VAN TRAA

Includes useful Recall information!

Product Safety & Compliance

Quick Guide

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International trade, transport & insurance

Contents

Introduction

In general, it is the responsibility of all companies dealing with food and consumer goods to ensure that only safe food and consumer products are for sale. These are not only the producers and retailers, but also traders, importers, websites etc. However, the exact rules and regulations can be found in European and national legislation, which can be quite a jungle to get through. Most companies are aware of the European Food Safety Regulation and the Product Safety Directive but the dozens of specific implementing regulations and directives are intricately intertwined and may seem incomprehensible even to the experienced practitioner. The risks of non-compliance with legal safety requirements are substantial. Any incident may end in consumer complaints, notifying obligations to governments and insurers, claims or even recalls with - unsurprisingly - major consequences for business operations, trade relations and reputation. So how do you act in the event of an incident? Swift decisions are often necessary. Especially if in addition a – silent - (product) recall is involved, the procedure can be quite hectic.

In this Whitepaper we will outline the four most important aspects of a recall.

Product safety: which rules apply for food and non-food products? Naturally, first you have to know when a product is not compliant with the applicable rules, before you initiate a recall.

Obligation to notify: not every incident involving a product should be notified to the regulators. However, failure to notify (on time) constitutes a violation and sometimes even a criminal offence. And which supervisor should you actually notify it to?

Measures: not every incident or every obligation to notify leads to a recall! But what measures should you take? And when *do* you have to resort to a recall?

Recall: If a product has to be recalled, many decisions have to be taken in a short period of time. In this guide we provide Tips & Tricks: from the setup of the press release to holding the supplier liable.

A recall means to call on consumers to return a product.
A withdrawal means a recall action within trade channels.

Product safety

European and national rules for food & non-food product safety

Food

The most important rules for food safety can be found in the General Food Law Regulation (Regulation 178/2002). In addition, however, there are dozens of specific regulations and national decrees regulating a variety of subjects. From novel foods and MRLs for residues and contaminants, from additives and allergens to hygiene regulations, best-before dates and organic claims.

It might be that the most important rule within the European Union (EU) is that businesses are not allowed to place unsafe products on the market. To this end, businesses have a duty of care to ensure only safe products are placed on the market on the basis of Article 17 of Regulation 178/2002. In addition, all businesses handling food must do so in a safe and hygienic way. In so doing, they prevent consumers from falling ill. With a so-called HACCP food safety plan, a company maps out what can go wrong. And how it can prevent mistakes. For example, businesses can and often should supervise:

- personal hygiene of employees;
- hygiene during transport (such as clean containers for raw milk);
- measures during handling or processing (e.g. use of clean machines that cut bread);
- adequate packaging (does a product freeze quickly enough);
- regular sampling and testing of the products;
- storage in sufficiently clean, dark, rooms.

Non-food

The European Union's rules on product safety are laid down in the General Product Safety Directive (Directive 2001/95/EC), which is implemented in national laws and regulations. According to this directive, all professional parties in the supply chain must comply with the rules within the framework of their respective activities:

- to only place safe products on the market;
- to inform consumers of any risks associated with the products they supply;
- to make sure any dangerous products present on the market can be traced so they can be removed to avoid any risks to consumers.

It is important to realise that even though the basis for EU law is the same throughout Europe, their implementation and effects can differ per Member State. For example, some countries have implemented stricter national rules in addition to EU law. Moreover, some subjects are not regulated at a European level, such as, for instance, the food contact material *bamboo.*

What is (un)safe?

Food

Food shall be deemed to be unsafe if it is considered harmful to health or otherwise unfit for human consumption. This standard is set out in Article 14(1) of Regulation 178/2002 laying down the general principles and requirements of food law. It is important to note that the concept of 'safe' is broader than in everyday speech.

In the assessment of whether or not any food is unsafe, the following considerations will be taken into account:

- the normal circumstances in which the food is used by the consumer as well as at all stages of production, processing and distribution, and;
- the information provided to the consumer, including information on the label, or other information generally available to consumers concerning the avoidance of specific adverse health effects from a particular food or category of foods.

In the assessment of whether or not any food is harmful to health, the following points shall be taken into account:

- not only the likely immediate and/or short-term and/or long-term adverse health effect of the food on the health of a person consuming it, but also its effect on their descendants;
- the likely cumulative toxic effects;
- the particular physical sensitivities of a specific category of consumers where in the event the food is intended for that category of consumers.

In the assessment of whether or not any food is unfit for human consumption, it is considered whether a food is unacceptable for human consumption as a result of contamination by extraneous matter or otherwise, or as a result of putrefaction, deterioration or spoilage, while having regard to its intended use.

In addition, it is important to note the general objective of food information on packaging as set out in Regulation 1169/2011. This regulation requires from any party that provides information on food to aim for a high level of protection of health and consumers' interests. Final consumers must be provided with the information necessary in order for them to be able to make informed choices and use food safely.

Non-food

In order to fully comply with these rules as a professional party in the supply chain of non-food products, one must also consider what actually makes a non-food product safe. For the purposes of the Product Safety Directive, a "safe product" means that under normal or reasonably foreseeable conditions of use, including duration and, where appropriate, setting up, installation and

maintenance requirements, a product does not present any risk or only the minimum risks appropriate to the use of the product which are deemed acceptable and consistent with a high level of protection for the safety and health of individuals.

Furthermore, the above implies that professional parties must also check whether the safety information is included in or with the products and whether it meets the language requirements laid down nationally. Please note that all necessary safety information must also be in the national languages of the Member State where the product is placed on the market.

Range: how much product is unsafe?

Article 14 subsection 6 of Regulation 178/2002 is very clear about this: “Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.” Experience shows that the latter is not easily accepted in the Netherlands, neither by the NVWA nor by Dutch judges, but it is certainly possible. When it comes to non-food products, all products with the same deviation fall within the scope of the measures to be taken, including recall.

Please note: Innovative products

A product is deemed to be safe if it meets all legal safety requirements under European or national law. But what if there are no directives or EU standards covering this product? Then the conformity of the product is determined according to other references such as national standards, European Commission recommendations and codes of practice. The bottom line being that the product must be safe for its intended use. We see problems in particular with innovative products or products that are subject to multiple rules. Think of mouth caps: is it a medical device or a textile product? Or CBD in food; is it a novel food? And what about the Opium Act?

Obligation to notify

Obligations to notify: non-compliance and potential harm

The NVWA indicates on its website that companies that may have placed unsafe food on the market or in storage must notify this. For both food and non-food, the NVWA is of the opinion that any deviation should be notified. However, the legislation and regulations show a slightly more nuanced picture of the obligation to notify.

Food

For a food product, it is important to establish whether it is 'merely' a non-compliance issue or a potentially harmful product. Both cases are subject to an obligation to notify pursuant to Article 19 of Regulation 178/2002. However, these obligations to notify take effect at a different time:

> *"If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. […]"*
>
> *"A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health.* […]"

Our analysis of the legislation and regulations is that there is an immediate obligation to notify the possible presence of a *harmful* product. In our opinion, the obligation to notify other deviations seems to arise only after it has been established that the product does not comply with food safety regulations. Please note that whether or not the product has left the direct control of the company only plays a role in the measures to be taken, this does not affect the obligation to notify. The reason given by the NVWA for this is that it also wants to be able to check what is happening with such a product and whether the company's control systems are functioning properly.

NVWA states: "Operators who place potentially unsafe food on the market or in storage must notify this to us."

Non-Food

In the case of non-food products, the obligation to notify is somewhat simpler. Article 21b of the Commodities Act (Warenwet) identifies which party is obliged to notify to the authorities: *"Any party who is aware, or on the basis of the information in his possession as a professional ought to have known, that goods, other than food or drink in so far as they may be used, traded or dealt in privately pose a risk to human health or safety"*.

Who should notify?

It is important that all parties in the supply chain for food and non-food products - from producers to sellers - are aware that they may be subject to an obligation to notify if they know, or should know, that a product is unsafe. Of course, agreements can be made about this between commercial partners, but in the end it is up to each company to decide whether they (should) notify.

Where should you notify?

In general, food safety or product safety problems should be notifyed to the NVWA, which is responsible for monitoring compliance with the rules. Please note, however, that sometimes (also) another supervisor is competent. For example, when a prohibited residue has been found in organic food products, in that case not only the NVWA must be informed but also the SKAL Foundation. Sometimes, the NVWA should not even be informed at all. For instance, if there is some deviation in products that make use of Wi-Fi technology only the Radiocommunications Agency should be informed.

How to notify?

Food

The notify of a food product is done via a form on the website of the NVWA (see Helpful Information for link).

Non-Food

Notifications of non-food products are made via the European Commission's Product Safety Business Alert Gateway (see Helpful Information for link).

Please be aware: Custom bonded warehouse

A lot of food and non-food products come from outside the European Union and are stored - before being cleared and placed on the market - in so-called ***custom bonded warehouses***. Many companies assume that European and national legislation concerning the safety of food and non-food products does not apply there. However, this is a more nuanced issue which is still under discussion. In our view, products stored ***with the intention*** of being placed on the market are already subject to European legislation. Only those products for which it is not yet clear whether, and if so where, they are being marketed would not ***yet*** have to comply with the specific European rules that apply to that product.

Measures

Notify ≠ Recall!

Many companies still think that making a notification as described above automatically leads to a recall. Nothing could be further from the truth. The observation of a deviation does mean that measures need to be taken but which measures are needed, depends on the circumstances of the case.

Food

For a food product, it is important to establish whether it is 'merely' a non-compliance issue or a potentially harmful product. Regulation 178/2002 indicates the following:

> *"If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection."*

> *"A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food."*

In other words, if there is no harmful product, then a recall only has to be triggered if other measures are not sufficient. If the product has not yet left the direct control, the food business operator does not, of course, have to withdraw it from the sales channels.

Non-food

In the case of non-food products, a so-called risk analysis must be carried out in order to determine which measures need to be taken. The following categories are used:

- Serious risk - requires immediate action.
- Moderate risk - requires some action.
- Low risk - usually requires no action for products on the market.

What measures should you take?

When it comes to the measures themselves, one has to think of:

- Recall from the consumer
- Withdrawal from sales channels and stop sales
- A public warning to consumers in national media
- A public warning directed at the specific sales channels
- Product design adaptation
- Adaptation of packaging
- Further research into product portfolio

It should not be forgotten that tracing the products in the supply chain is an important part of the measures to be taken.

In the Netherlands, the National Food and Consumer Product Safety Authority (NVWA) requires that a professional party is able to provide this information "one step forward and one step back" in the supply chain within four hours.

When should you take measures?

A frequently asked question is when a measure should be taken. Is this at the moment when a consumer or customer makes a complaint or only at the moment when an independent expert has identified the exact cause of the food safety problem? The answer cannot be given unequivocally. What is clear, however, is that the more concrete the suspicion of a safety issue, and the more serious the (probability and nature of the) risk becomes, the quicker you will have to take action. In doing so, a company should keep an eye not only on the purely legal circumstances, but also on the commercial ones.

Please note: fulfilment centres and e-commerce

The regulations to date currently focus on the operators 'producer', 'importer' and 'distributor'. However, this does not mean that operators of more innovative distribution channels, such as web shops and fulfilment centres, would not have obligations in the context of recalls. For the time being, the precise obligations of a web shop, a platform, a fulfilment centre or, for example, a meal deliverer should be examined for each specific regulation.

Recall

Stay ‘in control’!

Of course you hope it never happens to your company, but the reality is that it is becoming more and more common. That's why our advice is that any company dealing with food and consumer products should be prepared by means of roadmaps and manuals, instructions for the business and clear agreements with customers and suppliers.

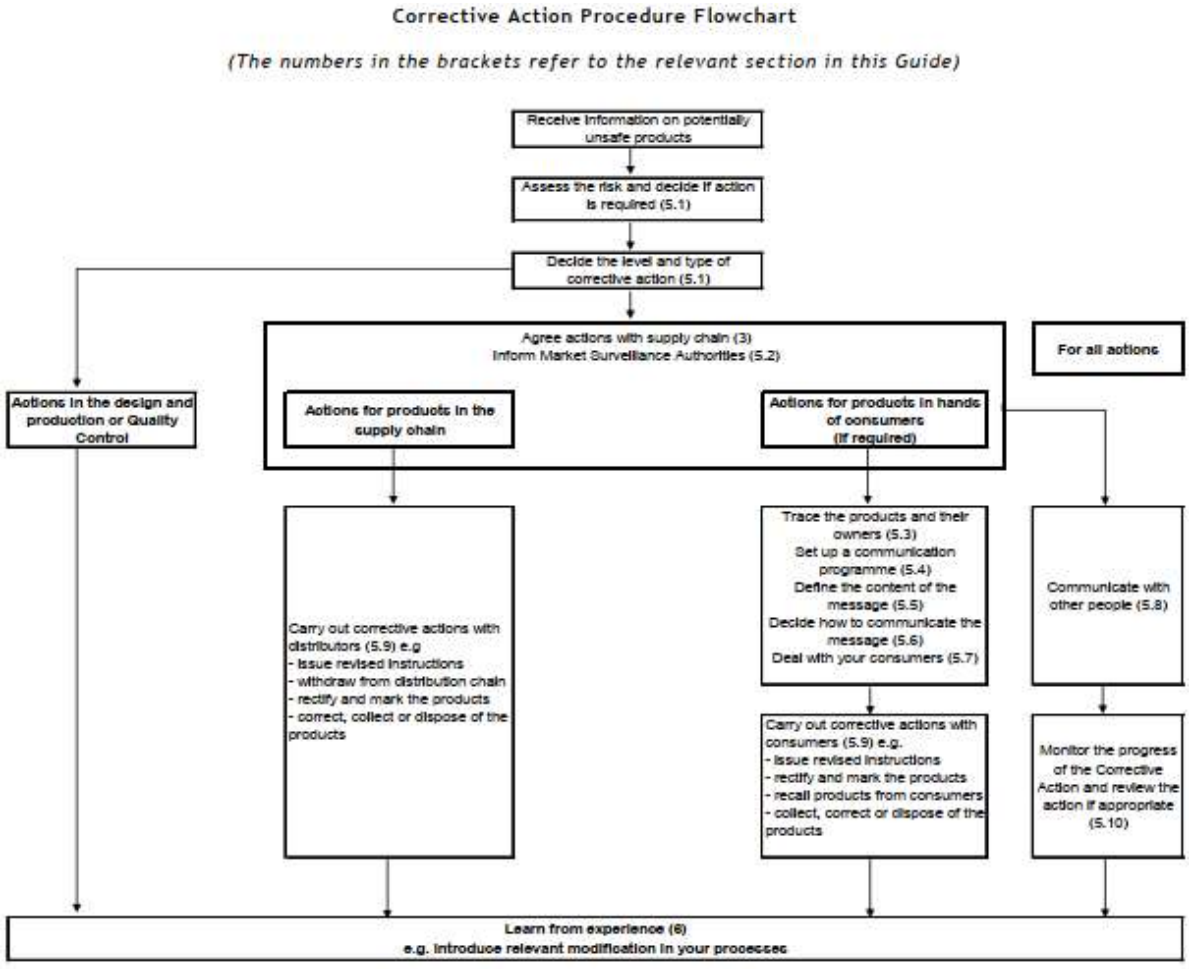
As soon as it becomes clear that a product may be unsafe – through a serious complaint or notification of a supplier or customer -, many decisions have to be made in a short period of time. Our most important tip for companies is to stay 'in control' and take responsibility.

This means that you should not point the finger too easily at another party in the supply chain and/or assume that 'someone else is taking all the measures and doing the notifying'. At the same time, it also means that it is important to fully cooperate with a recall.

A food business operator shall not prevent or discourage any person from cooperating with the competent authorities, in accordance with national law and legal practice, when this may prevent, reduce or eliminate a risk arising from a food.

How does a recall work in practice?

A good reference document for recalls is the Corrective Actions Guide, including product recalls on the European Union website (see Helpful Information). It contains the diagram below:



What does a recall message look like?

The NVWA has a good overview on its website of the information that a safety precaution should include:

- Put at the top of the text: IMPORTANT SAFETY WARNING.
- The product in question with a clear photo (jpg or png, minimum resolution 500x500).
- What is wrong with the product and the possible consequences.
- The name of the manufacturer and where the product was sold.
- When the product has been sold (or expiry date).
- The product code and the logo of the producer.
- Your contact details (for more information).
- Return information:
    - How the buyer can return the product and;
    - How the buyer can get his money back.

Please note: relationship with customers and suppliers and insurers

A recall often has far-reaching consequences for parties involved in the supply chain in question. Parties will often want to hold each other liable for the damage they have suffered or want to recover their damage from their recall insurer. However, we see many practical problems arising from this:

- (In)solvency of the other party.
- (Expensive) foreign arbitration clauses in contracts between (international) parties.
- Doubts about the need for measures taken.
- Problems with the re-importation into the EU of recalled products.

Helpful information

Food legislation

- https://ec.europa.eu/food/safety/general_food_law_en
- https://www.nvwa.nl/onderwerpen/themas/eten-drinken-roken
- EU: https://ec.europa.eu/food/safety/general_food_law_en
- NL: https://www.nvwa.nl/onderwerpen/themas/eten-drinken-roken
- General Food Safety Regulation EU: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004R0852
- Food Safety NL: https://wetten.overheid.nl/BWBR0001969/2018-11-17/0/informatie
- Food Risk and Hygiene General: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004R0852
- Food Risk and Hygiene Animal origin: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0853
- Food Contact Materials: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R1935-20090807
- Labelling and food information: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R1169
- Food microbiology: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02005R2073-20140601
- Food mycotoxins: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20140701
- Food contaminants: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993R0315-20090807
- Food residues of pesticides: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32005R0396

Non-Food legislation

- https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/product-safety-rules_en
- https://www.nvwa.nl/onderwerpen/themas/consumentenartikelen-non-food

Obligation to notify - Food

- https://formdesk.minlnv.nl/industrie/GFL-formulier_v5_nl
- https://www.nvwa.nl/onderwerpen/melden-onveilige-levensmiddelen/documenten/consument/eten-drinken-roken/melden/onveilige-levensmiddelen/meldwijzer-nvwa-onveilige-vensmiddelen

Obligation to notify - Non-Food

- https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en
- https://www.nvwa.nl/onderwerpen/melden-onveilige-producten-non-food

Measures - Food

- https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf
- https://www.nvwa.nl/over-de-nvwa/hoe-de-nvwa-werkt/onveilige-producten-van-melden-tot-waarschuwen

Measures - Non-Food

- https://ec.europa.eu/consumers/archive/cons_safe/action_guide_en.pdf
- https://www.nvwa.nl/binaries/nvwa/documenten/consument/consumentenartikelen/non-food/overige-non-food/veilig-voedsel-en-non-food-producten/veilig-voedsel-en-non-food-producten.pdf

Our most important tips for every recall

1. A stitch in time saves nine!
2. Know your rights and obligations.
3. Know who has to notify, to which supervisor and when.
4. Make a manual.
5. Make sure you have proper insurance cover and contractual arrangements.

What can Van Traa do for you?

- Provide advice on product compliance with European and national food and product regulations, in particular on innovative technology and novel foods, but also on MRLs, contaminants and residues, labelling, additives (health) claims.
- Provide information on registrations, approvals, certificates and CE markings. In particular Van Traa has a special expertise when it comes to organic food products and procedures at the Skal (organic authority).
- Prepare for, and assist with, inspections and raids.
- Provide legal assistance in legal procedures against imposed measures of the NVWA, Skal and other supervisors, such as warnings, sanctions and claims.
- Assist with claims from / to suppliers, customers, (recall) insurers, transporters, and consumers.
- Review general (transport and delivery) conditions and contracts.
- Assist in setting up and arranging authorised representatives.
- Multidisciplinary recall-desk 24/7 available at +31 (0)6 – 20 21 05 66.

Of course we can also provide tailor-made courses, webinars, manuals and instruction sheets.

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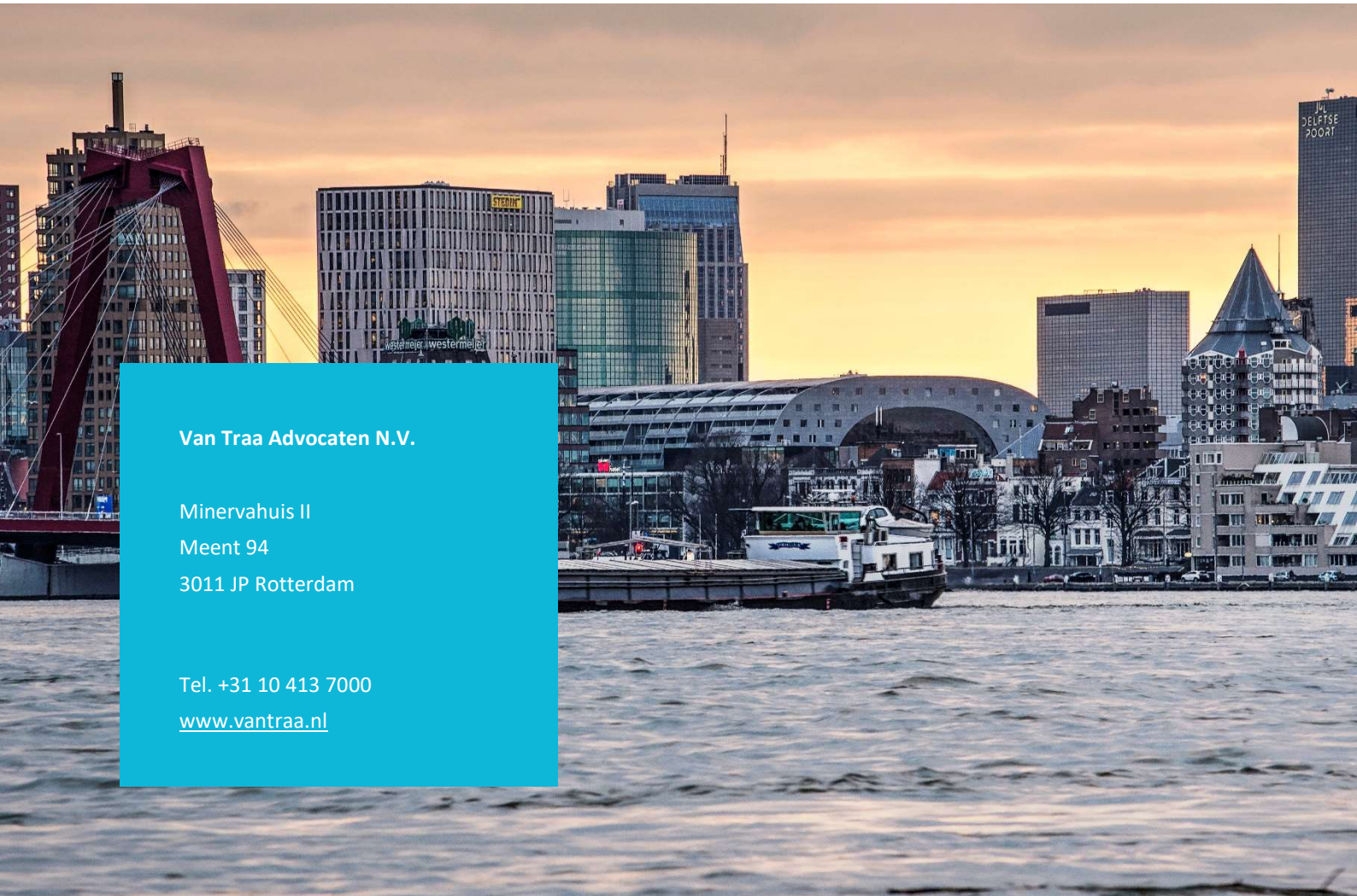

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