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Derivation of limit values for animal residues in
vegan and vegetarian foods

Bachelor Thesis

in the field of Nutrition and Home Economics (Ökotrophologie)

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List of Abbreviations

BLE	“Bundesanstalt für Landwirtschaft und Ernährung” Federal Agency for Agriculture and Food
BMEL	“Bundesministerium für Ernährung und Landwirtschaft” Federal Ministry of Food and Agriculture
BCV	Biocyclic Vegan Label Ltd
BVL	“Bundesamt für Verbraucherschutz und Lebensmittelsicherheit” Federal Office of Consumer Protection and Food Safety
<i>c</i>	Number of sample analysis tolerated over <i>m</i> and under <i>M</i>
EC	European community
ELISA	Enzyme-linked Immunosorbent Assay
EU	European Union
EVU	European Vegetarian Union
FSA	Food Standards Agency
GMO	Genetically modified organism
GMP	Good manufacturing practice
ISO	International Organization for Standardization
IVU	International Vegetarian Union
LOD	Limit of detection
LOQ	Limit of quantitation
<i>m</i>	Standard residue level
<i>M</i>	Maximum residue level MRL
MRI	Max Rubner-Institut
<i>n</i>	Number of samples
n.i.g.	No information given

NGO	Non-Governmental Organisations
NRZ-Authent	National Reference Centre for Authentic Food
PCR	Polymerase chain reaction
qPCR	Quantitative PCR
UK	United Kingdom
VEBU	“Vegetarierbund Deutschland e. V.” German Vegetarian Association
Veg*n	Vegan and Vegetarian

Annotations:

- For better readability, the terms vegan and vegetarian are hereafter summarized as "**veg*n**".
- German technical terms that are common in the international context are deliberately not translated.

Abstract

Introduction: The market for vegan and vegetarian (veg*n) food alternatives is growing exponentially. However, the lack of a legal basis for uniform definitions and production practices leads to food adulteration by companies on the one hand and to disappointment of consumer expectations on the other.

Objective: Deriving a limit value to create a regulated legal basis for the evaluation of residues of animal substances in veg*n foods. For this purpose, practices of Good Manufacturing Practice (GMP) are applied to assess contamination as either technologically unavoidable or deliberate deception.

Method: A literature review is performed to close the existing legal gap. In addition, the specifications of NGOs and third-party providers of certifying labels are summarised.

Result: There is no consensus among most veg*n organisations. Information on residues is either not openly communicated or is formulated in an abstract manner, making it difficult to establish a uniform threshold. The European Vegetarian Union (EVU) sets a limit of 0.1% for animal residues in veg*n food in its guidelines. This is widely applied, not least due to the high popularity of its own label for veg*n food (V-label). Likewise, the specifications of the V-label can be well established in practice. Based on the research conducted, a zero-tolerance requirement for residues, as demanded by some organisations, cannot be applied from an analytical point of view alone.

Conclusion: A uniform establishment of limit values remains a complicated undertaking and cannot be conclusively carried out in this work. The 0.1% requirement of the EVU seems to be the most technically and analytically valid one due to its practicable approach. Whether this requirement can find uniform legal acceptance must be further evaluated.

Zusammenfassung

Einführung: Der Markt veganer und vegetarischer (veg*n) Lebensmittel Alternativen wächst exponentiell heran. Fehlende rechtliche Grundlagen zu einheitlichen Definitionen und Herstellungspraktiken führen jedoch zu Lebensmittelverfälschungen der Unternehmen einerseits und zur Enttäuschung der Verbrauchererwartung andererseits.

Ziel: Ableitung eines Grenzwertes, um geregelte Rechtsgrundlagen zu schaffen, damit Rückstände tierischer Substanzen in veg*n Lebensmitteln bewertet werden können. Hierzu sollen Praktiken der “Guten Herstellungspraxis” (GMP) herangezogen werden, um Kontaminationen als technologisch unvermeidbar oder bewusste Täuschung bewerten zu können.

Methode: Eine Literatur Recherche soll die bisher existierende Rechtslücke schließen. Zudem werden Vorgaben von NGOs und Drittanbietern zertifizierender Labels untersucht und zusammengefasst.

Ergebnis: Die Mehrheit der veg*n Organisationen kommt zu keinem Konsensus. Viele Angaben zu Rückständen werden entweder nicht offen kommuniziert oder sind entsprechend abstrakt formuliert, sodass dessen einheitliche Etablierung erschwert ist. Die Europäische Vegetarier Union (EVU) gibt in ihren Richtlinien einen Grenzwert von 0,1% zu tierischen Rückständen in veg*n Lebensmitteln vor. Dieser findet, nicht zuletzt durch die hohe Beliebtheit des eigenen Labels für veg*n Lebensmittel (V-Label), breite Anwendung. Ebenso lassen sich die Vorgaben des V-Labels in der Praxis gut etablieren. Auf Grundlage der durchgeführten Recherche kann eine Null-Toleranz Vorgabe für Rückstände, wie sie von einigen Organisationen gefordert wird, allein aus analytischer Sicht nicht angewendet werden.

Fazit: Eine einheitliche Etablierung von Grenzwerten bleibt ein kompliziertes Unterfangen und kann in dieser Arbeit nicht abschließend getätigt werden. Die 0,1% Vorgabe der EVU scheint technisch und analytisch am stichhaltigsten aufgrund seiner Anwendbarkeit, zu sein. Ob diese Vorgabe einheitlichen rechtlichen Einzug finden kann, muss weiter evaluiert werden.

1.Introduction

The market for vegetarian and vegan (veg*n) food products is rapidly growing. Sales analysis showing a market growth of 21% in 2022 compared with 2020 for the veg*n plant-based food sector alone. Therefore, reaching a total value of 5.8 billion €. Germany represents the biggest market for plant-based alternatives on the European market (Curtain & Grafenauer, 2019; GFI Europe, 2022). While the European market is changing towards plant-based products and meat alternatives, the consumption of animal meat is decreasing (BZfE, 2023). The total sales units are further expected to grow in Europe (GFI Europe, 2022).

1.1 Framework Conditions

While the sector for veg*n food is expanding, there are yet to be legal regulations for such products (Domke, 2018; Hartwig, Sina & Smollich, 2022). With general food regulations finding application for concerns on safety or information's, there is no pertinent law for production criteria nor marketing (Comans & Schöllmann, 2016, pp. 1-7; Riemer & Seitz, 2021, pp. 5-7, 19-34). To date, unified and legally approved definition for veg*n foods is still missing (Domke, 2018; Hartwig, Sina & Smollich, 2022). With the veg*n market exploding in their exponential growth, legal laws remain a needed requirement (Gheihman, 2021).

Where the legislator leaves gaps in law, sub-legislation can fill this blank. Therefore, the International Standardisation Organisation ISO has published its ISO 23662 standard, to fill this gap. Technical criteria for fulfilling the product legal definition of veg*n foods have so far only been regulated by this standard at European level (Comans & Schöllmann, 2016, pp. 1-7; Domke, 2018). Here, legally relevant questions regarding production guidelines, contamination limits and other requirements are discussed, but the ISO standard does not provide a legal foundation. Due to the lack of the law basis, the ISO standard is utilized as a reference, but cannot pose legal demands (Beuger, Jäger & Müller-Amenitsch, 2022, pp. 7-13). This results in companies advertising their own products as veg*n but therefore not necessarily meeting this definition, regarding the commonly accepted definition of vegetarianism or veganism by most of the veg*n costumers (Stremmel et al., 2022).

1.2 Problem Definition

As demand and profit margins for veg*n foods increase, Counterfeiting becomes more attractive. In some cases, veg*n products have been mixed with animal ingredients to improve the texture and taste or to reduce the cost (Mi et al., 2015; WWF, 2023). Meanwhile, problems with veg*n foods have drawn increasing attention due to various inaccurate descriptions, fraud, as well as contaminations with animal components (Cheng et al., 2012; Wallace et al., 2012).

On the opposite, companies who try to adapt to this rising market, are facing the challenges of contamination residues. This contamination can have multiple origins (Comans & Schöllmann, 2016, pp. 7-9). Those companies that do not solely specialise in veg*n foods often rely on shared facilities for non-animal and animal products in their facilities. This, however, often leads to cross-contamination. Even though technical criteria, as defined by the ISO 23662, aim to decrease contamination by implementing Good Manufacture Practices (GMP), they are still not able to completely solve the problem (Beuger, Jäger & Müller-Amenitsch, 2022; ISO, 2021, pp. 37-38, 61-65).

1.3 State of Research & technical criteria

The fraudulent advertisements of veg*n foods, which pose a widespread problem, has a negative effect on consumer confidence in food products. Thus, a reliable food authentication tool is necessary for food safety (Mi et al., 2015). Analytical methods for the detection of animal substances in veg*n food have been established with quantitative polymerase chain reaction (qPCR) methods. With animal DNA as their target, small concentrations can be detected. (Köppel et al., 2021; Ren et al., 2017).

1.4 Objective

This paper reviews the literature and evaluates possible solutions to fill the gap in legal regulation surrounding veg*n foods. Therefore, basic EU Regulation to apply on veg*n foods are covered first, since they build the basic criteria for distributing veg*n foods on the European market. Furthermore, the feasibilities of certain thresholds will be examined within the scope of analytical methods and their detection limits. From these factors, an action plan is created which shall have its purpose as a guideline on setting up sample analysis to therefore verify residue limits of contaminations in veg*n foods from animal substances. Lastly, criteria's for veg*n labels from third-party organisation are compared and discussed. From this, possible limit values and requirements for the production of veg*n foods in the European market are suggested.

2. Theoretical background

Establishing guidelines for limit values of animal residues in veg*n foods is a complicated undertaking. To this end, Europe's most influential NGOs and associations in terms of vegetarianism and veganism will be examined. These organisations put a significant amount of effort into lobbying and advocating uniform definitions for the veg*n movements, so that their pioneering work can form a crucial basis for this literature research (ProVeg e.V.; 2019; Domke, 2018). Since there is currently no legal regulation for veg*n products, the label requirements given by these organisations are effectively legally binding. However, the positions taken, and requirements set out by the various organisations differ greatly in some cases. Even if there is some consensus, uniform guidelines are not yet possible. To draw a clearer picture of the certain situation, an overview of these organisations is given, and the specificities of the different labels are outlined. Differences in definitions and resulting problems are being highlighted. Finally, analytical methods for the detection of animal DNA in veg*n products are introduced.

2.1. Vegetarian & Vegan food NGOs in Europe

Europe has multiple NGOs in the fields of vegetarianism and veganism. Most of them are corporations, umbrella organisations, or sub-associations. In this instance, only the International Vegetarian Union (IVU) and the European Vegetarian Union (EVU) are shown, since they are the biggest organisations in this field. They have also progressed to most towards uniformly legal definitions for veg*n products. IVU and EVU share their members across. Also, these two organisations work very closely together and reflect an almost identical interest body in Europe.

2.1.1. IVU International Vegetarian Union

With its establishment in 1908, the IVU holds the distinction of being one of the oldest and largest vegetarian organizations globally. The IVU is committed to encouraging and supporting individuals in adopting a plant-based lifestyle, driven by ethical, environmental, and health considerations. They work towards creating a more compassionate and sustainable world by promoting veg*n diets as a means to reduce animal suffering, combat climate change, and improve human health (International Vegetarian Union, 2023).

2.1.2. EVU European Vegetarian Union

This organisation is often referred to as the umbrella organisation for vegan and vegetarian associations and societies in Europe. It is the organisation behind the V-Label, which represents the most influential label for veg*n foods in Europe. The EVU connects non-profit veg*n-organisations in the fields of vegetarianism and veganism throughout Europe. For instance, EVU offers free membership to all veg*n societies that work on a non-profit basis. A list of all current Members is displayed in table 4 in the appendix (EVU European Vegetarian Union, n.Y.).

EVU is politically active to promote legal terms of interest by their member organisations. Through EVU's German affiliate company of ProVeg, they have proposed a definition for vegetarianism and veganism. This definition was adopted by the "Verbraucherschutzministerkonferenz 2016" in Germany and later incorporated into the "*Leitsätze für vegane und vegetarische Lebensmittel mit Ähnlichkeit zu Lebensmitteln tierischen Ursprungs*" from the German Food Code Commission. The ISO 23662, which forms the current sub-legal definition for veg*n foods in Europe, was then built upon this document (Domke, 2018; EVU European Vegetarian Union, 2019; ProVeg e.V., 2019).

2.2. Overview of the Veg*n food Labels in Europe

There are several third-party label providers in the European area. For the European market the prominent V-Label is the most frequent used label and is ranked highest in terms of customer recognition (Gerke & Janssen, 2017). This is followed by Sunflower Label of the Vegan Society. Thus, being the second most used vegan food label in Europe, it is well known beyond Europe borders. Both certification organisations display Europe's most influential labels for veg*n foods (Domke, 2018; Stremmel et al., 2022).

While both form the most used third-party-labels in Europe, there are other smaller labels found as well. Even if these labels display a more niche application range, they still fill a crucial market share. In addition to these labels, a whole series of company-owned private labels are used on the market. These labels are created by the companies themselves and have guidelines and criteria defined by the producers themselves. Since these are not controlled by third parties and the manufacturers can define their own criteria due to the lack of comprehensive legislation in the EU, these labels are not very significant and often lack transparency. For the third-party providers, however, these labels represent a growing competition, as their market share continues to grow (Gerke & Janssen, 2017). All third-party Labels for veg*n foods are listed in table 1.

Table 1: Overview of Europe's third-party Labels for veg*n foods.







Organisation	Origin	Distribution area	Scope	Products	Unique Criteria's	Trademark Labels
V-Label GmbH	Switzerland	Europe, Asia	Veg*n	Food	Broadened application range for food. Criteria's softened compared to other Labels.	
The Vegan Society	UK	International	Vegan	Food, cosmetics, clothes	Ethical veganism approach with technical applicable criteria considered.	
EcoVeg	Germany	Germany	Vegan	Food	Only products restricted to Organic regulation (EC) 834/2007	
Vegan Society Germany e.V.	Germany	Germany	Vegan	Food, lifestyle products	No tolerances for animal residues. zero-Tolerance approach.	
BCV**	Germany	Germany	Vegan	Agriculture Products	Biocyclic-agriculture. Restrictions for harvesting & fertilising.	
Vegetarian Society	UK	UK	Veg*n	Food & Household wares	Further restriction on animal welfare, e.g., free range eggs.	

Table made on own compilations. Information's retrieved from respective internet Webpages listed in Table 5 in the appendix. Viewed on 13.06.2023.

*Illustrations of the labels retrieved from their respective internet homepages. Copyrights belong to their respective owners.

**BCV = Biocyclic Vegan Label Ltd.

2.2.1. V-Label GmbH

The V-Label GmbH has the exclusive ownership of the V-Label, which was registered as a trademark back in 1996. It has since then become the most frequently used Label on the European market (Gerke & Janssen, 2017). The V-Label company is represented by different organisations in each of its member states. A comprehensive list of all member organisations is shown in Table 4 in the appendix.

ProVeg International and its respective ProVeg Germany are the authorised organisations to perform the certification of the V-Label throughout Germany. ProVeg Germany was formerly known as VEBU “Vegetarierbund Deutschland e.V.” until rebranded (V-Label GmbH & ProVeg e.V., 2019). All audits are performed by ProVeg Deutschland e.V.. The guidelines and principles are therefore based on those of V-Label GmbH (ProVeg Deutschland e.V., 2018). The relationship between the responsible organisations behind the V-Label are shown in figure 1.

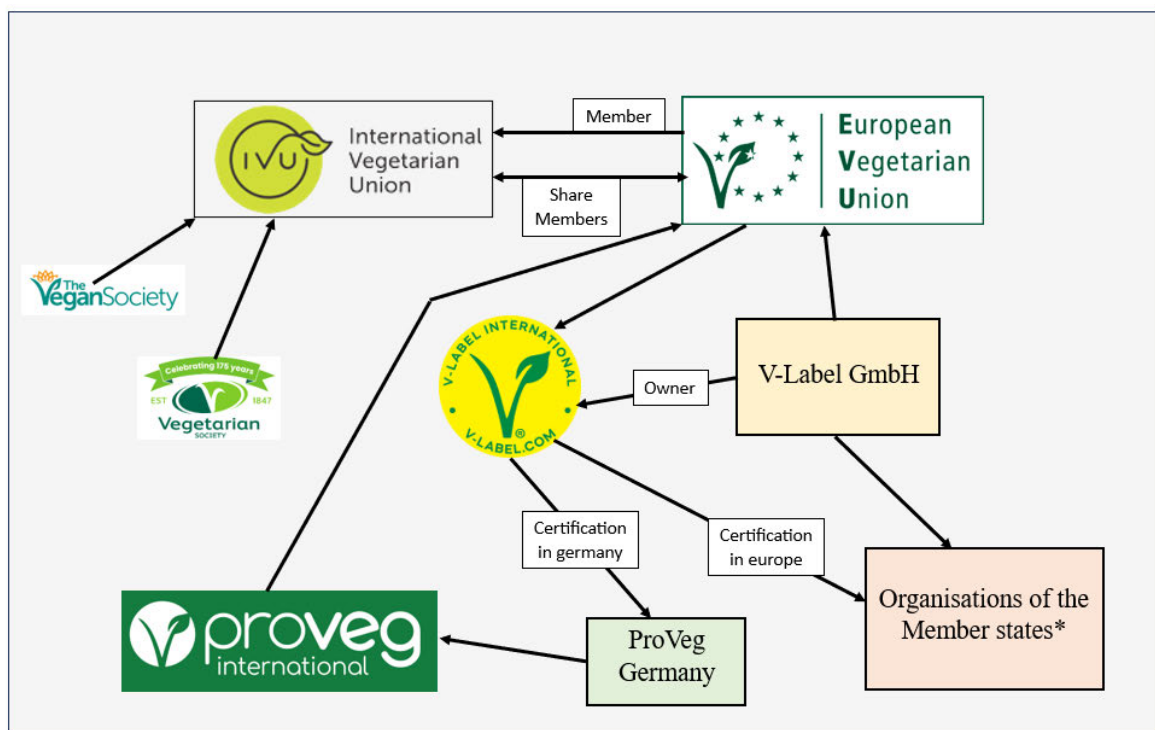


Figure 1: Relationships of the V-Label and the NGOs in Europe.

Figure is based upon own depiction.

*All member Organisation listed in table 4 in the appendix.

**Illustrations of the logos retrieved from their respective internet homepages. Copyrights belong to their respective owners.

2.2.2 The Vegan Society

Established in the United Kingdom in 1944, the Vegan Society holds the esteemed position of being one of the oldest vegan societies globally. Since its establishment, the Vegan Society played a crucial role in promoting the vegetarian lifestyle throughout Europe (Miguel, 2021; The Vegan Society, 2022b). The Vegan Society works as a Non-Profit organisation. Its primary objective is to inspire and support individuals in embracing a vegan lifestyle (The Vegan Society, 2014).

2.2.3 EcoVeg

EcoVeg combines vegan food with the restrictions of the Organic regulation (EG) 834/2007. All products labelled by EcoVeg are therefore in conjunction with the logo of the European Union for organic production. It is therefore not available individually and is a prerequisite for the award of this label. The label represents a stricter guideline on veganism compared to the EU organic label (VegOrganic e.V., 2017).

2.2.4 Vegan Society Germany e.V.

The Vegan Society Germany, known as “Vegane Gesellschaft Deutschland e.V.”, is a non-profit organization operating in Germany. Since its establishment in 2003, the organization has been actively involved in promoting veganism and advocating for animal rights. The Vegan Society Germany distributes their vegan Trademark Label. They approach a strict zero-tolerance approach for animal residue in the production (Vegane Gesellschaft Deutschland e.V., n. Y.-a, n. Y.-b).

2.2.5 Biocyclic Vegan Label Ltd

The Biocyclic Vegan Label Ltd is a non-profit organization based in Germany that supports and promotes the concept of bio-vegan agriculture. Established with the aim of combining the principles of organic farming and veganism, the organization encourages sustainable agricultural practices that are free from animal inputs and by-products. They are responsible for the biocyclic vegan label (Förderkreis Biozyklisch-Veganer Anbau e.V., 2023a).

2.2.6 The Vegetarian Society of the United Kingdom Limited

The Vegetarian Society works to raise awareness and promote vegetarianism on a larger scale. They collaborate with food manufacturers, retailers, and caterers to develop and promote vegetarian-friendly products and menus. Through their Vegetarian Society Approved trademark, they provide a recognizable symbol that assures consumers that a product is suitable for vegetarians (The Vegetarian Society of the United Kingdom Limited, 2023).

2.3. Definition of veganism and ethical beliefs

To further depict the condition of implementing limit values for animal residues, it is crucial to first set regulating definitions. Without these, it is unclear as to whether limit values can apply or not in a given situation. To define what is considered to be an animal residue or not, veg*n definitions are therefore scrutinised. Consequently, all substances not covered by these definitions are thus counted as animal residues, under the premise alone of these substances being food.

Food may be called “vegan” if it has been produced free of animal components. The term “animal” is generally used to refer to living beings with a cell nucleus, so-called eukaryotes. These do not obtain the energy they need for their metabolism from sunlight, as plants do, but instead from food. They also require oxygen for respiration and are not fungi. The term therefore covers the group of multicellular organisms known as metazoans (Comans & Schöllmann, 2016, p. 51).

Besides the lack of a uniform definition of veganism, this is also missing for substrates that can be classified as vegan and non-vegan. Since the definition "free from animals" is sometimes difficult to implement in practice, different views on certain ingredients have emerged. Some ingredients are used whose suitability for veganism is questionable. This often leads to an incongruence between consumer expectations and the food product. Whether a product is vegan or not cannot be determined by its list of ingredients alone. (Stremmel et al., 2022).

The concept of veganism has changed several times over the course of time. Originally, veganism was a traditional worldview in which an animal-free diet was expressed. Currently, there are other considerations besides animal rights, such as health or the environment, and many more. The vegan food industry of vegan products has thus detached itself from the traditional understanding of veganism and has put the pure vegetable nature of the products in the foreground. The term "vegan" is used partly ideologically and partly in terms of product law (Beuger, Jäger & Müller-Amenitsch, 2022; Chuck, Fernandes & Hyers, 2016). Veganism is distinguished from vegetarianism. This is described in simple terms as a group of individuals who abstain from the dietary consumption or other use of any animal product (Hirschler, 2011).

The consumer protection ministers of the federal states of Germany in April 2016 have defined the Term of veganism and vegetarianism as the following:

“No products of animal origin and

in which no ingredients or processing aids of animal origin have been added or used at any stage of production or processing.

In the case of vegetarian foods, in deviation from this definition, milk, colostrum, farm poultry eggs, bee honey, beeswax, propolis or wool fat/lanolin (from wool obtained from live sheep) or products derived therefrom may also be used.”

(VSMK Nordrhein-Westfalen, 2016), Translated by Deepl.com on 16.06.2023.

On this basis, the German Food Standards Commission published the *Guidelines for Vegan and Vegetarian Foods* in 2018 and was later adopted into the ISO 23662. This defines the concept of veganism more broadly and adds additives and technical aids of animal origin to the list of excluded substances. This definition also mentions the permission of microorganisms in vegan products for the first time (German Food Code Commission, 2018).

In contrast to these rather product-law definitions, the Vegan Society has come up with a definition that is more strongly oriented towards total absence of animal interpretation. The concept of the Vegan Society is also based on the entire lifestyle of a vegan and not only on their diet. In addition, clothing and all products of animal origin should be avoided. The Vegan Society defines veganism as follows:

“Veganism is a philosophy and way of living which seeks to exclude—as far as is possible and practicable—all forms of exploitation of, and cruelty to, animals for food, clothing or any other purpose; and by extension, promotes the development and use of animal-free alternatives for the benefit of animals, humans and the environment. In dietary terms it denotes the practice of dispensing with all products derived wholly or partly from animals.”

(The Vegan Society, 2022a).

The International Vegetarian Union (IVU) has expanded this definition to include the areas of entertainment, sport, and research. Even though the concept of the use of the animal is brought to the forefront here, animal suffering is not as prominent:

“Vegan: excludes any use of any animal products for any purpose, including animal flesh (meat, poultry, fish and seafood), animal products (eggs, dairy, honey); the wearing and use of animal products (leather, silk, wool, lanolin, gelatin); also excludes animal use in entertainment, sport, research etc.”

(International Vegetarian Union, 2013).

Basically, these different definitions show the difficulties in vegan legislation. Since the concept of veganism is interpreted in different ways, it is difficult for the legislator to enforce a uniform definition that is acceptable to both the consumer and the food industry. Since different approaches either product-legally or ideologically with different intensities are existing, a uniform definition is yet to be declared (Chuck, Fernandes & Hyers, 2016; North et al., 2021).

2.4. Analytical aspects

Finally, the analytical possibilities of detecting animal residues will now be demonstrated. These are also essential in order to be able to detect specified limit values. It therefore makes little sense to set limit values that cannot be detected using current technology. Therefore, limit values strongly depend on the analytical conditions, which can change over time.

According to the food basic law (Regulation (EC) No. 178/2002), in Germany, official food monitoring is the responsibility of the federal states (BMEL, 2022b). This is divided into three levels. At the highest level, the responsible ministry coordinates the monitoring. Below that, the regional councils or district governments supervise the monitoring authorities of the districts and independent cities. These offices for food and veterinary monitoring carry out the on-site inspections. Companies that produce, process, and sell food are obliged to ensure the safety and quality of the products used through their own controls. This is to be achieved through the companies own controls and verified by the official monitoring controls on-site (BVL, n. Y.).

All vegan food inherits the claim of being free from animal substances. This claim must be verified by the local food control authorities. (Köppel et al., 2021) The required method for this must be sensitive and stable enough to even detect even traces of animal origin in food after they have been processed. Thermal impaction like pasteurisation or storage have an impact on the proteins (Druml et al., 2016; Köppel et al., 2021). While there are multiple ways to analyse animal traces in food, most of these methods face the disadvantages of either not being able to detect denatured proteins, higher cost and time consumption, or that the target substances must be known in advance. The quantitative Polymerase chain reaction-Method, known as qPCR, can simultaneously detect DNA from animals, fish, and plant in the food sample. This method is cost-efficient and highly sensitive. High sensitivity expresses the detection range within the samples (Mi et al., 2015).

Within the scope of analytical methods, an either qualitative or quantitative set-up can be approached. While the qualitative method can only assess whether a certain molecule or substance can be found within the food matrix, a quantitative method can also calculate the amount of that substance (Trullols, Ruisanchez & Rius, 2004). Since a qualitative method cannot give a conclusion on the concentration, the limit of detection (LOD) is lower than the limit of quantification (LOQ). This means that smaller concentrations of certain substrates can be detected by a qualitative method. For analytical question on whether or not a food sample exceeds the certain concentration of animal origin, a quantitative approach has to be taken to evaluate the amount (Trullols, Ruisanchez & Rius, 2004).

The qPCR can detect all relevant animal species. DNA segments that exist in most vertebrates that do not exist in plants are required for this method (Mi et al., 2015). Higher animals, like mammals or poultries, use myostatin in their muscle contraction unit. Its coding gene represents a good target for the detection of all higher animals (Köppel et al., 2021; Spsychaj et al., 2016). Materials that contain only small amounts of DNA can hardly be detected by PCR. V-Label tolerates animal residues of up to 0,1%. The qPCR method represents a detection value of <0,05%. Therefore, the set requirements by the V-Label can be complied with (Köppel et al., 2021; Mi et al., 2015; Wallace et al., 2012).

For vegetarian food the methodical approach is slightly different from that of the vegan method since vegetarian food allows the usage of ingredients like milk or eggs, a single DNA analysis is not able to differentiate between vegetarian and vegan. The DNA of milk and that of bovine meat, as well as the DNA for eggs and that of poultry meat is identical (BLE, n. Y.). To assess vegetarian food for traces of animal DNA, the first approach is made by a PCR-based method, to analyse animal DNA. In the instance of a positive finding of bovine or poultry DNA, an ELISA allergen method follows ELISA stands for Enzyme-linked Immunosorbent Assay and represents a method for analysing certain antibody-proteins, which often expresses allergic reactions. For this method, an antibody antigen reaction is performed. The method can then differentiate whether the protein expresses the origin of either bovine meat or milk and between poultry meat and eggs (Asensio et al., 2008; Wu et al., 2019). The downside of the ELISA method is that it is only able to detect native proteins, since processed proteins denature and therefor change the formation of their active substrate centre, antibodies can no longer react to this. Differentiation between vegetarian and vegan for highly processed vegetarian foods cannot be made with the ELISA method (Asensio et al., 2008).

To date, the PCR-method, mainly qPCR, and the ELISA antigen method represent the analysis methods for verification of vegan and vegetarian foods. The NRZ Authent in Kulmbach is currently developing a mass spectrometric method for examining veg*n foods for the presence of animal components. The analysis uses specific animal protein markers to identify the origin of animal ingredients. This method expresses a lower limit of quantification and is able to differentiate between vegetarian products like milk from bovine meat (BLE, n. Y.).

3. Method

In order to derive a limit value for animal residues in veg*n food and to therefore evaluate the authenticity for these foods, a literature review with the inclusion of online resources, is performed. For this purpose, already existing statements and requirements for limit values, information from relevant NGOs and third-party label providers were screened. This research was first conducted on the European area and later further expanded by NGOs from the USA, Canada and Australia. The research presented here mainly focuses on the European market due to the similarities within the EU food law legislation. To give a broader context, frequently used labels in other Western societies were added. Therefore, the organisations Certified Vegan from USA, VegeCert from Canada and Vegan Australia are displayed in Table 6 in the appendix.

All electronic sources gathered for the overview of label criteria in table 2 are shown in the list 5 in the appendix. Various online databases and guideline documents were screened for this research. The overview of the labels was dissected into the following aspects:

- Permission for the use of animal ingredients
- Permission for the use of processing aids of animal origin
- Animal testing
- Contamination threshold for animal residues
- Consequences for failing requirements
- Trace marking
- Usage of GMOs
- Packaging of animal origin
- Criteria for harvesting & fertilisation
- Further limitations and requirements

Furthermore, information regarding the restriction for setting up limit values for veg*n foods in the EU are shown in the following chapter. This information was gathered from legal EU regulations. The laws used to determine the legal situation for veg*n food were consulted at the following website:

- *Community legislation* on <https://eur-lex.europa.eu/>

Only laws on EU basis were considered. This was necessary to give a general limit value suggestion for the EU market. Further regulating national laws were not considered, since their content would have gone beyond the scope.

The databases *PubMed*, *HAW Bibliotheks Catalog* and the library of the *Max Rubner Institute* were used to obtain specialist literature to enhance the criteria from the NGOs and the legal framework conditions. For this research, articles were consulted that dealt with the topic of animal detection methods for the determination of residues in food, and further conditions regarding those residues for limit values. Sub-legal regulations were only collected from literature, whereby the ISO 23662 was provided by the library of the *Max Rubner-Institute*. Literature in German and English were included.

In addition, information from websites of official institutions and authorities such as the Federal Office of Consumer Protection and Food Safety (BVL), the Federal Ministry of Food and Agriculture (BMEL) and the Food Standards Agency (FSA) were used.

One limitation in the research was the limited access to the guidelines of the labels. The full content of these is often only made available to certified companies. The documents or sources made available online often did not contain all the necessary information in complete quantity (see table 5 for a full list of documents). A further limitation was that there is a legal situation that is still developing, so changes may occur promptly that could not be taken into account in this work.

4. Results

The presented results are based upon the literature review detailed in the previous chapter. Therefore, basic EU regulations to apply on veg*n foods are covered first. These build the basic criteria for distributing veg*n products on the European market. It is important to mention that there is no law directly covering a unique section for such foods, regulations rather apply for most kinds of products. Only regulations that strongly impact the sale of veg*n foods are mentioned here. Further listed in the results are the criteria from veg*n labels in Europe. These form a crucial role when it comes to setting a legal basis for veg*n foods as well as capturing the current market realities. Further information from literature and scientific articles are posted, which reflect important recommendations.

4.1. Law on the application for veg*n Foodstuffs

Veg*n foods are subject to a wide range of regulations and laws in the EU and its member states. One of them is covered by the basic regulation in food law, the Food Basic Regulation (Regulation (EG) No. 178/2002). Even though this Regulations do not solely cover veg*n foods, it is instead important because it defines whether a product is considered to be a food for human digestion. For the following regulations to be applicable, veg*n products must be considered food defined by the Food Basic Regulation. Furthermore, the Basic Food Regulation excludes plants post-harvest from the definition of a food (Art. 2 para. 1 lit. c of Regulation (EG) No. 178/2002). This means substances of animal origin (e.g., animal manure) used during harvesting are therefore not consider for the product-legal definition of vegan foods.

4.1.1. Food Hygiene

Veg*n food may be subject to the Regulation of Hygiene rules for food of animal origin (Regulation (EG) No. 853/2004) in certain cases. This legislation regulates the processing and distribution on the market of food of animal origin. In such a case, a sub-regulation implies that respective local authorities must be informed, and approvals must be granted. If food falls under the category of the Regulation No. 853/2004, it is subject to stricter hygiene and documentation requirements. This serves to manage animal-borne diseases. Whether food is subject to this Regulation depends on the total proportion of animal components in the product. For example, if a vegetarian meat alternative consists mainly of milk proteins or egg white powder, it could be subject to Regulation No. 853/2004. However, this is not always the case, as similar products with a lower proportion of the same animal ingredients would not be subjected (Comans & Schöllmann, 2016, pp. 11-12). The crucial factor here is the proportion of animal ingredients. (Art. 1 para. 1 and 2 of Regulation (EC) No. 853/2004).

4.1.2. Market Perception

The market perception is derived from the consumer's general understanding as to what they would perceive the respective product to be (compare with chapter 2.3.). The market perception serves as the authoritative basis for assessment in disputed legal issues, regardless of whether the composition, quality or presentation of foodstuffs are concerned. Guiding principles, court rulings, publications or industry guidelines form a helpful basis for determining the market perception when legal requirements are lacking (Kiontke et al., 2021).

In order to determine the market perception, legal definitions of the topic need to be determined and then used. Since such definitions are still lacking on the European market, sub-legal definitions such as ISO standard 23662 and the guidance document of the German Food Code Commission are used. Statements by food inspection authorities also play a decisive role. For example, the FSA in the UK has provided information on the terms vegetarian and vegan in its guidance document under points 13 and 14 (Food Standards Agency, 2006). Furthermore, court rulings are also taken into account in the assessment of the consumer's common perception. In addition to these, further factors involved in the formation of consumer traffic expectations are weighted. These can be NGOs, which can have a significant influence on the consumer perception through their political activities, newsfeeds and consumer cooperations (Comans & Schöllmann, 2016, pp. 2-6).

Taking these points into account, a general valid definition of the term vegetarian and vegan has emerged so far, which can be described as follows:

“The term vegetarian shall not apply to food which is or is made from or with the help of products obtained from animals which are dead, slaughtered or have died as a result of their consumption.”

“The term vegan does not apply to foods that involve animals or animal products or that are made from or with the help of animals or animal products (including products from live animals).”

(Comans & Schöllmann, 2016, p. 2) translated by Deepl.com on 15.06.2023.

However, due to some disagreement within associations and NGOs, the definitions can sometimes vary from one's description (see chapter 2.3.). These definitions are therefore decisive for the understanding of the consumer expectations when it comes to defining the term vegetarian or vegan. If products are processed or produced in fundamental deviation from this definition and are still advertised as veg*n, the consumer is misled. (Comans & Schöllmann, 2016, pp. 2-6).

4.1.3. Product Deception

The designation of a foodstuff is governed by the Food Information to Consumers Regulation. Food products must be labelled with the name provided for it by law or, if no such name exists, with its customary name or a descriptive name. (Art. 17 para. 1 of Regulation (EU) No. 1169/2011). "Descriptive terms" (cf. Art. 2 para. 2 lit. P of Regulation (EU) No. 1169/2011) are terms which describe the food and, where necessary, its use and which are sufficiently precise to enable consumers to identify the true nature of the food and to distinguish it from food with which they might be confused with (Art. 2 para. 2 lit. P of Regulation (EU) No. 1169/2011) & (Riemer & Seitz, 2021, pp. 5-7, 29-32).

For veg*n food products, misleading description in the case of imitations is a relevant problem. It must be clarified that the product is an imitation, otherwise the product might be perceived as misleading. (Art. 7 para. 1 of Regulation (EU) No. 1169/2011). In the case of foodstuffs or an ingredient which the consumer assumes is normally used but which has been replaced, this must be clearly indicated. For example, a plant-based sausage must indicate that it does not contain meat but instead a meat alternative. This information must be present on the front of the packaging (Comans & Schöllmann, 2016, p. 44). It does not make sense to label all foods as vegan or vegetarian. Mono-products such as teas or spices, mineral water, and raw products such as unprocessed vegetables are usually purely plant-based in nature and do not need to be labelled. In some cases, labelling can be interpreted as advertising with self-evident facts and can therefore be illegal. (Art. 7 para. 1 lit. c of Regulation (EU) No. 1169/2011).

Trace marking, which is a voluntary statement to improve food safety if traces of allergens are indicated, is generally permitted. The aim of this is to inform specific consumer groups that the product in question could be affected by traces of allergens. This contributes to better information communication and is purely voluntary on the part of the producer. Allergic persons are those that are particularly vulnerable and therefore require increased information. Information such as "may contain traces of meat" is not relevant to food safety. This statement can be made and is legal under food law concerns and. It informs consumers that products of animal origin were also produced during the manufacture of the corresponding vegetarian foods and that cross-contamination cannot be completely ruled out. This information allows the buyer to freely decide whether they want to bear the risk of cross-contamination. This in turn improves the conscious purchasing decision of the customer (Art.36 para. 2 of Regulation (EU) No. 1169/2011) & (Comans & Schöllmann, 2016, pp. 40-41).

4.1.4. Approval under the circumstances as a Novel Food

For the production of veg*n foods, the source of protein is often a crucial factor. For example, in meat products this is supplied by the muscle meat. However, there are several alternative vegan protein sources. It becomes problematic when alternative protein sources, which have not yet been used on a large scale in the EU, are used to produce new plant-based food products. Such products then fall under the Novel Food Regulation (EU) 2015/2283. Foodstuffs isolated from micro-organisms, fungi, or algae or which have a specifically modified molecular structure also fall under the Novel Food Regulation. Products that fall under this regulation may only be introduced to the market and sold to end consumers after they have been approved. Associated with the Novel Food Regulation are testing of animals, which should be viewed critically. For all new products introduced into the EU since 15.05.1997, in the sense that they have not previously been consumed in significant quantities, animal testing is required by law. This, however, competes with the ethical definition of veganism and excludes corresponding products to the Novel Food regulation from the certification of vegan labels (Beuger, Jäger & Müller-Amenitsch, 2022, pp. 47-50).

4.2. Sublegal Norms on veg*n Foods

To date, no legally approved definition for the terms veg*n and no legal requirements for dealing with cross-contamination for veg*n products exist on the European market. In such a case, the general provisions of food law and the opinion of manufacturers, are to be assessed to determine the violation of legal rules. The ISO 23662 standard is intended to act as a legal proposal for the time being. It defines technical requirements and describes product-relevant criteria. The guidelines of the German Food Book Commission focus on the sales market for veg*n products and regulate sales denominations (Gottwald & Müller-Amenitsch, 2020, pp. 41-42).

4.2.1. ISO-Norm 23662

The *ISO 23662* norm describes the definitions and technical criteria for veg*n foods. It therefore covers the usage of additives, flavourings, enzymes, and carriers in addition to ingredients and processing aids. This norm regulates separate production facilities, which are sometimes required by vegan labels. Therefore, separate production facilities are not mandatory under the requirement of an implemented GMP system. Limit values for animal residue are still not covered by the ISO-Norm (ISO, 2021). The ISO standard is not a law that has been democratically legitimised. It is based on the expertise of market participants. Companies are therefore free to decide whether or not to use this standard. The ISO standard also fulfils a bridging function, since at present no regulations have been enacted into law at national and international levels. It can also serve as a factual interpretation in court, for example if products advertised as vegan do not meet the consumer's expectations (Beuger, Jäger & Müller-Amenitsch, 2022, pp. 41-42).

4.2.2. Guidelines of the German Food Code Commission

First of all, the guidelines of the German Food Book Commission regulate the criteria for the production of veg*n food with resemblance to food of animal origin. This guideline formed the basis for the latter published ISO-Norm 23662 (Domke, 2018). Like the ISO-standard, the guidelines of the German Food Code are not legal norms and therefore not legally binding. Nor do they have the character of administrative guidelines. In assessments and statements, the guidelines can therefore be cited as an aid to interpretation, but not as a legal basis (BMEL, 2022a). These guidelines define veg*n foods. Therefore, a list of unpermitted substances is stated. The guidelines regulate comprehensively regulate the sales denominations of veg*n food. Further, no limit values or practice guidelines are stated in this document (German Food Code Commission, 2018).







4.3 Comparison of third-party veg*n labels







Information from third-party labels throughout Europe have been gathered and are compared in table 2. Not all of the important criteria could be derived from those organisations, since disputed information for some labels sometimes ended up being shortened as other labels. Unprovided information was marked as “n.i.g.=no information given”. However, most label companies provided the necessary information, meaning that a comprehensive list could be created. For further comparison, three major label-providers from the USA, Canada, and Australia are compared in the appendix under table 6.

However, there are instances where these requirements do not match with each other. This also comes down to the different alignments of the labels. Since a company like the Vegan Society Germany e.V. represents a stricter vegan label than the all-encompassing V-label does. The Vegan Society Germany’s label claims to promote animal welfare to a higher level, which is why the requirements are correspondingly more stringent. To consider the requirements from each label and to further evaluate limit values, it is therefore necessary to include their ethical and political backgrounds.

With a general consensus of animal ingredients being inadmissible in vegan foods, this agreement diverges when it comes to setting limit values for residue in veg*n foods. The V-Label states a limit value of 0,1% of unwanted contamination, which is contrasted by the Vegan Society Germany e.V. whose limit value is set as zero-tolerance. Further information on this is found in Table 2 and discussed under chapter 5 in the discussion.

Table 2: Overview of criteria for the vegan label organisations in Europe

Guidelines	Use of animal ingredients	Use of processing aids of animal origin	Obligatory Separate production line	Animal Testing
Organisations				
 V-Label*	Not allowed	Not allowed	Not necessary. GMP measures to prevent contamination are sufficient	Generally forbidden for ingredients, endproducts, research, and cooperating companies. Exception for tests on products which pose a benefit for the animal and do not threaten the animal well-being – measured by veterinarians
 Vegan Society	Not allowed	Not allowed	Not necessary. GMP measures to prevent contamination are sufficient	Not allowed for ingredients, end-products or other products and brands from the company
 EcoVeg	Not allowed	Not allowed	Spatially or temporally separated. Storage of ingredients must be separated	n.i.g.
 Vegan Society Germany e.V.	Not allowed	Not allowed	Facilities, equipment and machinery used for the production, processing and packaging are exclusively for vegan products	Not allowed
 BCV	Not allowed	Not allowed	Not necessary. GMP measures to prevent contamination are sufficient	No livestock farming or animal products allowed. Complete abstinence from all kinds of animal usages.
 Vegetarian Society*	Not allowed	Not allowed	Not necessary. GMP measures to prevent contamination are sufficient	No animal testing carried out or commissioned

<i>Guidelines</i>		Contamination Thresholds for animal residue	Consequences (if criterias failed)	Trace marking	GMO
<i>Organisations</i>					
 V-Label	Incidental contamination by animal residues tolerated as long as 0,1% or 1g/kg per End-product is not exceeded	Corrective measures. If technically unavoidable - statement by the manufacturer but no exclusion from certification process	Allowed	GMO labelled products generally excluded from certification. A maximum contamination of 0,9% (mass percent) is allowed	
 Vegan Society	Manufacturing and ingredients must not have involved the use of animal products, byproduct or derivatives.. Residue traces are tolerated.	n.i.g.	Allowed**	No animal genes or animal derived substances. Other GMOs must be labelled	
 EcoVeg	Incidental and technically unavoidable traces of animal substances in the food do not jeopardise the use of the seal.	Corrective measures	n.i.g.	Not allowed**	
 Vegan Society Germany e.V.	Zero-Tolerance threshold	n.i.g.	Allowed for allergic substances	Not allowed	
 BCV	n.i.g.	n.i.g.	n.i.g.	Not allowed	
 Vegetarian Society	n.i.g.	n.i.g.	n.i.g.	Not allowed. Exemption for Vegetarian rennet used in cheese-making (Vegetarian Label)	







<i>Guidelines</i>		Harvesting & fertilisation	Packaging of animal origin	Further limitations & Special requirements
<i>Organisations</i>				
	V-Label	Seeding and cultivating not considered. Fertilizers of animal origin allowed	Allowed	Restriction of biotechnological extraction of ingredients or ingredients – needs to comply with vegan guidelines.
	Vegan Society	n.i.g.	n.i.g.	Stricter regulations for animal testing compared to other labels
	EcoVeg	n.i.g.	n.i.g.	Only plant-based foods may be used as agricultural ingredients. This also applies to so-called composite ingredients, which consist of several substances. Restricted to Organic regulation (EG) 834/2007
	Vegan Society Germany e.V.	n.i.g.	Not allowed	Zero-Tolerance for residues. Stricter regulations regarding animal welfare
	BCV	No organic inputs of animal origin such as manure and slaughterhouse waste (blood, bristle, feather meal and horn shavings) allowed during the whole agricultural process	Not allowed	No livestock farming and the use of fertilisers and other inputs of animal origin. Further restrictions regarding: soil, surface-water and marine protection, air pollution control, protection of biodiversity and social standards for farmers.
	Vegetarian Society	n.i.g.	Not allowed	Only free-range eggs.

Table made on own compilations. Information's retrieved from their guideline documents published online and their respective internet Webpages listed in table 5 in the appendix. Viewed on 20.06.2023. Further information's retrieved from (Gerke & Janssen, 2017).

Illustrations of the labels retrieved from their respective internet homepages. Copyrights belong to their respective owners.

n.i.g. = no information's given

*Only the vegan Labels are considered in this table

**information retrieved from Vegan Australia certified under https://www.veganaustralia.org.au/cross_contamination retrieved on 05.06.2023

5. Discussion

The prerequisites for setting limit values are an existing legal framework and lay out the verifiability for reference values. For the former, however, a uniform definition is still needed. Due to the different views, especially on the concept of veganism, it is difficult to set a generally valid legal definition (Domke, 2018). In this part, all information gathered in the previous chapter is discussed here. There will also be some input regarding the factors for setting a limit value for animal residue in veg*n foods. A concept of how to measure and take samples for the evaluation of such residue is shown at the end. To further expand the idea of tolerating residue in veg*n foods, a further interpretation of a second, so-called “maximum residue level” (MRL) is introduced.

5.1. Factors determining the limit value

Contamination residues in veg*n foods can have a variety of different origins (Comans & Schöllmann, 2016, pp. 7-9; Cottenet & Blancpain, 2021) Therefore, the factors for determining such residue can differ as well. As such, the important factors for such residue will be discussed. To do this, analytical and technical factors will be discussed. Further introduced will be factors surrounding harvesting and fertilisation.

5.1.1. Limit values determined by analytical aspects

One aspect to always be considered when setting limit values is always the feasibility of implementation, taking into account the framework conditions, as well as detection methods and sources of input (Grabowski, Klein & López, 2013; Hartwig, Sina & Smollich, 2022).

First, the question of the limit value must be settled. If the limit value is an absolute zero-tolerance one, qualitative detection methods can be introduced. Due to the lower LOD compared to the LOQ, these values are more resolved and thus more precise detection is possible (Trullols, Ruisanchez & Rius, 2004). However, it should also be mentioned here that an absolute zero-tolerance limit value cannot be proven at the current state of research (Matissek, 2020, p. 45). Although a PCR method is able to detect meat traces as little as 0,0001%, it is therefore not able to detect smaller amounts, nor is it able to reproduce this precision on highly processed or complex foods (Hird et al., 2006; Nalazek-Rudnicka et al., 2022). Adding stable calculation factors and increasing the LOD up to the LOQ, a reproducible analytical value of 0,001% can be established. This detection limit is the maximum that can be demanded so far. An absolute zero-tolerance, as demanded by some NGOs, cannot yet be proven on an analytical basis (Cottenet & Blancpain, 2021; Matissek, 2020, p. 45; Wearne, 2015).

If, on the other hand, contaminant residues are tolerated, then quantitative methods must be used. (See chapter 2.4.). If a contamination limit is specified, it must also be within the limit of detection for quantification (LOQ). The V-label and other NGOs guarantee a tolerable contamination limit of 0.1% or 1g/kg. This could be detected by means of common qPCR methods.

From an analytical point of view alone, a zero-tolerance limit value cannot be enforced. The necessary precision to meet this requirement is still lacking. Analytical detection methods are an important parameter for setting a limit value, as otherwise limits can be set, but without detection methods they are of little use. Although the level of the detection limit does not necessarily have to be based on the lower limit of analytical methods, it does form a stable basis. A limit value of 0.1%, on the other hand, as required by many certification companies, is thus analytically detectable and meaningful.

5.1.2. Limit values determined by technological aspects

From a consumer point of view, animal inputs, especially when they are avoidable, are not acceptable. The Institute of Food Science and Technology describes Good Manufacturing Practices (GMP) as a comprehensive set of guidelines and protocols that outline the necessary steps and precautions for maintaining the quality and safety of a product during its production and testing. By strictly following GMP, manufacturers can demonstrate their commitment to producing high-quality and safe products (Manning, 2018). In the matter of a consumer complaints or legal action, the implementation of GMP can help reduce the manufacturer's liability and protect them from potential prosecution. Adhering to GMP standards is crucial for mitigating risks, ensuring regulatory compliance, and upholding industry best practices throughout the manufacturing process.

To prevent cross-contamination, GMP measures and the installation of separate filling facilities are the most suitable methods for effectively limiting it (Comans & Schöllmann, 2016, pp. 9-10). A decisive counterargument to this is the cost of such a facility. In addition, the current market situation does not allow for a demand for segregated facilities in general. Particularly small companies that have previously processed animal products and now want to try their hand at the vegan market would not take the risk of a loan for a new bottling plant to be able to test new products. This in turn would result in slower growth of competition and the risk that the production of vegan products would only be left to new vegan-specific companies or bigger companies who have the budget to fulfil these requirements.

In order to set a limit value, it is imperative to consider the technological prerequisites of the market participants. Although separate facilities to produce animal and non-animal products are desirable, they are currently still unacceptable, especially in view of a veg*n market shift (Alae-Carew et al., 2022; Pabel & Schiller, 2017). Complete avoidance of cross-contamination is currently largely unfeasible, which is why small quantities of such residues should be tolerated here too. This enables companies in the transition to more veg*n products to do so.

5.1.3. Limit values determined by the practices of harvesting

Conventional agriculture mostly uses animal meal, manure, horn manure, or bone manure as fertiliser. This method therefore uses animal products (Hentsch, 2020; Kratz et al., 2011). Even if these are no longer detectable in end products, as the substrates have been metabolised by the plants, this process represents a violation of veganism for vegans who represent on a stricter belief. The fact that such procedures can theoretically be included under the term “vegan” shows the complexity of this definition. However, there are already certain approaches to solve this problem, but their implementation is still to be regarded as a niche area but shall not be explored further here.

There is also the question of how to deal with insecticides, as these are supposed to protect the plants from predators but have the effect of killing insects. For a problem such as this, the question arises as to whether dispensing with insecticides and the associated reduction in crop yields still meets the purpose of promoting a more sustainable diet. At such points, vegans must also realise that their strict interpretation of the concept of veganism would ultimately lead to them having no alternative but to switch to growing their own fruit and vegetable, according to the current economic situation (Beuger, Jäger & Müller-Amenitsch, 2022, pp. 5-6).

Insects and their eggs or larvae, which are present on the plants during harvesting and are therefore also harvested, can also pose a problem during the harvesting process. These insects find their way into the harvested product and are later processed as raw materials by food companies. There are sorting facilities for this purpose, but they are not able to guarantee complete coverage, especially since such small components can effectively never be completely sorted out (Gottwald & Müller-Amenitsch, 2020, pp. 38-40).

The basic regulation 178/2002 defines plants as food only after they have been harvested. Food safety criteria are therefore only applied to a plant after this step. The points mentioned above are an important criteria for the definition of vegan products according to ideological standards, but they do not represent implementable parameters in terms of product law. If labels for vegan products are awarded that are based on these measures, these must also be taken into account throughout the entire supply chain in addition to the farmers' legal harvesting requirements. There are already some approaches to this, such as those used by the Biocyclic Vegan Label with its biodynamic approach. Here, fertilisers of animal origin are completely dispensed with (Förderkreis Biozyklisch-Veganer Anbau e.V., 2023b). However, since the majority of agriculture practices are still conventional, a wholesale shift to new approaches would be a major undertaking.

5.2 Consensus on limit values

Limits of animal residues in veg*n food have left a controversial debate in society and among interest groups. While the majority of third-party labels give preference to permissible residue contamination subject to appropriate measures in terms of GMP and technically correct working practices, there are also supporters of a zero-tolerance residue threshold. The Vegan Society Germany e.V. advocates for zero-tolerance for residues or contamination in veg*n products. Food products can only be labelled as vegan if they can prove that the products in question have not been contaminated with animal substances during production. For them, any form of toleration is a subterfuge to leave animal residues within the products. Thus, the companies would not make sufficient efforts to do everything necessary to exclude contamination.

The FSA from the UK also advocates for this approach. Article 17 of the Guidance Document states that companies must be able to prove that products advertised as vegetarian or vegan have been produced, processed and stored under these conditions. Otherwise, they may not be advertised as such. (Food Standards Agency, 2006).

This is contrasted by the EVU standpoint. They state that suitable measures for the avoidance of animal residues are sufficient, as long as these measures are within the framework of GMP requirements and the residues are of unintentional origin. This position is held by the majority of third-party suppliers, both in and outside Europe. (See Chapter 4.3). The Vegan Society from the UK agrees with this position. Even though they state on their website that the presence of animal traces is generally not permitted, their guidelines allow residues of animal products, subject to the aforementioned duties of requirements. (compare (The Vegan Society, 2022c) & (Gerke & Janssen, 2017)).

As long as the concept of veganism has not been uniformly clarified, it will be difficult to establish uniform criteria regarding limit values. Although the arguments of the advocates for a zero-tolerance can be commonly judged as sensible, they cannot be realistically implemented in practice. This theorem would lead to products that are considered vegan by nature, such as vegetables and fruits, being counted as non-vegan due to the slightest trace contamination with animal residues. This would ultimately confuse the consumer unnecessarily, which cannot be in the serious interest of hardline vegans. (Zühlsdorf, Nitzko & Spiller, 2013). From a food law perspective, cross-contamination is legal if it occurs despite measures taken. Other products that are non-vegan are also subject to the tolerance that contaminants are allowed if measures to prevent them are also in place. Any other treatment would therefore discriminate against this type of food or production.

5.3. Implementation of limit values

To implement limit values, the following proposal is made and displayed in table 3. This proposal follows the assumption that unwanted or unintentional contamination expresses its appearance selectively and in uniformly spots within the product is made. For evaluating limit values, an analysis plan of the concept from the Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs is created. This follows the idea of having two different residue levels, for one which can be exceeded under certain aspects and one that mustn't be exceeded for any sample. Also, multiple numbers of samples need to be taken, to verify the content for veg*n foods. Therefore, the results from the different sample analysis are evaluated with the scheme presented in table 3 and displayed by an overview in the following figure 2.

Under the assumption of the occurrences for unintentional cross-contamination as selective at certain spots during production, samples must be taken from different batches or at different times during production (e.g., beginning, middle, end). If one or few batches have tested positive, this could be due to unintentional cross-contamination. In the case of a permanently increased findings of animal material, this would be due to an intentional introduction of animal raw materials. This is always under the consideration that all analyses fall below the previously defined MRL. Permanently increased limit level must be eliminated by measures taken from the producer.

The number of samples must be statistically calculated by means of a decision rule using a hypothesis test. Depending on factors need to be taken into considerations, such as production capacity, product output volume, type of product, and devices used to produce the food. The listing of factors is therefore not final and further factors may need to be taken into consideration. Effects differ for small and large food producers. Smaller production volumes mean greater fluctuations due to contamination. Facilities and equipment also make a significant difference. Larger companies, or those with more budget, are more likely to be able to obtain aseptic filling equipment, for example, or to keep the production process largely closed and automated, thereby reducing potential sources of contamination.

The table defines a standard residue level as “*m*”. This residue level takes on the statement for residue levels of the majority of veg*n associations. And, since some certification bodies allow the exceeding of their residue level, there needs to be a maximum of which degree this exceeding is tolerated. Therefore, the idea of another, so called “maximum residue level, *MRL*”, displayed as “*M*”, was made as a suggestion. The value for this MRL needs to be calculated and evaluated as well. However, a final value for the maximum- and standard residue level cannot be made in this thesis and therefore needs to be further evaluated by research and governmental agreements.

Table 3: Sampling plan for the evaluation of veg*n foods.

This plan is a modified version of the Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs.

Food category	Forbidden substances	Sampling-plan		Residue level		Analytical method
		$n^{(1)}$	$c^{(2)}$	$m^{(3)}$	$M^{(4)}$	
Vegetarian	Def. ISO 23662 Vegetarian	5*	1*	0,1% / 1g/kg**	1,0% / 10g/kg**	qPCR, ELISA antigen
Vegan	Def. ISO 23662 Vegan	5*	1*	0,1% / 1g/kg**	1,0% / 10g/kg**	qPCR
Evaluation:	<p>> M = maximum residue level exceeded = intentional contamination > m = Residue level exceeded, further evaluation depending on “c” > c = authorized number of samples exceeded = static unintentional cross-contamination < c = random unintentional cross-contamination < M + < m + < c = requirements fulfilled = no contamination</p>					
Measures:	<p><u>Intentional contamination</u>: Complaint, labelling as veg*n not possible</p> <p><u>Static unintentional cross-contamination</u>: Audit and product assessments – corrective measure plan. If contamination is technological unavoidable, statement required. Stricter control of products. Labelling under restrictions as veg*n possible</p> <p><u>Random unintentional cross-contamination</u>: corrective measure plan. Labelling as veg*n possible</p>					

Table only as a recommendation example, based upon the consensus of the majority of NGOs and vegan associations.

⁽¹⁾ n = number of samples

⁽²⁾ c = tolerated number of sample analysis over m and between m and M

⁽³⁾ m = standard residue level

⁽⁴⁾ M = maximum residue level *MRL*

*Sampling numbers for n and c are only exemplary, their values have to be calculated by a hypothesis test using statistical assumption factors for the number of samples and the tolerated number of samples over m and under M

** Residue level m is only exemplary, based upon the guidelines of most NGOs and vegan associations (see table 2). The value for M is made up as a suggestion, and not based upon guidelines.

The table 3 shows a sampling-plan for the evaluation of veg*n foods. The measure plan is based upon the consensus for the limit of a residue level of most NGOs and vegan associations. Therefore, a residue level of 0,1% or 1g/kg is adopted. Further, a second residue level MRL is suggested based upon own evaluation, which mustn't be exceeded by any sample to describe the product as vegetarian or vegan. In the table, the two different residue levels are set up. For this, a sample crossing the MRL, the contamination is defined as an intentional contamination.

Depending on the amount of stirring and mixing of the product after contamination occurred, the amount of animal origin can be higher than the standard residue level but is only found in a few samples. Constant and unintentional contamination, mostly due to soiled production devices like a filler polluted with animal substances for a bottling plant, can introduce small amounts into every package. This is analytically observed with a higher amount found within the sample, but still detains at an accepted level or slightly above. Corrective measure plans need to be made to eliminate sources of contamination. If the sources are technically unavoidable, further assessments are needed.

The situation is different if the contamination is deliberate. Meat products nowadays achieve lower profit margins than their veg*n counterparts. Thus, animal raw materials can sometimes be cheaper than their alternatives. (Foodwatch Deutschland, 2021; WWF, 2023). There are also various other conceivable driving factors that can motivate such action. Unknown or little exposure to the production of raw materials sourced from other companies may well mean that they were produced using non-vegan methods, even though the product itself falls into the vegan category. Due to profit margins, it is therefore more cost-effective to continue to produce a non-vegetarian product but market it as vegetarian or vegan, provided that the animal ingredient is not prominent in the quantity ratio (e.g., processing aids). To reduce production costs, ingredients of animal origin are then inserted into the product and still advertised as vegetarian or vegan. Reducing the costs only makes a significant difference if the ingredients are inserted in higher amounts, and thereby increasing the contamination levels.

For the evaluating process of how to treat veg*n products when certain analysis parameters apply, is displayed in figure 2. The Illustration is based upon the measure plan from table 3 and the defined values from the previous chapter. The figure shows the path of which scenario certain definitions of intentional or unintentional contaminations are applied. It is therefore set up as a guidance tool on how to evaluate the results found from the samples taken to measure animal residues in veg*n food. The classification of certain contamination based upon assumption and measures from table 3.

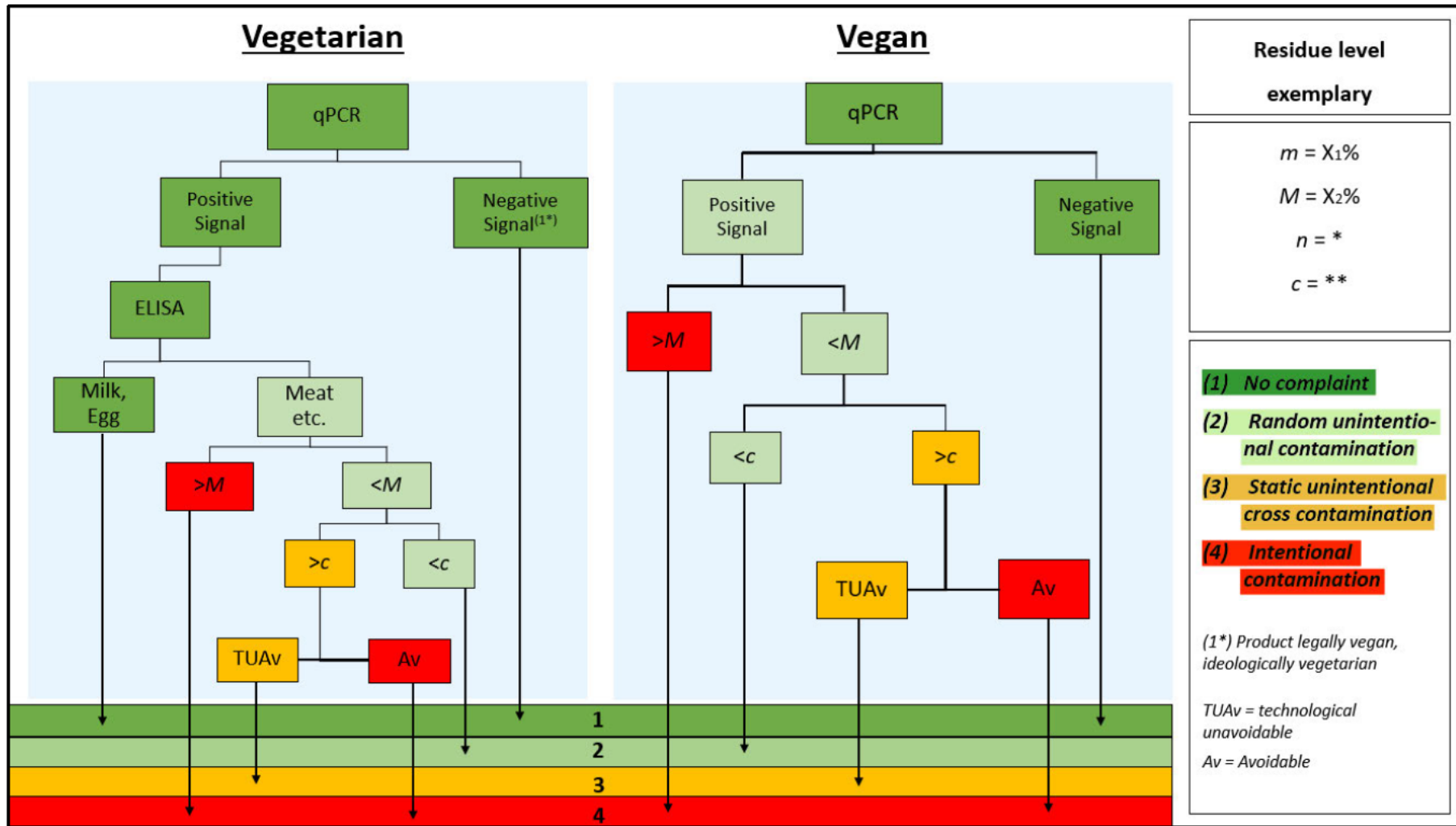


Figure 2: Decision tree for the progress of evaluating veg*n label possibilities.

Figure is based upon own depiction and table 3.

* / ** n and c must be statistically evaluated to insert their quantities. Suggestions for m & M under evaluation. See chapter 5.2 and 5.3 for further information.

(1-4) Supposition definitions outlined in previous chapter and table 3.

5.4. Consequences of the limit value

In this chapter, the consequences of the determination of a certain limit value will be briefly discussed. To this end, it will be addressed how stricter limit values increase the waste of food and cause confusion in the consumption habits of the general public.

Since limit values are considered in practice as a knock-out criterion for the selection of certain foodstuffs, they thus impact the quantity of goods that are sorted out. In other words, if limit values are formulated more stringently, the quantity of rejected goods will be greater. Since the limit value represent contamination by animal residues, it will be difficult to introduce corrective measures. This is because these residues could not simply be removed by corrective measures (e.g., reheating in the case of microbial uncertainties). It would also be questionable to sell these contaminated batches as special items on the market as non-vegan batches. The alternative would have to be the destruction of the contaminated food, which would increase the waste of food.

Furthermore, stricter limits would exclude those products that would generally be considered veg*n by the average consumer. This exclusion would cause confusion for the consumer and in certain cases complicates a vegan lifestyle. Therefore, the establishment of a limit value needs to address the consumer needs and help them make decisive decision.

5.5. Relevance for the mean population

Another question remains as to how relevant the implementation of limit values is for the general population. Despite the growing market for plant-based alternative products, the small population of veg*ns and people adhering to the zero-tolerance approach raise doubts about the relevance of limit values.

Studies show the proportion of vegetarians and vegans in the German population to be at 8.5% and in the UK at around 3% for 2008 (Ruby, 2012). The vegan population remains even smaller. From this, an even smaller population group can be defined, which is really in the interest of implemented limit values. Even if these are indispensable as a basis for legal regulation, the vegetarian and especially flexitarians could show little interest in limit values for animal residues in veg*n foods. This is especially true for flexitarians since they still consume meat and that generally low residues generally have hardly any nutritional impact.

Equally doubtful should be the perception of those vegans who take a stricter ideological view. Some controversial vegan associations can sometimes hold very strict opinions, but this may not reflect the bigger proportion of the vegan population. By this, a zero-tolerance approach would not, or only slightly, constitute the view of most of the vegan population.

6. Conclusion

Lastly, an overview of the complexity of this topic shall be given here. Since the term veganism is understood in many different ways and has also acquired different political and ethical backgrounds, a uniform definition is a difficult task. The definitions already presented by the Consumer Protection Ministerial Conference and ISO 23662 provide a solid basis for an interpretation of product law but will never be able to truly satisfy the entire vegan population.

From this paper, it appears that the majority of proposals for animal residue limits in veg*n foods are 0.1% or 1g/kg. However, it should be noted that this opinion is not held by all associations or organisations. In this regard, the idea to further delimit the concept of veganism into different categories like product-legal and ideologically ethical veganism, could be presented. However, this is only presented as a suggestion.

In addition, it should be noted that a zero-tolerance, as demanded by some organisations, is not demonstrable based on analytical aspects. Since non-verifiable regulations are subject to nullity, this limit value does not represent a realistic limit value. However, an actual valid limit value still needs to be established. In this context, the limit value of 0.1% provided by the V-label should be emphasised, as it is analytically verifiable and can be enacted in practice. However, a further comprehensive evaluation must be carried out in order to definitively implement this limit value.

Furthermore, the action plan is intended as a concept for the basis of representative detection methods for veg*n foods. Since technologically unavoidable contamination often occurs in practice and cannot be excluded, a further maximum limit value should be used, which differs from the "standard limit value m " as appearing in this paper as MRL " M ".

The proposals resulting from this work are to serve as a basis for the comprehensive and conclusive evaluation for setting of limit values. However, further production-related factors must be taken into account in order to be able to make a final evaluation and determination.

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Directory of Legal Sources

Food Basic Regulation	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, last amended by Parliament Regulation (EC) 1642/2003 of July 22, 2003 (OJ L 31 of 01.02.2002, P. 1)
Hygiene rules for food of animal origin Regulation	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs, last amended by Commission Regulation (EC) 2074/2005 of December 05, 2005 (OJ L 139 of 30.04.2004, p. 55)
Novel Food Regulation	Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/200, last amended by Parliament Regulation (EU) 2019/1381 of June 20, 2019 (OJ L 327 11.12.2015, p. 1)
Organic Regulation	Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, last repealed by Parliament Regulation (EU) 2018/848 of May 30, 2018 (OJ L 189, 20.7.2007, p.1)

Microbiological criteria Regulation	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, last amended by Commission Regulation (EU) 1441/2007 of December 05, 2017 (OJ L 338 of 22.12.2005, P. 1)
FIC Regulation	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation, last amended by Commission Regulation (EU) 1155/2013 of August 21, 2013 (EC) No 608/2004 (OJ. L 304 of 22.11.2011, P. 18)

Appendix

Table: Overview of all V-Label Partner Organisation. List retrieved from <https://www.v-label.com/about-us/> retrieved on 01.06.2023.

V-Label Partner Organisations	Country
Unión Vegana Argentina	Argentina
Vegane Gesellschaft Österreich	Austria
ProVeg Belgium	Belgium
Association Eco Vegan Animals	Bosnia and Herzegovina
Bulgarian Veg Society	Bulgaria
Fundación Vegetarianos Hoy	Chile, México, Columbia
Animal Friends Croatia	Croatia
ProVeg Czechia	Czechia
Dansk Vegetarisk Forening	Denmark
Yve Oy	Finland
Association Végétarienne de France	France
ProVeg Germany	Germany
Greek Exports	Greece, Egypt, Kosovo
Öko-völgy Alapítvány	Hungary
Vegetariërsbond	Netherlands
Grønn Framtid	Norway
Unión Vegetariana del Perú	Perú
PolVeg	Poland
Associação Vegetariana Portuguesa	Portugal
Asociația Veganilor din România	Romania
APAPP - Association of Alternative Food Producers*	Russia
Sloboda za životinje	Serbia
Slovenská Vegánska Spoločnosť	Slovakia
Padma Institute– Food for Life	Slovenia
ProVeg South Africa	South Africa
Unión Vegetariana Española	Spain
A Better Future AB	Sweden
Swissveg	Switzerland
Vegan Demeği Türkiye	Türkiye
PolVeg	Ukraine

*Translated by <https://www.deepl.com/translator> on 04.06.2023




Table 4: Information sources for the criteria of the third-party labels.

Organi- sation	Description	Retrieved on	URL
EcoVeg	Guideline Document	05.06.2023	https://www.vegorganic.de/wp-content/uploads/2020/12/Richtlinien-EcoVeg-21112020.pdf
EcoVeg	Guideline Document	05.06.2023	http://www.vegorganic.de/wp-content/uploads/2017/12/EcoVeg-Richtlinien-17.03.16.pdf
EcoVeg	Information Flyer	05.06.2023	https://www.vegorganic.de/wp-content/uploads/2018/05/Infoblatt-02.2017.pdf
Biocyclic Vegan	Internet Homepage	13.06.2023	https://biozyklisch-vegan.org/
Biocyclic Vegan	FAQ Website	13.06.2023	https://biozyklisch-vegan.org/faq/
Biocyclic Vegan	Information Flyer	13.06.2023	https://biozyklisch-vegan.org/infomaterialien/
V-Label	Guideline Document	01.06.2023	https://www.v-label.com/wp-content/uploads/2022/12/regulations-de.pdf
V-Label	Guideline Document - Annex	01.06.2023	https://www.v-label.com/wp-content/uploads/2022/09/criteria-int-fwcng02-v0102-en.pdf
V-Label	FAQ Website	01.06.2023	https://www.v-label.com/faqs/
The Vegan Society	FAQ Website	04.06.2023	https://www.vegansociety.com/vegan-trade-mark/trademark-faqs
The Vegan Society	Trademark Overview Website	04.06.2023	https://www.vegansociety.com/the-vegan-trademark
The Vegan Society	Key facts & Definitions	16.06.2023	https://www.vegansociety.com/about-us/further-information/key-facts
Vegan Australia	FAQ Website	05.06.2023	https://www.veganaustralia.org.au/faq
Vegan Australia	Cross-Contamination	05.06.2023	https://www.veganaustralia.org.au/cross_contamination

Vegan Australia	Information Document	05.06.2023	https://d3n8a8pro7vhm.cloudfront.net/veganaustralia/pages/12669/attachments/original/1630045590/Vegan_Australia_Certification_Introduction.pdf?1630045590
Vegan Australia	Certify Information Website	05.06.2023	https://www.veganaustralia.org.au/get_certified
Vegan Australia	Guideline Document	05.06.2023	https://www.veganaustralia.org.au/get_certified and *)
*) https://cdn2.search.ipaustralia.gov.au/1944358/TRADE_MARK/R9095034/1.0/R9095034.PDF			
Certified Vegan	Certify Information Website	05.06.2023	https://vegan.org/certification/
Certified Vegan	Certification Criteria Website	05.06.2023	https://vegan.org/certification-process/
Vegan Society Germany	Guideline Website	13.06.2023	http://vegan-label.de/veganlabelkriterien.html
Vegan Society Germany	Ethnic Information Website	13.06.2023	https://www.vegane.org/tiere-ethik-und-umwelt/
Vegan Society Germany	Society Information Website	13.06.2023	https://www.vegane.org/mission-statement/
VegeCert	Guideline Information Website	05.06.2023	https://vegecert.com/standards/
VegeCert	Information Website	05.06.2023	https://vegecert.com/
VegeCert	Certification Information Website	05.06.2023	https://vegecert.com/get-certified/why-get-certified/
Vegetarian Society	Certification Information Website	13.06.2023	https://vegsoc.org/vegetarian-and-vegan-approved-trademarks-business/
Vegetarian Society	FAQ Website	13.06.2023	https://vegsoc.org/vegetarian-and-vegan-approved-trademarks/

Table 5: Overview of criteria for the major vegan label organisations from USA, Canada, and Australia.

Table not final, only examples chosen considered by frequency, usage, and influence.

Organisation	 Certified Vegan (USA)	 Vegan Australia (Australia)	 VegeCert* (Canada)
Guideline			
Use of animal ingredients	Not allowed	Not allowed	Not allowed
Use of processing aid of animal origin	Blacklist of unpermitted substances	Allowed with a traceable supply chain	Not allowed
Obligatory Separate production line	Not necessary, GMP measures to prevent contamination sufficiently	Not necessary, reasonable measures must be taken to prohibit cross-contamination	Not necessary, GMP measures to prevent contamination sufficiently
Animal Testing	Not allowed for: ingredients, products, manufacturer, or independent party for any type of research	Not allowed	n.i.g.
Contamination Thresholds for animal residue	n.i.g.	Minimise cross-contamination/ no Thresholds defined	Allergen testing to indicate any non-vegan residue. Allergen Threshold: 5 parts per million or fewer
Consequences, if Threshold or Testing criteria failed / not met	n.i.g.	n.i.g.	Not deemed suitable for vegan certification
Trace marking	Allowed**	Allowed, even recommended when shared facilities are used	Allowed**

GMO	No animal genes in ingredients and end-product	n.i.g.	n.i.g.
Further limitations & Special requirements	Products containing sugar need to include verification from the sugar supplier that the sugar is not filtered through bone char	Certified products must not have wording or images on the packaging or related material that suggest or depict any animal being used, exploited, or harmed	Threshold definition linked with allergen traces.
Packaging of animal origin	Packaging material of animal origin not mentioned. Products must be sold in some type of packaging to be able to qualify for the vegan label. This also includes fruits and vegetables	n.i.g.	n.i.g.
Harvesting & fertilisation	Soil, fertilizer, or farming practices are not considered	To certify single ingredient products, it must indicate that no animals were deliberately harmed in the farming process from soil preparation to growing and harvesting.	n.i.g.

Table made on own compilations. Information's retrieved from their guideline documents published online and their respective internet Webpages listed in table 5 in the appendix. Viewed on 20.06.2023. Further information's retrieved from (Gerke & Janssen, 2017).

Illustrations of the labels retrieved from their respective internet homepages. Copyrights belong to their respective owners.

n.i.g. = no information's given

*Only the vegan Labels are considered in this table

**information retrieved from Vegan Australia certified under https://www.veganaustralia.org.au/cross_contamination retrieved on 05.06.2023

Eidesstattliche Erklärung

Verfasst von: Herr **Martens** René

Ich versichere hiermit, dass ich die vorliegende Bachelorarbeit mit dem o.a. formulierten Thema ohne fremde Hilfe selbstständig verfasst und nur die angegebenen Quellen und Hilfsmittel verwendet habe. Wörtlich oder dem Sinn nach aus anderen Werken entnommene Stellen sind unter Angabe der Quellen kenntlich gemacht.

Hamburg, den 10.07.2023

Ort, Datum

Unterschrift: _____

René Martens

