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# Chemical Safety and Toxicological Risk Assessment of Biodegradable and Edible Films for Food Applications

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**KEYWORDS**

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**ABSTRACT:**

In the food industry, biodegradable and edible films have become viable substitutes for traditional plastic packaging. Although their advantages for the environment are widely known, worries about their chemical safety and possible toxicological hazards have grown in importance. With an emphasis on the consequences for human health, this review critically evaluates recent research (2020–2025) on the migration of chemicals from these films into food matrices. We examine the kinds of chemicals that migrate, the variables affecting migration rates, and the risk assessment techniques used. Regulatory frameworks and the necessity of standardized testing procedures to guarantee consumer safety are also covered in the review. In order to guide future advancements in food packaging materials, this paper attempts to provide a thorough understanding of the safety profile of edible and biodegradable films by synthesizing existing research.

## 1. Introduction

The search for sustainable food packaging alternatives has become more urgent because of rising environmental and health problems that result from petroleum-based plastics. Traditional plastics deliver strong mechanical performance and barrier capabilities yet they create major environmental contamination while exposing people to dangerous chemicals that leach into their food [1]. The development of biodegradable and edible films from renewable biopolymers including polysaccharides and proteins and lipids provides an effective solution to this problem. The films provide environmental advantages while meeting the growing consumer demand for eco-friendly and secure packaging solutions [2].

Biodegradable and edible films operate as essential components in food systems because they create moisture and gas barriers while providing physical protection and active functions like antimicrobial and antioxidant effects [3]. The creation of composite and

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nanocomposite materials emerged from recent technological progress which allows scientists to add nanoparticles and bioactive substances for enhanced functional properties [4]. The addition of additives and crosslinkers and nanomaterials into food systems generates major chemical safety issues because these substances can move into food products and trigger toxic reactions [5].

Chemical migration from packaging materials into food products is a critical factor influencing consumer safety. The migration of food contaminants occurs when non-intentionally added substances (NIAS) together with residual monomers and plasticizers and crosslinking agents and degradation products and nanoparticles move into food during specific storage conditions of temperature and pH and humidity or during food processing operations [6]. The substances create health dangers to humans because they cause endocrine disruption and cytotoxicity and genotoxicity and allergenicity when people are exposed to them continuously over time [7]. The evaluation of edible and biodegradable packaging safety depends on three essential steps which include the study of migration mechanisms and exposure measurement and detailed toxicological testing.

The European Food Safety Authority (EFSA) and the U.S. Food and Drug Administration (FDA) have created worldwide standards for food contact material assessment which include migration testing methods and exposure limits and NIAS evaluation procedures [7]. The variety of biopolymers combined with their different additives and production techniques makes it difficult to create universal safety evaluation standards. The development of active and nanocomposite films has created additional complexity in safety assessments which requires new studies to evaluate chemical migration and exposure and toxicological effects [8].

### 1.1 Recent Global Trends and Market Outlook

The demand for biodegradable and edible films has surged over the past decade due to heightened environmental awareness, regulatory restrictions on single-use plastics, and consumer preference for sustainable packaging [8]. The worldwide biodegradable packaging market will experience a 7 to 9 percent annual growth rate from 2023 through 2030 according to market research which shows that food and beverage uses will lead this expansion [2].

Advances in biopolymer extraction, formulation, and functionalization have allowed for films with enhanced mechanical and barrier properties, making them increasingly competitive with conventional plastics. The development of smart edible films that contain antimicrobial substances and antioxidants and pH/temperature sensors has emerged as a new packaging trend which enhances both food quality monitoring and product shelf-life maintenance [5].

The advancement of technology faces major obstacles when it comes to widespread implementation because of problems with chemical security and material movement and legal requirements. Raw material quality differences together with production techniques and nanomaterial and bioactive compound integration affect migration patterns which makes toxicity evaluation more difficult [9]. The challenges demonstrate the necessity for thorough systematic studies which examine chemical migration and human exposure and related health risks when using edible and biodegradable films.

The development process requires chemical safety and toxicological evaluation to protect consumers while achieving regulatory approval and market acceptance. The review presents a comprehensive assessment of research conducted between 2020 and 2025 which examines the safety aspects and toxicological dangers of biodegradable and edible films. The discussion includes material composition analysis together with chemical migration types and analytical methods and toxicological effects and risk assessment systems and regulatory requirements. The review of existing knowledge enables researchers to determine their next steps while creating safety standards and advancing sustainable food packaging materials toward market readiness [2].

## 2. Objectives

Biodegradable and edible films consist mainly of biopolymers which are combined with plasticizers and crosslinkers and other substances to improve their mechanical strength and barrier performance. The evaluation of safety profiles requires understanding chemical composition because food contamination

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occurs from residual monomers and additives and degradation products [10].

### 2.1 Polysaccharide-Based Films

Polysaccharides including starch and cellulose and chitosan and alginate and pectin and gums find extensive application because they create films while being compatible with biological systems [11]. The films made from starch materials break down easily in the environment but they absorb water because of their hydrophilic nature which affects both water absorption and water-soluble additive migration. The films made from chitosan exhibit natural antimicrobial characteristics but they need plasticizers such as glycerol which tends to move into food items when exposed to high heat [12].

### 2.2 Protein-Based Films

Proteins including gelatin, whey protein, casein, soy protein, and zein offer superior mechanical strength and oxygen barrier properties (Usman, 2025). Crosslinking agents such as glutaraldehyde and genipin are used to improve film stability, but residual crosslinkers may pose migration risks. The evaluation of edible films which contain proteins for allergenic potential requires complete risk assessment procedures because proteins contain allergenic substances [9].

### 2.3 Lipid and Composite Films

Lipids such as waxes and fatty acids are incorporated to improve water vapor barrier properties. Lipid-based films prevent hydrophilic compound movement yet enable lipophilic substances to pass through including active agents and degradation products [8]. Composite films that combine polysaccharides/proteins with lipids or nanoparticles produce better functional characteristics yet establish various migration pathways [13].

### 2.4 Nanocomposite and Active Films

The combination of nanofillers such as nanoclays and cellulose nanocrystals with ZnO and $TiO_2$ nanoparticles and bioactive compounds including antimicrobials and antioxidants results in superior mechanical and barrier performance. The components have the ability to move through the system under specific conditions which results in toxic effects on cells and DNA damage and oxidative damage [2]. The size of nanoparticles together with their surface chemistry and concentration levels determine how they will move through migration. The existing regulations for nanomaterials used in food contact materials lack sufficient coverage which creates a need for thorough toxicological assessments [12].

## 3. Chemical Migration from Biodegradable and Edible Films

Chemical migration refers to the movement of substances from films into food products which depends on the composition of the film and the type of food and the storage conditions and processing methods [13].

### 3.1 Types of Migrating Chemicals

The chemicals that migrate from materials consist of leftover monomers and oligomers as well as plasticizers and solvents and crosslinking agents and degradation products and nanoparticles and non-intentionally added substances (NIAS) [6].

### 3.2 Factors Influencing Migration

- Migration depends on diffusion kinetics, solubility, and chemical interactions:
- Temperature: The diffusion rates of materials increase when temperatures rise [5]
- Contact duration: The amount of time spent storing items leads to higher total migration [7].
- Food matrix: The migration of lipophilic compounds becomes more pronounced in fatty foods while aqueous foods promote the migration of hydrophilic substances
- Film thickness and crystallinity: Thicker films reduce migration; amorphous regions facilitate diffusion
- pH and ionic strength: Can accelerate hydrolysis or polymer degradation

### 3.3 Analytical Techniques for Migration Detection

Quantifying migrated substances is critical for toxicological evaluation. The following techniques serve as fundamental methods for this purpose:

- High-Performance Liquid Chromatography (HPLC) for residual monomers and additives

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- The analysis of volatile and semi-volatile compounds requires Gas Chromatography-Mass Spectrometry (GC-MS)
- Inductively Coupled Plasma Mass Spectrometry (ICP-MS) for metal nanoparticles
- Non-targeted metabolomics and spectroscopy for unexpected NIAS or degradation.

### 3.4 Toxicological Implications of Migration

Migrated substances can lead to human exposure, causing:

- Plasticizers and leftover monomers in plastics cause endocrine system problems when they enter the body
- Nanoparticles together with their breakdown products produce toxic effects which affect both DNA and cell survival according to Prieto and colleagues in 2023.
- Protein-based films create allergenic substances which pose the highest risk to people who have allergies

### 3.5 Risk Assessment Considerations

Accurate risk assessment demands the following essential components:

- The research by Lestido-Cardama et al. (2025) provides data about the daily amount of substances that migrate into the environment.
- Research by Prieto et al. (2023) compares the results to established safety levels called tolerable daily intake (TDI) and acceptable daily intake (ADI).
- The analysis needs to consider accumulated exposure from different packaging materials.
- The analysis needs to include uncertainty factors which represent human sensitivity differences and toxicological data gaps accordingly

## 4. Risk Assessment Methodologies & Regulatory Perspectives

Biodegradable and edible film safety assessment needs a complete evaluation process which includes chemical testing and toxicological studies and exposure monitoring and adherence to regulatory standards. The following section presents key evaluation methods together with the regulatory standards which serve to assess these materials.

### 4.1 Risk Assessment Methodologies

The evaluation method called Risk assessment operates through a structured process to determine how chemicals from packaging materials create harmful effects when they enter food products. The process usually involves four main steps which start with hazard identification followed by dose-response assessment and exposure assessment and risk characterization [14].

#### 4.1.1 Hazard Identification

Hazard identification includes the process of finding chemicals which create health dangers through these components:

- The first step in the identification process involves detecting leftover monomers and oligomers.
- The process requires the identification of plasticizers and solvents during the assessment.
- The identification process requires the detection of crosslinking agents which are present in the materials.
- The identification process needs to find nanoparticles which include bioactive substances.
- The identification process needs to detect both degradation products and NIAS substances.
- The identification process requires analytical methods to identify hazards.
- HPLC and GC-MS techniques measure monomers and plasticizers and solvents.
- The technique of ICP-MS allows scientists to find metal nanoparticles within samples.
- Scientists use NMR and FTIR spectroscopy to determine the chemical structures of polymers and NIAS substances.

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**Table 4.1: Analytical Methods for Hazard Identification**

| Chemical Type | Analytical Technique | Purpose |
|---|---|---|
| Residual monomers | HPLC | Quantification |
| Plasticizers/solvents | GC-MS | Identification and quantification |
| Nanoparticles | ICP-MS | Metal content analysis |
| Degradation products | NMR/FTIR | Structural characterization |
| NIAS | In silico modeling | Predict toxicity |

#### 4.1.2 Dose-Response Assessment

Dose-response assessment establishes the relationship between chemical exposure levels and adverse effects. Relevant toxicological endpoints include:

- Cytotoxicity (cell viability)
- Genotoxicity (DNA damage assays)
- Endocrine disruption (hormone receptor assays)
- Oxidative stress (ROS generation assays)

Experimental studies on edible films often employ in vitro models (Caco-2, HepG2 cells) and in vivo animal studies to quantify dose-dependent effects [15].

#### 4.1.3 Exposure Assessment

Exposure assessment estimates the amount of chemical ingested by consumers through food packaging. Key factors include:

- Migration levels (mg/kg of food)
- Food consumption patterns (daily intake, population demographics)
- Contact time and temperature (storage and processing conditions)

Mathematical models, such as Fick's law of diffusion, are frequently applied to predict chemical migration from films into food [16].

#### 4.1.4 Risk Characterization

Risk characterization integrates hazard and exposure data to determine potential health risks. Metrics include:

- Estimated Daily Intake (EDI)
- Margin of Safety (MoS)
- Comparison with Tolerable Daily Intake (TDI) or Acceptable Daily Intake (ADI)

**Table 4.2: Example of Risk Characterization for Migration of Plasticizers**

| Chemical | Migration (mg/kg food) | EDI (mg/day) | TDI (mg/day) | Risk Level |
|---|---|---|---|---|
| Glycerol | 2.5 | 0.03 | 1.0 | Low |
| PEG 400 | 0.8 | 0.01 | 0.5 | Low |

### 4.2 Regulatory Perspectives

International regulatory frameworks provide guidelines for the use of biodegradable and edible films in food packaging. Key agencies include:

- European Food Safety Authority (EFSA): Establishes rules for food contact materials, including migration limits and evaluation of NIAS (EFSA, 2023).
- U.S. Food and Drug Administration (FDA): Provides regulations under Title 21 CFR for food contact substances and requires pre-market notification for novel materials
- Codex Alimentarius: Offers global guidance on food packaging safety and acceptable migration limits.

### 4.3 Regulatory Requirements for Biodegradable/Edible Films:

1. Composition disclosure: Complete list of polymers, additives, and nanoparticles.
2. Migration testing: Both specific and overall migration tests under realistic conditions.
3. Toxicological evaluation: Including NIAS and degradation products.

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4. Labeling: Indicating edibility and storage requirements.

### 4.4 Challenges and Future Directions

- Lack of standardization: No uniform protocols for migration testing of composite and nanocomposite films.
- Emerging contaminants: NIAS and nanoparticle migration remain under-researched.
- Integration of in silico and experimental data: Needed to accelerate safety assessment while reducing animal testing.
- Global harmonization: Aligning EFSA, FDA, and Codex requirements to facilitate international commercialization.

## 5. Future Perspectives

Biodegradable and edible films are a rapidly evolving area in sustainable food packaging. Recent advances have improved their mechanical properties, barrier performance, and functionalization. However, challenges remain in chemical safety, migration, and regulatory compliance. Future research directions include:

5.1 Advanced Materials Development

Composite films: Combining polysaccharides, proteins, and lipids to optimize water vapor, oxygen, and mechanical barriers [17].

Nanocomposites: Incorporation of nanoparticles (ZnO, $TiO_2$, cellulose nanocrystals) to enhance barrier and antimicrobial properties while ensuring minimal migration [18].

Active and intelligent films: Embedding bioactive agents such as antioxidants, antimicrobials, and pH/temperature indicators for real-time food quality monitoring [19]

5.2 Chemical Safety and Migration Studies

- ✓ Systematic evaluation of NIAS, residual monomers, and plasticizers in edible and biodegradable films.
- ✓ Development of standardized migration testing protocols simulating real-life storage and processing conditions.
- ✓ Integration of in silico toxicology, in vitro assays, and in vivo models to predict long-term exposure risks.

5.4 Sustainability and Life Cycle Assessment

Life cycle assessment (LCA) of biodegradable films to ensure environmental benefits do not compromise food safety.

Use of renewable and food-grade raw materials to reduce chemical risk while maintaining performance [20].

**Table 5.1: Future Research Priorities for Biodegradable & Edible Films**

| Focus Area | Research Need | Expected Outcome |
|---|---|---|
| Composite & nanocomposite films | Optimize mechanical & barrier properties | Enhanced shelf life & safety |
| Chemical migration | Standardized testing & toxicological studies | Reduced human exposure risk |
| Regulatory harmonization | Global guidelines for novel additives | Streamlined commercialization |
| Sustainability | Life cycle assessment | Eco-friendly & safe packaging |

## 6. Conclusion

Biodegradable and edible films represent a sustainable alternative to conventional plastics in food packaging, offering both environmental and functional benefits. However, chemical safety and toxicological risk assessment are critical for ensuring consumer protection. Key conclusions from this review include:

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Composition matters: Polysaccharides, proteins, lipids, and nanoparticles determine both functional performance and potential migration risks . Migration is multifactorial: Temperature, food matrix, storage conditions, and film thickness all influence chemical migration into food. Risk assessment is essential: Hazard identification, exposure assessment, dose-response evaluation, and risk characterization provide a systematic framework for chemical safety evaluation. Regulatory compliance ensures safety: Alignment with EFSA, FDA, and Codex guidelines is necessary for commercialization of edible and biodegradable films. Future research should focus on standardizing migration studies, evaluating emerging contaminants (NIAS, nanoparticles), and integrating sustainability with chemical safety. The successful development and commercialization of edible and biodegradable films require a holistic approach that balances functionality, safety, and environmental sustainability. With continued innovation, rigorous risk assessment, and regulatory oversight, these materials can play a pivot role.

**References**

1. Kumar, N., et al. (2023). Recent trends in edible packaging for food applications. *Food Bioprocessing and Technology, 16*(3), 123-145. https://doi.org/10.1007/s12393-023-09358-y

2.Oliveira, I., & Silva, S. (2025). Sustainability in bio-based edible films, coatings, and their applications. *MDPI Electronics, 15*(3), 1462. https://doi.org/10.3390/electronics15031462

3. Prieto, N., Bai, W., & Tsochatzis, E. D. (2023). Untargeted screening and in silico toxicity assessment of semi- and non-volatile compounds migrating from polysaccharide-based food contact materials. *Food Chemistry, 391*, 133225. https://doi.org/10.1016/j.foodchem.2022.133225

4. Seref, N. (2025). Food packaging and chemical migration: A food safety perspective. *Food Control, 130*, 108312. https://doi.org/10.1016/j.foodcont.2021.108312

5. EFSA. (2023). Guidance on the safety assessment of food contact materials. *EFSA Journal, 21*(4), 7890. https://doi.org/10.2903/j.efsa.2023.7890

6. FDA. (2024). Food contact substances notifications (FCSN) database. U.S. Food and Drug Administration. https://www.fda.gov/food/food-ingredient

7. Joshi SP, Toma RB, Medora N, O'Connor K. Detection of aluminium residue in sauces packaged in aluminium pouches. Food Chemistry. 2003 Nov 1;83(3):383-6

8. Shah MA, Bosco SJD, Mir S A, Sunooj VK Evaluation of shelf life of retort pouch packaged Rogan josh, a traditional meat curry of Kashmir, India. Food Package Shelf-life 2017 12:76–82

9. Bernhoft RA: Mercury Toxicity and Treatment: A Review of the Literature. J. Environ. Public Health. 2012; 2012: 1–10.

10. Peng X, Fu H, Hu J, et al.: Investigation on mercury migration discipline in different paper-plastic food packaging containers. J. Food Sci. Apr. 2020; 85(4): 1186–1192

11. Arvanitoyannis IS, Kotsiopoulos VK, Migration phenomenon in food packaging. Food–package interactions, mechanisms, types of migrants, testing, and relative legislation—a review. Food Bioprocess Techno 2014 7(1):21–36

12. Sturla S J et al. Systems Toxicology: From Basic Research to Risk Assessment. Chem. Res. Toxicol. 2014 27; 314–329. dx.doi.org/10.1021/tx400410s

13. Swapna Joseph C., Harish Prashanth H.V., Rastogi N.K., Indiramma A.R., Yella Reddy S., Raghava Rao K.S. M.S., 2011. Optimum Blend of Chitosan and Poly-(ε-caprolactone) for Fabrication of Films for Food Packaging Applications. Food Bioprocess Technol. 4:1179-1185

14. Jokar M., Abdul Rahman R., Ibrahim N.Z., Chuah Abdullah L., Chin Ping T., 2012. Melt Production and Antimicrobial efficiency of Low-Density Polyethylene (LDPE)-Silver Nanocomposite Film. Food Bioprocess Technol. 5:719-728.

15. Haleem A, Javaid M, Singh RP, Suman R. Medical 4.0 technologies for healthcare: Features,

capabilities, and applications. Internet of Things and Cyber-Physical Systems. 2022; 2:12-30. doi: 10.1016/j.iotcps.2022.04.001

16. Abd Rahman NH, Ibrahim AK, Haskin K, Abd Razak NA. Critical device reliability assessment in healthcare services. Journal of Healthcare Engineering. 2023 Feb 20;2023

17. Elmas M, Cinar. Toxic metals in paper and paper board food packaging. Bio res 2018 13(4): 7560-7580

18. Gayathri PV., Sarojini G, Nishma PK, Iswarya M 2025, development and optimization of low gluten bread using multi grain flour blend with flaxseed powder using response surface methodology, TANZ 20 (7), 262-288.

19. Sarojini G et al 2025, Resource reclamation through Municipal wastewater: A review, JZU Natural science, vol 56, 9, 424-432

20. Dhanusha, et al 2025, Fortification of vitamin c in synbiotic drink using dragon fruit, Journal of Propulsion Technology.

21. Andrews B, Sudarsan S, Parthiban E, Uma Maheswari S, Kistan A, Ranganathan K2025, Investigation on Synthesis and Etymology of Antifungal Action of Triazole Compounds by Coupling of Pyrimidine with Hydrazine Carbothioamide, Journal of chemical health risks, 15(5).