) also does not have a substantial effect on the concentration of bacteria present on the potatoes. But these products are susceptible to bacterial growth and should be kept refrigerated. These products must be heated by the food handler (mass caterer, consumer) to make them suitable for consumption. This heating step is sufficient to make it a microbiologically safe product.

When fresh potatoes are processed into potato products, a heating step (e.g. pre-cooking or cooking/frying, dehydrating) is always involved. Only spore-formers (bacilli and clostridia) can survive these processing steps.
However, various publications and outbreaks (see Annex 7) show that pathogenic microorganisms (various types of bacteria and viruses), which do not survive the cooking process, do occur on potato products. Analysis of these data shows that this is due to different types of post-process contamination occurring either during processing (industry) or during food preparation. This last-mentioned stage falls outside the scope of this risk assessment.
The most important source of post-process contamination during the processing of potato products are herbs and herb mixes. This relates to *Salmonella* contamination, which is particularly relevant to ready-to-eat high-fat products such as crisps. In addition, the risk of *L. monocytogenes* must be controlled in all types of ready-to-eat food. Special attention should be paid to this pathogenic bacterium during the processing of potatoes. This is because *L. monocytogenes* continuously enters the production environment of the processing industry along with the raw material (fresh potato) and this pathogen is perfectly capable of forming biofilms in the processing environment and contaminating the end product from there. Post-packaging pasteurisation (if relevant) may reduce the risk arising due to post-process contamination.

Distribution and consumption of potatoes and potato products
The largest number of reported outbreaks relating to potato products occurred in situations where the hazard (the microorganism) became a risk due to the conditions allowing for growth in the product. Prepared products were stored for too long by the food handler at an inadequate temperature (outside the refrigerator), during which time *B. cereus* (within a few hours) and *C. botulinum* (within a few days) could grow and form toxins.
These pathogenic bacteria are also a relevant threat with respect to handled and processed products (chilled). The pathogens are introduced through the raw materials (fresh potato), survive the handling (peeling, slicing) and processing (cooking) of potatoes, and are able to grow and form toxins at refrigerator temperature (<7°C). The heating step required for further preparation does not inactivate the *B. cereus* enterotoxin. Formation of the highly toxic botulinum toxin by *C. botulinum* must be prevented at all times, even though this toxin would not survive the cooking process. Vacuum-packed products in particular pose a risk with respect to *C. botulinum*. Processed chilled potato products should therefore be stored at ≤7°C (preferably ≤4°C). Additional control measures are often required (especially for products with a longer shelf life) such as lowering the pH value or water activity, modified atmosphere packaging (MAP) and/or adding preservatives.

Dehydrated potato products (e.g. instant mashed potatoes, potato starch) are not sterile, but the risk *(B. cereus*) only arises if they are stored incorrectly (too long at too high a temperature) after preparation (mass caterer, consumer). It is assumed that frozen potato products are always sufficiently heated before consumption and do not pose a risk.

B2. Chemical risks

Chemical hazards to food safety are defined as chemical substances that may be intentionally or unintentionally introduced into food. Unintentional introduction refers not only to environmental contaminants that can be taken up by the crops during cultivation, but also plant toxins that occur naturally in the plant or mycotoxins that are produced by fungi on the plant. This may also include substances that enter the food via the machines used or packaging materials. In addition, there are chemicals that can be formed during processing, for example, during the heating process.
Chemicals that are intentionally used in the production of potatoes and potato products include, for example, the plant protection products used during cultivation or the additives used during processing.

Hazard identification
To prepare an inventory of the chemical hazards, the processes and actions taking place at each stage of the potato chain, as well as the chemical substances that could end up on or in potatoes during that stage, have been examined (Figure 3). Annex 8 contains an overview of the potential chemical hazards per stage in the chain, with a detailed risk assessment (plus source references) for each chemical hazard. The hazards that pose a risk or potential risk to food safety in potatoes and/or potato products are outlined in Table 5. These risks are explained in more detail in the text following the table, based on the stages in the potato chain. This also includes a brief description of the chemical hazards that do not pose a risk to the potato chain as well as the chemical hazards for which insufficient information is available for assessing the risk to the food safety of potatoes and potato products.

Table 5: Chemical hazards in the potato chain per stage that can pose a risk to the food safety of potatoes and potato products.

Hazard category	Substances	Source or pathway of introduction
Stage 3: Production of ware potatoes, cultivation		
Plant toxins	Glycoalkaloids (incl. solanine, chaconine)	Naturally occurring in potato plant
Heavy metals	Lead Cadmium	• Contaminated arable land (through the use of fertilisers, including earlier use of sewage sludge or • Atmospheric deposition (regional))
Stage 4: Handling and processing of ware potatoes		
Substances formed by heating	Acrylamide	Substances generated during the heating process

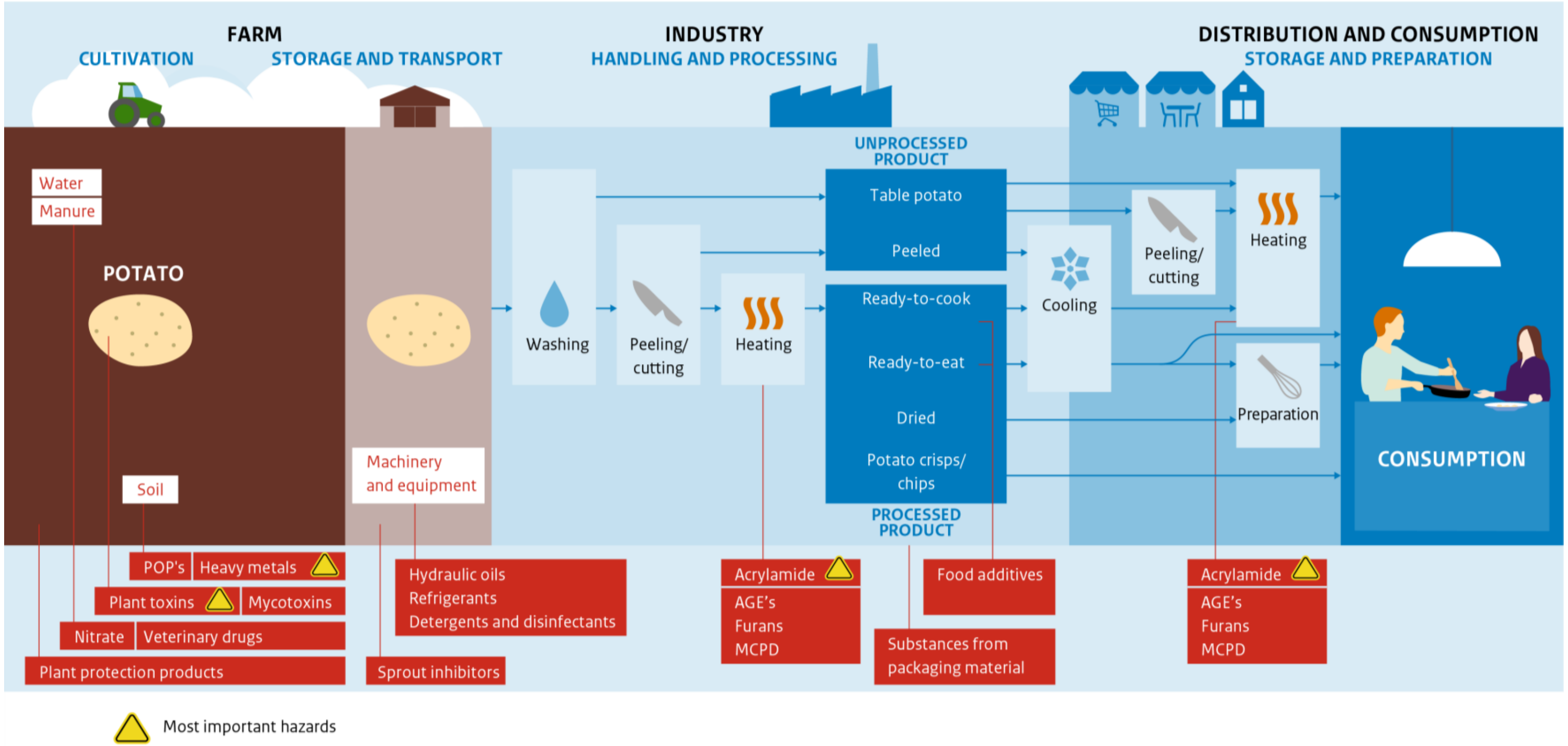

Figure 3. Chemical hazards in the various stages of the potato production chain

Production of ware potatoes - cultivation phase

Natural toxins can be formed in and on potatoes during the growth of the plant. Plant toxins are substances formed by the plant to protect itself from fungi and insect attacks, such as glycoalkaloids and tropane alkaloids. For potatoes, solanine (glycoalkaloid) and calystegines (tropane alkaloid) are the most important plant toxins. The highest concentrations are found in and just under the skin and around the 'eyes' of the potato. A large part of these substances are removed when the potatoes are peeled. Boiling, frying or deep-frying the potatoes also helps remove some of the plant toxins.
No legal limits have been established at the EU level for the occurrence of glycoalkaloids and tropane alkaloids in potatoes. A glycoalkaloid limit of 200 mg/kg (fresh weight), which is legally established in Sweden and Finland, is applied in the Netherlands but not legally stipulated here. Germany applies a limit of 100 mg/kg fresh weight, which has also been laid down via national legislation in Hungary. The total glycoalkaloid levels measured in potatoes on the Dutch market lie below the applicable limit of 200 mg/kg fresh potatoes, and in most cases, also under 100 mg/kg. Based on exposure calculations, it has been assessed that there is a possible acute food safety risk for glycoalkaloids in prepared, peeled potatoes when consuming large servings[20]. No statement can be made on food safety risks in the event of chronic exposure. The risk of calystegines in potatoes cannot be determined due to the lack of information on the toxicity of calystegines and the absence of health-based limit values[21].

Mycotoxins are toxins produced by fungi that occur particularly in crops such as maize and grain. Species of fungi that cause potato rot *(Fusarium)* can lead to the production of the mycotoxins deoxynivalenol (DON) and diacetoxyscirpenol (DAS) in potatoes during cultivation. Mycotoxins in potatoes do not pose a risk to the food safety of potatoes and potato products; the concentrations are low (below the Limit of Detection (LOD)) and exposure calculations show that potatoes only contribute to the total exposure to mycotoxins from food to a limited extent.

Persistent organic compounds such as dioxins and polychlorinated biphenyls (PCBs) are widespread in the environment. Persistent environmental contaminants (dioxins, PCBs, brominated flame retardants, perfluorinated compounds, PAHs and organochlorine pesticides) are mainly found in vegetable oils and fats and/or food of animal origin. They are not present or only found to a negligible extent in potatoes. Potatoes therefore contribute virtually nothing to the intake of these substances through food and these substances do not pose a risk to the food safety of potatoes and potato products.

As a result of a radiation accident, radioactive substances can contaminate the environment and food. The measured radiation level (caesium) in Dutch potatoes is well below the European maximum permitted level in foodstuffs. Without the occurrence of a radiation incident, there is no risk to the food safety of potatoes on account of radioactive substances.

[20] 'Large servings' refers to servings larger than the 'P95 serving'. (The P95 serving is the serving size at the 95 percentile and is the minimum amount per serving that is consumed by 5% of the population). The P95 serving for potatoes and potato products is about 300 grams.
[21] The health-based limit value for a substance is the maximum amount of the substance that a human can ingest without risks to health (mg or µg of substance per kg of body) (https://rvs.rivm.nl/normen/consumenten).

During the cultivation of potatoes, heavy metals (cadmium, lead, arsenic, mercury) can be taken up from the soil or groundwater by the potato plant. For cadmium and lead, the concentrations in the skin are higher than in the tuber. Consumers can be exposed to heavy metals via food. The total intake via food (especially for children) is higher than desirable for both lead and cadmium. The contribution of potatoes to the total intake of heavy metals from food is 5-10% for lead and 15-20% for cadmium. The contribution of potatoes to the total intake of arsenic and mercury is minimal compared to other foods, such as fish. Therefore, for these last two heavy metals, the food safety risks through the consumption of potatoes are assessed to be negligible.

Fertilisation of the field provides nutrients for potato cultivation. The nitrogen present in manure is converted in the soil into nitrate and can be absorbed in this form by the potato plant. In the tuber, the nitrate concentration is highest just below the skin. Washing, peeling and then cooking or deep-frying the potatoes reduces nitrate concentrations. Although nitrate also has positive health effects, an excess of nitrate can lead to adverse health effects. Intake of nitrate from all types of food leads to exceedances of the health-based limit value, which means that health risks cannot be excluded. For small children, potatoes can make a substantial contribution to nitrate intake (4-35%).
Other contaminants from animal manure can also be introduced into the plot: residues of veterinary medicinal products, or in some cases, residues of drug waste that has been illegally mixed with the manure. The extent of the use of slurry in potato cultivation is not known. It is also unknown whether MDMA, residues from the production of XTC and veterinary medicinal product residues enter potatoes via manure. Hence, the risk for the food safety of potatoes cannot be assessed.

Various plant protection products are used during cultivation, residues of which can remain on or in the potatoes. These products are used both prior to planting (for the treatment of seed potatoes and of the soil) and during the growth phase (against weeds, insects and fungi). In the Netherlands, more than 250 plant protection products with 80 different active substances are authorised for use in potato cultivation. Seven active substances are approved for use for seed potatoes but not for ware potatoes.
A ware potato plot is sprayed 10 to 15 times a year and different plant protection products may be used simultaneously or consecutively. Inspections for the presence of active substances in potatoes and potato products show that levels above the Maximum Residue Limit (MRL) (by a few percent) are found on a sporadic basis. However, not all plant protection products that are authorised for use in potatoes are regularly analysed because some of them cannot be analysed with the multi-residue methods used by the NVWA/WFSR. These methods are also used to analyse substances that are no longer authorised. Enforcement is based on exceedances of the MRL. An exceedance of the MRL implies that the food fails to meet the legal limit and may therefore no longer be marketed as food. MRL exceedances may indicate a conflict with the conditions of use set out in the statutory instructions for use and an unnecessarily higher exposure of the consumer to plant protection products. However, the MRL is not a toxicological limit value and therefore an exceedance of the MRL does not automatically imply a risk to food safety. It is possible that, even at concentrations above the MRL, the intake will remain below or far below the health-based limit value for acute and chronic exposure.

For 31 selected active substances[22], the maximum amount of potatoes that someone can eat in a day so as to not exceed the health-based limit values, if the plant protection products are present at MRL level, has been calculated. This results in unrealistically large servings (up to tens of kg of potatoes per day) for both adults and children. This is also an unrealistic worst-case approach because some of the plant protection products will have been removed during the washing, peeling and boiling/frying/deep-drying of the potatoes. The peeling process, in particular, makes a considerable difference. Based on these calculations, the risks to food safety due to the use of plant protection products in potato cultivation have been assessed as negligible. However, there are a few caveats necessary. Firstly, all the plant protection products authorised for use in potato cultivation have not been systematically analysed using the multi-residue methods. As a result, it may have been wrongly assumed that these substances are not found in potatoes. This also applies to substances that are authorised in the countries from which potatoes are imported but that are not analysed when the potatoes are imported. The second caveat concerns a number of products that are only authorised for use for seed potatoes. If seed potatoes are used as ware potatoes - as is common in case of oversized seed potatoes - they could contain substances that are not authorised for ware potatoes. The Arable Farming Food and Feed Safety (*Voedsel- en Voederveiligheid Akkerbouw, VVAK*) certification scheme states that seed potatoes must meet the same requirements as ware potatoes if the grower decides to place all or part of the seed potato harvest on the market as ware potatoes. Situations may arise in which the grower is only faced with the choice of placing the seed potatoes on the market as ware potatoes after the seed potatoes have been harvested. The third caveat is that the simultaneous exposure to the substances from other foods has not been taken into account in this risk assessment. Similarly, simultaneous exposure to different substances with a potential cumulative effect has not been considered in this risk assessment since there is no widely accepted method available as yet for assessing the cumulative risks.

Harvesting, transport and storage of ware potatoes
Sprout inhibitors and fungicides are used during the storage of potatoes to control sprouting and the formation of mould. In the Netherlands, about 20 sprout inhibitors are authorised for this purpose, the vast majority of which are based on the active substance chlorpropham. In addition, a few products based on five other active substances (1,4-dimethylnaphthalene, maleic hydrazide, carvone, ethylene and green mint oil[23]) are also authorised.
The authorisation of products based on the active substance chlorpropham ended on 8 January 2020, with a grace period for use until 31 July 2020 in the Netherlands. This means that chlorpropham may continue to be used for treating the 2019 potato harvest but may not be used for the 2020 harvest. Once the ban is in effect, the MRL will be lowered to the LOD (0.01 mg/kg). With the enforcement of this low MRL, chlorpropham will no longer pose a risk to the food safety of potatoes. However, chlorpropham remains detectable for a long time in the storage sheds because cleaning proves difficult in practice. The European potato sector has therefore applied for a temporary MRL that is higher than the LOD. This dossier has been submitted to the Dutch Board for the Authorisation of

[22] From the 80 authorised substances, 31 active substances have been selected based on three criteria: exceedance of MRL (in the Netherlands (2016 to 2018) and/or the EU (2014)), RASFF notification (1990 to 2018) and a toxicity classification of 'high' (for explanation, see the substantiation of the chemical risks in Annex 8.3.7).
[23] As of 5 June 2020, a new sprout inhibitor based on orange oil has been authorised.

Plant Protection Products and Biocides (*College voor de toelating van gewasbeschermingsmiddelen en biociden, Ctgb*) and is currently (April 2020) being assessed by EFSA. Until a decision regarding a temporary MRL is taken in the EU, the existing MRL (10 mg/kg) will remain in force.
The risk posed by the use of sprout inhibitors based on the active substances maleic hydrazide or 1,4-dimethylnaphthalene for the food safety of potatoes cannot be determined because there is no or hardly any information available about the levels present in or on potatoes. Neither of these two substances, as alternatives to chlorpropham (after the ban on 31 July 2020), are being analysed by any of the multi-residue methods (NVWA in 2018) used for the analysis of plant protection products. Carvone is authorised for use only with seed potatoes, which may not subsequently be used as ware potatoes. Moreover, since carvone is not suitable for use with ware potatoes, the likelihood that ware potatoes are contaminated with carvone is estimated to be very small. Based on this low likelihood, the food safety risk of carvone for potatoes is assessed as negligible.
No risks to the food safety of potatoes are expected from sprout inhibitors based on ethylene and green mint oil.

During the harvesting, transport and storage of potatoes, contaminants from sorting machines, conveyor belts, cooling installations or other machines can contaminate the potatoes. Hydraulic oils and lubricants used in harvesters for the harvesting and storage of potatoes are made of refined mineral oils and additives. Residues from oils intended specifically for use in food production (with a food grade oil classification) do not pose a risk to health (up to 10 mg/kg). However, no information has been found about the extent to which food grade oils are used in potato cultivation or about their specifications. No information has been found about the mineral oil levels found in potatoes. Therefore, it is not possible to assess the risk of the use of hydraulic oils and lubricants in potato cultivation.

During the storage of potatoes, mechanical ventilation systems with fans and heating or cooling equipment may be used for air conditioning in the storage sheds. Refrigerants used for this purpose are penta/tetra/trifluoroethane or the less environmentally damaging propane CO_2 and ammonia CO_2. The latter are being increasingly used since synthetic refrigerants are being phased out from 2020. However, because refrigerants are volatile substances, some of the leaked quantities will evaporate and it is therefore unlikely that refrigerants pose a risk to the food safety of potatoes. Mechanical cooling is expected to be used more in the future since it is seen as a good alternative to the use of sprout inhibitors.

Disinfectants are used to disinfect machines and materials used for harvesting, sorting and processing potatoes and for cleaning the crates used for storage and transport. This is done to prevent the spread of plant diseases and to reduce microbiological risks. If used properly and rinsed thoroughly, no residues of cleaning agents and authorised disinfectants should remain. Little is known about which cleaning agents and disinfectants are used in potato cultivation.
There are disinfectants that are only authorised for use with seed potatoes (the quaternary ammonium compounds DDAC and BAC and tosylchloramide-sodium). BAC and DDAC are not found in potatoes and do not therefore pose a risk to the food safety of potatoes. They could enter the food chain if seed potatoes are used as ware potatoes or if materials used for the cultivation of seed potatoes are subsequently used in the cultivation of ware potatoes. In addition, these substances are also generically authorised for use for the disinfection of cultivation

materials and/or tools. For other disinfectants, either no risk is expected to occur (benzoic acid and hydrogen peroxide) or the risk cannot be assessed due to insufficient data (chlorate and perchlorate as conversion products of sodium hypochlorite).

Handling and processing of ware potatoes
During the processing of potatoes, substances may be added intentionally, such as food additives (e.g. preservatives) or processing aids used for washing and sorting the potatoes.
Processing aids are substances used during the production process, such as antifoaming agents and polymer flocculants used for washing and rinsing the potatoes and substances used for sorting the potatoes (in a clay or sorting bath). Following an incident in 2004 with contaminated clay (containing dioxins) used in a sorting bath, the sector tries to ensure that the clay used for washing and rinsing the potatoes is free of dioxins (based on a declaration from the supplier).

Food additives such as acids, preservatives and antioxidants can be intentionally added to potato products during the handling and processing of potatoes. Sulphite may be used to prevent browning, and it also has an antimicrobial effect. EFSA's estimates of exposure from food indicate that the health-based limit value for sulphite is exceeded, but it should be noted that this value needs to be re-evaluated as soon as new toxicity data become available. Potato products appear to be an important source (more than 5%) of exposure to sulphites. No data were found regarding the presence of food additives in potatoes and potato products in the Netherlands. It is therefore not known whether these additives are always being used in the right manner or whether the set maximum use levels of the authorised additives in potato products are being exceeded.

Certain substances are created as a result of heating potato products such as chips and crisps. For example, acrylamide is formed when starchy products are heated above 120ºC.
No legal limits have yet been set for acrylamide in food, but there are European benchmark levels that serve as a guide for reducing acrylamide levels via risk-mitigating measures. These measures may include the selection of a suitable potato cultivar (less sugar), adjustments in storage and transport, adjustments in the recipe (frying time and temperature) as well as the inclusion of an advised method of preparation on the label.
In the Netherlands, the NVWA has been monitoring acrylamide levels in chips (cafeterias and restaurants) and crisps for a number of years now and this has revealed levels far above the benchmark levels. High levels of acrylamide are found especially in chips made from potato dough. Exposure studies for the Netherlands (2009 and 2014) indicate that exposure to acrylamide is far higher than desired. It is therefore important to reduce the formation of acrylamide in food and keep this to a minimum. Deep-fried potatoes and crisps are the biggest contributors to this: 35% for young children (2-6 years), 56% for children (7-15 years) and 43% for adults.

In addition to acrylamide, other substances, such as AGEs, can also be formed when foods rich in sugars are heated. There is not enough occurrence data to assess the food safety risk of AGEs in potatoes and potato products. Moreover, no health-based limit values are available.

Other substances that can be created by heating (including cooking) food are furans and methylfurans. The risk of furans in potatoes and potato products for food safety cannot be properly determined due to insufficient data on the occurrence of furan and related methylfurans in prepared potato products. Coffee, grain and grain products are by far the most important contributors to the intake of furans from food. MCPD is a substance formed due to the high temperatures used during the production of vegetable oils and fats. Although the dietary intake of MCPD may exceed the health-based limit value, especially in case of younger children, the risk to food safety from potato products is assessed as negligible. Potato products, such as crisps and chips (prepared with vegetable oils and fats), make a relatively small contribution (less than 5%) to the total intake of MCPD from food.

Substances from packaging materials and other food contact materials can migrate to and contaminate the potato product. It is not known what type of plastic is used for packaging pre-fried chips and potato products. Cardboard containers for chips may have been treated with PFAS to make them grease-resistant. There is insufficient information on the presence of PFAS and their potential migration into food.

B3. Physical risks

Physical hazards are contaminants possibly present in a product that subsequently pose a threat to the health of the consumer when the product is used or consumed. These include foreign objects that can be unintentionally introduced into the food and cause choking, cuts and other physical injury. Physical hazards that are inherent to the product itself or the method of preparation are not included in this category as these are generally part of the hazards of consuming food, for example, when the high temperature, shape or consistency of food is such that intake leads to a risk of choking or injury.

Hazard identification
To prepare an inventory of the physical hazards, the processes and actions taking place at each stage of the potato chain, as well as the foreign objects that could end up among the potatoes or in the potato products during that stage, have been examined (Figure 4). This has resulted in the following list of physical hazards in the potato chain, as reported:

- Metal particles, including lead shot (hunting ammunition)
- Plastic
- Glass
- Wood
- Rubber
- Stones
- Chunks of flavouring agents
- Hand grenades
- Golf balls
- Residues of earlier crops, especially the crown roots of the maize plant
- Bones and other remains of animals

The hazards listed here can lead to various physical consequences, such as cuts (due to presence of metal, plastic and glass) and choking (plastic, rubber). Other effects may also include damage to the teeth or more serious injuries if explosives are involved.

Apart from the absolute numbers of reports in the database, further exposure data are not available. Reports from other sources about the detected physical contaminants are not quantifiable and no reports of injuries have been found. Exposure is estimated to be low.

The basic assumption made for the risk assessment is that there is no safe limit of exposure to physical hazards in potato products. In other words, this means that the products must be free from physical hazards by the time they reach the consumer. However, this does not mean that the mere presence of a physical hazard immediately implies a risk to the consumer. In case of a choking hazard, for example, this depends on the size of the object, and in case of a cutting hazard, the edges and points of an object.

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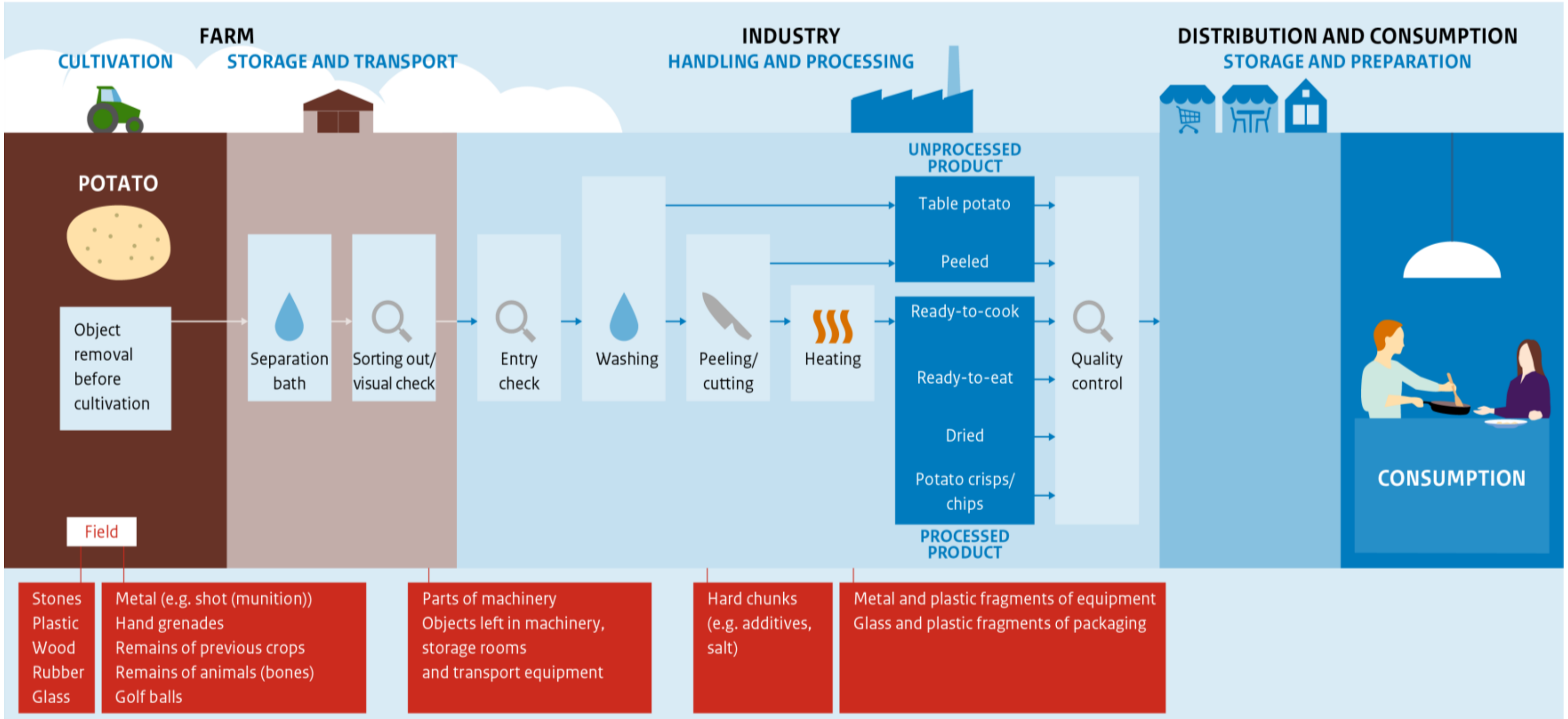

Figure 4. Physical hazards in the various stages of the potato production chain

Production of ware potatoes - cultivation phase
During the cultivation phase, certain physical hazards can be introduced into potato lots that were not present on the plot prior to cultivation. During cultivation, objects from public roads, agricultural machines or arising out of other uses of the plot such as hunting may get transferred to the soil.

Before the start of the cultivation, the rule for a "mandatory removal of contaminants (pieces of glass, plastic, etc., especially along public roads)" applies to the plot (Akkerbouw Certificeringsoverleg, 2019). Hunting of game is not permitted if there is a risk of lead shot (hunting ammunition) entering potato lots intended for potato processing companies (VAVI, 2019). Special attention must be paid to foreign objects with a specific weight similar to that of the potato, for example, golf balls and maize stumps saturated with moisture. A commonly used method to remove contaminants from lots of harvested potatoes is to pass the potatoes through a salt or clay bath. But this does not separate the foreign objects with the same specific weight as the potatoes from the lot. As a result, these objects may be carried along with the lot when the potatoes are washed. To prevent this, the lot can be inspected or visually checked. This can be done using inspection tables or a conveyor. This process is labour intensive. Aviko (Aviko, 2019) observes that the increase in scale has led to a decrease in the manpower available for inspection and cleaning, and consequently more foreign objects are being introduced in the processing phase.

In addition to the foreign objects that may be carried from the plot during harvest, new physical hazards may be introduced during this phase. Parts of machines and transport equipment can be transferred to the potato lots. In addition, objects left behind in the machines and transport equipment during earlier use or cleaning may be carried along with the harvested potatoes. Foreign objects may also have remained behind in storage facilities that can subsequently be introduced into the potato lots as physical hazards. The visual inspection and cleaning of the potato lots at the time of removal from the storage facility and delivery is explicitly stated in the VVAK Guide (Akkerbouw Certificeringsoverleg, 2019) as a condition for the prevention of physical hazards.

Handling and processing of ware potatoes
When handling and processing potatoes, companies must take measures to prevent the occurrence of physical hazards in the product. The industry has several options at its disposal to carry out this task. Potato lots are sieved and washed upon entering the factory, and infrared detection facilities are present. In the event that a contamination introduced with a potato lot is noticed late in the production process, the production line is shut down and cleaned. To ensure that adequate attention is paid to the removal of foreign objects, the general terms and conditions of the processing industry stipulate that the costs of any damage caused by foreign objects will be recovered from the grower or supplier (NAO, 2012; VAVI-LTO, 2012; Aviko, 2020). The HACCP guidelines also require companies to take into account the hazards introduced during processing and to take appropriate measures.

Foreign objects can be introduced in a number of ways during the processing and handling of potatoes. This includes glass and plastic from packaging material, metal particles and plastics from machines and conveyors, and objects used in cleaning and maintenance that are unintentionally left behind in the process. In addition, improperly processed additives, such as aromas and flavourings that remain in chunks, may create hard, sharp sections in the end product. These hazards must also be removed with the help of measures based on the HACCP guidelines before the product reaches the consumer.

C. Other risks to public health, the environment and nature

Plant protection products

Over 250 plant protection products are authorised based on 80 different active substances, with fungicides as the largest group.
In potato cultivation, a relatively large amount of plant protection products is used per hectare compared to other arable crops (kg of active substance per hectare). In organic cultivation, there is a strict limitation on the use of plant protection products. Only a small part of the potato cultivation in the Netherlands (1-2%) is organic.
Besides the intended effect, the active substance of a plant protection product can also have undesirable or harmful effects. For example, exceedances of environmental quality standards continue to occur and the occupational safety standards are not yet adequate. This is partly due to careless use of the products and non-compliance with regulations, and also partly because the simultaneous use of several plant protection products with the same active substance is not taken into account in the authorisation. A study conducted among local residents has shown that the current authorisation frameworks do not underestimate the exposure of local residents. This observation is based on the fact that the measured exposure lies below the health-based limit values. Various leads have emerged for additional follow-up studies, for example, on vulnerable groups or other health-related effects such as in relation to cognitive development.

Another undesirable effect of the use of plant protection products is the development of resistance of *Aspergillus fumigatus* to azoles due to exposure to azole-based fungicides. These products are also used in potato cultivation. It is not known whether the use of these products in potato cultivation makes a major contribution to the total exposure.

Plant protection products policies and authorisation
Dutch plant protection policy is outlined in the *Second Memorandum on Sustainable Plant Protection for 2013-2023* entitled '*Healthy Growth, Sustainable Harvest'* (*Gezonde Groei, Duurzame Oogst*) (EZ, 2013). Integrated Pest Management (IPM) is an important approach in this respect, aimed at reducing agricultural dependence on the use of chemical plant protection products. In April 2019, the Minister of Agriculture, Nature and Food Quality endorsed this approach in the Future Vision for Plant Protection 2030 (*Toekomstvisie gewasbescherming 2030*) (LNV, 2019). In June 2019, the interim evaluation of the Second Memorandum on Sustainable Plant Protection by the Netherlands Environmental Assessment Agency (*Planbureau voor de Leefomgeving, PBL*) (PBL, 2019) was published.
Active substances of plant protection products are assessed and re-assessed at the European level based on a European harmonised assessment framework. Authorisation of products containing these authorised active substances is granted at the Member State level. The authorisation of a product applies to its specific use for a plant and is based on the assessment of whether the product is effective and safe for humans, animals and the environment. Products are authorised for a period of 10 or 15 years (the so-called low-risk products), after which a reassessment is carried out.

In the Netherlands, the Ctgb is responsible for the implementing the authorisation policy with respect to plant protection products.

Use, products and active substances
There are over 250 plant protection products available for potato cultivation with a total of about 680 different authorised applications (pest-crop combination) based on 80 different active substances, with fungicides forming the largest group of products. Three products, that are authorised as fungicides, contain microorganisms *(Bacillus amyloliquefaciens* (formerly subtilis) str. QST 713, *Coniothyrium minitans* strain CON/M/91-8 and *Pseudomonas* spp. strain DSMZ 13134) as active substances. For seed potatoes, no growth regulators are authorised and three sprout inhibitors are authorised[24].

In potato cultivation, a relatively large amount of plant protection products are used per hectare compared to other arable crops: up to 10 kg active substance per hectare of ware potatoes and up to 20 kg active substance per hectare of seed potatoes. For most other crops, up to a maximum of 5 kg active substances per hectare is used.

In organic cultivation, there is a strict limitation on the number of authorised plant protection products. Only a small part of potato cultivation in the Netherlands is organic cultivation: a little more than 2% of the farms and about 1% of the agricultural area used for potatoes (StatLine, 2020).

The active substance of a plant protection product may have undesirable or harmful effects in addition to its intended effects. Although these effects are taken into account in the authorisation procedure, exceedances of environmental quality standards continue to occur and the occupational safety standards are not yet sufficient. This is partly due to careless application of products by growers and non-compliance with the regulations, and also partly because the simultaneous use of several plant protection products with the same active substance is not taken into account in the authorisation. In potato cultivation as well, various products are applied in close succession and simultaneously (as a tank mix).

Risks
The policy on plant protection products in relation to local residents falls under the purview of the Ministry of Infrastructure and Water Management. This chain assessment briefly describes the associated risks but does not assess them in the same way as in the chapter on food safety.
A report by the Health Council of the Netherlands (*Gezondheidsraad*)(Gezondheidsraad, 2014) indicates that people living near agricultural plots are concerned about their health and recommends that further research should be carried out among populations living near agricultural plots. In response to this report, the Ctgb has started to explicitly assess the exposure of local residents since 2014. A study on the exposure of local residents was carried out by the RIVM (RIVM, 2019). This study shows that the measured exposure is below the health-based limit values. The study also provides various leads for additional follow-up studies, for example, on vulnerable groups or other health effects such as in relation to cognitive development.

[24] As of 5 June 2020, a new sprout inhibitor based on orange oil has been authorised.

The policy and supervision of plant protection products in connection with the safety of product users and workers falls under the purview of the Ministry of Social Affairs and Employment. Nevertheless, the Health Council has concluded that the level of safety related to occupational exposure is not always sufficient in practice. A possible cause for this may be inadequate compliance with the regulations or the fact that specific substance properties are not adequately addressed in the authorisation procedure. In the interim evaluation of the Healthy Growth, Sustainable Harvest memorandum, the PBL concludes (PBL, 2019) that growers and the government are still not paying sufficient attention to the occupational risks of working with plant protection products. In the potato chain, occupational exposure to plant protection products occurs during the pre-treatment of the tubers, the spraying of the plots containing the potato crops and the storage period.

Exposure to azole-based fungicides is a major source of resistance of *Aspergillus fumigatus* in health care settings. Fungicides used in agricultural applications can also contribute to this resistance. A number of azole-based products are authorised for use in potato cultivation. It is not known whether the use of such products in potato cultivation makes a major contribution. A survey carried out by the NVWA (NVWA, 2015) showed that the discontinuance of azole-based products had little or no effect at the time on the degree to which fungi could be kept under control in potato cultivation because of the broad range of chemical products being used. The picture has changed somewhat in 2020, because now there are indications that other authorised products have a reduced efficacy, due to a possible development of resistance to these products.

The policy on plant protection products in relation to the environment falls under the purview of the Ministry of Infrastructure and Water Management. Despite the requirements imposed on the use of plant protection products in order to limit emissions into the environment (nozzles, cultivation-free zones), by far the greatest impact on the environment is caused by the impact on surface water. Besides the possible effects on the ecosystem, plant protection products in surface water and groundwater can also cause problems for drinking water extraction. Active substances of plant protection products used in arable farming are found in surface water in excessively high concentrations, i.e. above the prevalent water quality standards.
The environmental impact, measured from 2002 to 2017, appears to be lower for ware potatoes from 2009 onwards, compared to the preceding period. For seed potatoes, there has been a decreased impact since 2011. For starch potatoes, a decrease in impact was observed from 2008 onwards, but this was followed by an increased impact in the period 2012–2014 (see Annex 10).

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