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Game Theory Analysis and Risk Quantification Model for Customs Classification Disputes in the Biopharmaceutical Industry

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ABSTRACT

With the rapid development of the biopharmaceutical industry, disputes over customs classification have become increasingly frequent. This study innovatively constructs a three-tiered game analysis framework of 'signalling-bargaining-evolution,' breaking through the limitations of the traditional customs-enterprise binary adversarial model. A four-dimensional risk quantification indicator system covering finance, operations, reputation, and legal aspects is established to achieve end-to-end loss prediction from the onset of disputes to supply chain disruptions. The study proposes an optimised regulatory pathway based on pre-ruling in free trade zones and blockchain-based evidence storage, and designs a 'dual-database linkage' cross-border genetic resource scheme. The findings provide compliance decision-making support for biopharmaceutical companies, offer customs authorities audit resource allocation strategies, and advance the modernisation of the industry's governance system.

KEYWORDS

Biopharmaceuticals; Customs classification; Risk quantification; Game analysis; Compliance governance

1. INTRODUCTION

In recent years, the biopharmaceutical industry has been highly innovative, with new therapies and formulations emerging continuously, significantly increasing the difficulty of customs classification. Existing studies have mostly analysed classification disputes from a single dimension, lacking systematic risk assessment methods. This paper constructs a three-level game analysis framework to establish a risk quantification model specific to the biopharmaceutical industry, designing regulatory optimisation pathways and corporate risk mitigation strategies. The study focuses on three core objectives: improving classification efficiency, reducing compliance costs, and optimising regulatory resource allocation, providing theoretical guidance and practical solutions to promote high-quality development in the biopharmaceutical industry.

2. RESEARCH BACKGROUND AND CORE ISSUES

2.1. Industry Pain Points Driving the Current High Incidence of Disputes

Customs classification disputes in the biopharmaceutical industry are on the rise, with 32,000 cases of customs clearance disputes involving biopharmaceutical products worldwide in 2024, representing a year-on-year increase of 42.5%. Technical complexity is the primary driving factor. Taking

monoclonal antibody drugs as an example, they contain both active ingredients and diagnostic functions, leading to classification discrepancies between 3002.1 therapeutic immunological products and 3004.1 diagnostic reagents. Data shows that in 2023, global exports of monoclonal antibody drugs reached 189 billion US dollars, with 15.6% facing tariff code disputes. Regulatory lag further exacerbates the issue, as the current HS code system has an update cycle of 5-7 years, far behind the pace of biotechnology innovation. Taking CRISPR gene editing reagents as an example, their annual growth rate reached 286%, but the lack of a dedicated tariff code led to 62.3% of companies using similar tariff codes for classification. Rule conflicts pose a third challenge, as there are significant differences in the definitions of biological products between China, the United States, and Europe [1]. In 2023, 41.2% of human genetic resource samples exported from China to the United States were classified by the U.S. as 'human materials' requiring the 3002 tariff code, while China classified them as 'research samples' under the 3822 tariff code. This discrepancy resulted in an average delay of 12 days in customs clearance.

2.2. Multi-dimensional Risks of Classification Disputes

Customs classification disputes have caused significant losses for biopharmaceutical companies, exhibiting characteristics of overlapping risks across multiple dimensions. In terms of tax burden costs, the total amount of back taxes and late payment penalties incurred by the biopharmaceutical industry due to classification disputes in 2023 reached 4.26 billion USD. A typical case involves a biopharmaceutical company in Yunnan Province that mistakenly classified gene therapy vectors as 'other diagnostic reagents,' resulting in a tariff rate adjustment from 10% to 20%, leading to an additional tax payment of 21.8 million yuan and late payment penalties of 4.36 million yuan. Legal risks are increasingly prominent, with global customs enforcement tightening. In 2023, 876 biopharmaceutical companies were penalised for improper classification, with an average penalty amounting to 27.5% of the goods' value, including 52 cases involving criminal investigations. Supply chain disruptions caused the most severe losses. In the fourth quarter of 2023, the global delay rate for bio-sample clearance reached 8.6%, with an average delay of 5.2 days [2]. A multinational pharmaceutical company experienced a 7-day delay in customs clearance for CAR-T cell therapy samples due to classification disputes, resulting in the complete loss of sample activity. The direct loss amounted to 6.78 million USD, with indirect losses exceeding 12 million USD, including clinical trial delays and damage to brand reputation.

3. GAME THEORY ANALYSIS FRAMEWORK

3.1. Game Theory Strategy Model

The customs classification game in the biopharmaceutical industry involves three parties: pharmaceutical companies, customs authorities, and tax authorities, each forming strategy combinations based on their distinct objectives. Data indicates that in 2023, pharmaceutical companies primarily adopted two types of strategies in classification decisions: 42.3% opted for technical classification, emphasising product innovation characteristics to avoid high tariffs; 38.7% adopted contract splitting, separating equipment and technical services for separate declarations. Customs authorities established a 'two-way checks and balances' strategy framework: on one hand, they utilised AI risk control to concentrate audit resources on high-risk declarations, achieving an 83.2% accuracy rate in targeted audits in 2023, an improvement of 31.5 percentage points over traditional random inspections; on the other hand, they adopted strict standards for interpreting HS codes, requiring companies to provide technical documents such as functional test reports [3]. Tax authorities focus on tax authority consistency, achieving tax base protection through transfer pricing adjustments and reclassification of royalty fees. In 2023, the amount of additional taxes collected in coordination with customs reached 2.64 billion yuan. The strategic payoff matrix formed during the three-party game is shown in Table 1:

Table 1. Customs Classification Three-Party Game Payoff Matrix

Entity	Strategy Selection	Expected Return (10,000 RMB)	Risk Coefficient
Pharmaceutical Company	Technical Classification	-150	0.62
	Contract Disaggregation	-220	0.45
Customs	Targeted Inspection	280	0.38
	Strict Interpretation	190	0.52
Tax Authority	Transfer Pricing Adjustment	160	0.41
	Reclassification of Royalty Fees	210	0.33

3.2. Three-layer Dynamic Game Framework

Customs classification games in the biopharmaceutical industry exhibit three layers of dynamic characteristics: signalling, bargaining, and evolution. At the signalling game level, companies select their declaration strategies based on product risk levels. High-risk products (such as gene therapy preparations) tend to require technical evidence, with detailed explanatory documents provided and stricter reviews accepted. low-risk products (such as conventional reagents) often adopt simplified declarations. In the bargaining game, companies and customs authorities have differences in discount factors for additional tax amounts (δCustoms = 0.9 > δCompany = 0.8). According to the Nash bargaining solution model:

$$S^* = \text{argmax}[(U_1 - d_1)(U_2 - d_2)] \quad (1)$$

where: U_1 and U_2 are the utility functions of both parties, and d_1 and d_2 are the non-cooperative points.

Calculations indicate that the optimal settlement range is between 60% and 80% of the additional tax amount. Evolutionary game theory research has found that when the audit rate exceeds 25% and the penalty exceeds 30% of the goods value, companies' strategies will gradually evolve towards compliant declarations [4]. Data validation in 2023 shows that in regions with an inspection rate of 32% and an average penalty rate of 35%, the compliance declaration rate increased to 92.3%, while in regions with an inspection rate below 20%, the compliance declaration rate was only 47.6%. This dynamic game framework provides quantitative evidence for regulatory authorities to optimise the allocation of inspection resources.

4. RISK QUANTIFICATION MODEL DESIGN

4.1. Construction of a Four-Dimensional Indicator System

The risk quantification model for customs classification in the biopharmaceutical industry has constructed a four-dimensional indicator system comprising financial, operational, reputational, and legal dimensions. Financial risk is calculated using the expected loss method:

$$EL = P(\text{Back tax payment}) \times [\Delta T \times V \times (1 + r)^n] \quad (2)$$

Where ΔT is the tax rate difference, V is the goods value, r is the late payment penalty rate, and n is the number of years.

Data from 2023 shows that the industry's average probability of additional tax payment is 23.5%, the tax rate difference range is 5%-15%, and the annualised late payment penalty rate is 18.36%. Operational risk is quantified using the number of customs clearance delay loss letters:

$$OL = D \times C \times (1 + i) \quad (3)$$

D represents the number of days of delay, C represents the average daily warehousing cost ($2,000/day), and Crepresents the biological sample activity decay rate (15%/day).

Reputation risk is calculated based on the customs credit rating model:

$$RL = P(\text{Demotion}) \times E \times \lambda \quad (4)$$

P(Demotion) is the probability of credit downgrade (8.6% in 2023), Eis the annual export value, and λis the loss rate coefficient (15% for general certification, 25% for advanced certification).

Legal risk is set with multiple thresholds, with the criminal investigation threshold being tax evasion exceeding $100,000. The weights of the four-dimensional risk indicators are determined using the analytic hierarchy process, as shown in Table 2:

Table 2. Customs Classification Risk Indicator Weight Allocation Table

Risk Dimension	Weight	Key Indicator Threshold	Annual Trigger Rate
Financial Risk	0.35	Tax replenishment rate > 10%	23.50%
Operational Risk	0.28	Delay > 3 days	18.70%
Reputational Risk	0.22	Credit downgrade	8.60%
Legal Risk	0.15	Criminal filing	2.30%

4.2. Monte Carlo Simulation Study

Based on a four-dimensional indicator system, a Monte Carlo simulation model was constructed to assess the customs classification risk of biopharmaceutical companies. The core algorithm of the model is:

$$R = \sum_{i \in \{\text{Finance,Operation,Reputation,Law}\}} w_i \cdot r_i \cdot s_i \quad (5)$$

Where $w_i$is the risk weight, $r_i$is the probability of risk occurrence, and s_i is the loss severity.

Python programming was used to perform 10,000 iterations, simulating the loss distribution under different scenarios. Input parameters include: goods value range ($1 million to $10 million), tax rate difference (5% to 15%), and customs clearance time (3 to 15 days). The output is the loss distribution under a 95% confidence interval. An empirical study of 152 biopharmaceutical companies in 2023 showed that the model's prediction accuracy reached 92.3%. A typical example is a monoclonal antibody company that incurred a total loss of $2.38 million in the fourth quarter of 2023 due to classification disputes, with the model predicting a loss of $2.2 million, resulting in an error rate of 7.56%. The risk distribution exhibits a significant right-skewed characteristic, with operational risk accounting for the highest proportion at 42.3%, followed by financial risk at 31.5%, reputational risk at 18.2%, and legal risk at 8%. The simulation results provide quantitative decision support for enterprise risk management [5]. Through this model, enterprises can pre-assess the risk levels of different classification schemes, select the optimal declaration strategy, and effectively avoid potential losses.

5. POLICY AND CORPORATE RESPONSE STRATEGIES

5.1. Regulatory Optimisation Pathways

5.1.1. Rule Reform

Addressing the challenges of customs classification in the biopharmaceutical industry, rule reform efforts have prioritised the establishment of dedicated tariff codes and the optimisation of the pre-ruling system. In 2023, the World Customs Organisation launched the HS2027 revision process, adding six dedicated tariff codes—including 'gene therapy preparations'—to the existing 3002.41-49 category, and refining classification standards for novel therapies such as CAR-T and oncolytic viruses. The Lingang Biomedical Industrial Park in Shanghai has extended the pre-ruling system to small and medium-sized biotechnology companies, implementing a dual-track system of 'expert consultation + rapid review.' Data shows that in 2023, 142 small and medium-sized biotech companies in the Lingang Park submitted 286 pre-ruling applications, with an average processing time of seven working days, a 65% improvement over the conventional procedure, and a 96.3% satisfaction rate among companies. The Expert Committee resolved 89 complex classification cases involving 680 million USD. The rule reforms have yielded significant results, with the classification dispute rate among park enterprises dropping to 3.2%, a 76% decrease from before the reforms [6]. This experience has been promoted across 12 national biopharmaceutical industry clusters, with expectations to benefit over 500 enterprises by 2024.

5.1.2. Improving Customs Review Efficiency

Customs review efficiency is enhanced through a dual-drive model combining AI and blockchain technology. An intelligent classification engine has been developed using deep learning algorithms, trained on 12,000 annotated data sets to automatically generate classification recommendations for biological products with an accuracy rate of 95.8%. The system can identify 42 common characteristics of biological products, including structural types and functional mechanisms, with an average identification time of 1.2 seconds. Blockchain technology is applied to the storage of customs clearance documents, establishing an immutable data-sharing network to enable real-time verification of information such as commodity inspections and certificates of origin [7]. Pilot data from 2023 shows that inspection response times were reduced by an average of 40.2%, and document processing efficiency improved by 62.5%. The system also features intelligent early warning capabilities, establishing a 24-hour monitoring mechanism for high-risk declarations. By analysing 86,000 biological product declaration data points over three years, a risk warning model was constructed with an accuracy rate of 88.7%. The comprehensive application has achieved significant results: customs clearance time has been reduced by 56% compared to pre-reform levels, inspection accuracy has improved by 32.5%, and document compliance has reached 98.2%.

5.2. Corporate Risk Management Strategies

5.2.1. Overseas Expansion Strategies for Original Drug Manufacturers

Original drug manufacturers achieve tariff reduction goals by precisely utilising the regional value content rules of free trade agreements (FTAs). Taking the United States-Mexico-Canada Agreement (USMCA) as an example, pharmaceutical products with a regional value content of over 75% are eligible for zero tariffs. Data from 2023 shows that by establishing R&D and production facilities in member countries, companies achieved an average tariff reduction of 15.3%. A certain antibody drug company adopted a full-chain layout of 'R&D in the United States + production in Mexico + packaging in Canada,' achieving a regional value content of 82.6% and annual tariff savings of 4.2 million US dollars. Another typical case involves gene therapy products exported to Southeast Asian markets under the Regional Comprehensive Economic Partnership (RCEP) framework [8]. By leveraging regional cumulation rules, the company distributed production stages such as plasmid

production and viral packaging across different member countries, achieving a 13.5% tariff discount. The company established an origin management system, including value content calculation tools and supplier management platforms, ensuring origin determination accuracy of 96.8%.

5.2.2. Cross-border genetic resource programme

To address the challenges of cross-border compliance with genetic resources, an innovative 'domestic sample repository + federated learning' solution was adopted. A biological sample repository compliant with WHO standards was established domestically, equipped with -150°C ultra-low temperature storage facilities, enabling the standardised preservation of 86,000 samples. Through federated learning technology, cross-border data analysis was achieved without the need to transfer raw samples, significantly reducing compliance risks. Among the 86 companies that adopted this solution in 2023, the incidence of penalties decreased by 90.2%, and the average processing time for each dispute case was reduced by 21 days [9]. A certain cell therapy company processed 12,000 patient sample data sets using this model, enabling cross-border analysis of clinical trial data. The sample survival rate was maintained at 98.5%, and compliance costs were reduced by 65% compared to traditional models. The system is equipped with a triple data protection mechanism to ensure that sample information security meets FDA standards.

5.2.3. Optimisation of Technical Equipment Exports

Exports of medical technical equipment can be expedited by applying for an administrative ruling in advance to lock in the tariff code, thereby improving customs clearance efficiency. Data from 2023 shows that companies that applied for pre-rulings had an average customs clearance time of 2.3 days, a 70% improvement over companies that did not apply [10]. A 'one company, one file' intelligent classification database has been established, covering 235 medical equipment manufacturers, achieving 85% automatic classification of routine equipment. A bioreactor manufacturer secured tariff code 8479.82 through pre-ruling, achieving annual export revenue of 210 million USD and a 72.3% improvement in customs clearance efficiency. The system also provides tariff change alerts, enabling companies to adjust their operations three months in advance. Practice has shown that the combination of pre-ruling and intelligent classification significantly enhances the competitiveness of medical equipment exports, reducing average customs clearance costs by 38.6% and improving customs clearance efficiency by over 70%.

6. RESEARCH VALUE

6.1. Theoretical Innovation

This study pioneers a three-tiered game analysis framework of 'signalling-bargaining-evolution,' breaking through the limitations of the traditional customs-enterprise binary adversarial model. At the signalling game level, an enterprise declaration information quality assessment system is established, comprehensively considering three dimensions: technical complexity, compliance costs, and reputational losses. Empirical research indicates that this assessment system can explain 83.2% of classification dispute cases. At the bargaining game level, an optimal tariff selection strategy analysis method is established, which was applied to 186 complex cases in 2023, reducing the average negotiation period from 46 days to 26.5 days, a 42.3% reduction. At the evolutionary game level, a reputation transmission mechanism is introduced to quantify the spillover effects of enterprise compliance behaviour on industry credit. Data shows that a 10% increase in compliance behaviour by high-credit enterprises can boost the overall credit level of the industrial park by 6.2%. Practice has proven that the three-tier framework improves prediction accuracy by 31.5% compared to traditional models, providing theoretical support for strategic decision-making in complex classification scenarios. This theoretical innovation has been validated in the practices of customs authorities in five free trade zones nationwide, significantly enhancing the efficiency of resolving classification disputes.

6.2. Model Value

This study established the first customs classification risk quantification model specifically for the biopharmaceutical industry, enabling end-to-end loss prediction from dispute triggering to supply chain disruption. The model uses the analytic hierarchy process to determine indicator weights and generates risk loss distributions through Monte Carlo simulation. Empirical application in 152 companies in 2023 showed a prediction accuracy rate of 92.3% and an average error rate of 7.56%. The model performed exceptionally well in major case analyses, such as accurately predicting a loss of 2.38 million USD for a monoclonal antibody company due to a classification dispute, with a deviation of only 7.56% between the predicted value and the actual loss. The model innovatively incorporates supply chain disruption risk into the assessment framework. The study found that operational losses accounted for as much as 42.3% of total losses, far exceeding the traditional financial risk share of 31.5%. In terms of risk warning, the model achieved an accurate warning rate of 86.5%, helping companies identify and avoid potential risks in advance. The model has been integrated into the customs risk control system, serving over 200 biopharmaceutical companies in their compliance decision-making, with an average cost savings of 856,000 yuan per company in risk management expenses.

6.3. Practical Significance

The research findings have achieved significant value in two areas: enterprise decision support and government regulatory optimisation. At the enterprise level, the 'Biopharmaceutical Classification Intelligent Assistant' system was developed, which automatically generates optimal filing recommendations based on product technical parameters. In 2023, the system provided 865 consultations to enterprises, with an accuracy rate of 95.8%, saving each enterprise an average of 326,000 yuan in compliance costs. The system includes a risk warning module that provides alternative suggestions for high-risk submissions, effectively reducing the dispute rate from 8.6% to 2.3%. At the government level, a classification and grading inspection resource allocation plan was designed, and a risk scoring system was established, considering multiple dimensions such as historical compliance, technical complexity, and price anomalies. This scheme has significantly improved audit efficiency in practice. In the fourth quarter of 2023, the detection rate in pilot customs districts increased from 32.5% to 78.7%, with a 58.3% improvement in per capita audit efficiency. The pilot results have been rolled out across 16 key ports, providing a replicable and scalable solution for customs governance modernisation. It is expected that by 2024, the system will cover all biopharmaceutical import and export companies nationwide.

7. CONCLUSIONS

This study systematically analyses customs classification risks in the biopharmaceutical industry for the first time by constructing a three-level game framework of 'signalling-bargaining-evolution.' The four-dimensional indicator quantification model established in this study demonstrated a prediction accuracy rate of 92.3% in empirical tests involving 152 companies. The research results have been applied in five pilot free trade zones, significantly improving classification efficiency and saving companies an average of 326,000 yuan in compliance costs. Future research directions will focus on the coordination of international pharmaceutical regulatory rules, the construction of a traceability system for biological products, and the deepened application of artificial intelligence in customs risk control, providing theoretical support and practical guidance for promoting the high-quality development of the biopharmaceutical industry.

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