



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION**  
**AND CERTIFICATION SYSTEMS**

**Twenty-third Session**

**DISCUSSION PAPER ON REGULATORY APPROACHES TO THIRD PARTY CERTIFICATION**  
**IN FOOD SAFETY**

*Prepared by Canada and the United Kingdom*

## Introduction

1. Third party certification schemes were introduced by the food industry in response to business and global market demands to assure food safety outcomes, reduce supply chain risks, and differentiate products. The need to assure food safety outcomes was also driven by regulatory changes in some countries, e.g. the United Kingdom (UK), that required operators to “take all reasonable precautions”. Third party schemes were seen to provide an off-the-shelf solution to this requirement on the basis that they could be used as evidence for a “due diligence” defence.
2. Third party certification schemes allow individual companies to demonstrate the integrity of their products and production systems through conformity with a standard. Such standards often largely replicate, or incorporate, a country’s national legislative requirements, or relevant internationally recognised standards. Schemes usually have formal governance arrangements in place, and use accredited third parties to independently verify compliance with the scheme’s standard. Until recently, competent authorities have paid little attention to third party certification schemes preferring to keep a clear separation between them and the competent authority’s official controls. However, a trend is emerging in some countries’ regulatory modernisation programs to recognise certain aspects of third party certification schemes. The rationale in these countries has been to strengthen their National Food Control System (NFCS) as defined in the *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013). Competent authorities have sought to integrate the elements of a scheme’s standard that overlap with national regulatory requirements. This collaboration recognises that public and private food safety objectives are converging.
3. At its 22<sup>nd</sup> Session, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS22) proposed a program of work to establish a common approach on how third party certification schemes could be utilised in a regulatory context. Canada and the UK were tasked with co-authoring a discussion paper in order to bring more clarity to the issue based on the research and analysis to date.
4. This paper discusses the opportunities and challenges as well as the potential for more effective collaboration between the public and private sector on the use of third party certification schemes with a particular focus on the opportunities that exist to strengthen NFCS through:
  - a. support for the activities of national competent authorities
  - b. access to audit and intelligence data generated by the schemes
  - c. improvements to risk-profiling of food businesses
  - d. better prioritisation of competent authority resources
  - e. increased confidence in levels of compliance with regulatory requirements

5. The paper positions CCFICS as the most appropriate committee within Codex to undertake new work to help promote a consistent approach to the use of third party certification schemes, in line with the *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013). Such public/private collaboration is consistent with the key characteristics<sup>1</sup> of a country's NFCS detailed in the Codex Guidelines regarding the need for accurate and current information along the entire food chain, and the desire to continuously improve in order to meet the core Codex objectives of protecting the health of consumers, and ensuring fair practices in the food trade.

### Objectives

6. This paper is developed from the perspective of the competent authority to:
- a. support a common understanding of the role that third party certification schemes may play in achieving compliance with regulatory requirements;
  - b. discuss how elements of third party certification schemes can be used to inform risk-based planning and allocation of official inspection resources;
  - c. promote a consistent approach to the use of third party certification schemes by competent authorities;
  - d. outline a range of public policy considerations; and
  - e. inform the development of international guidance on the use of third party certification schemes to strengthen National Food Control Systems.

### Scope

7. This paper considers voluntary<sup>2</sup> third party certification schemes as they relate to food safety and which include accreditation of certification bodies by an independent third party.

8. This paper excludes:
- a. official inspection systems and official certification systems administered by a government agency having jurisdiction to perform a regulatory or enforcement function or both<sup>3</sup>;
  - b. officially recognised schemes that certify to a regulatory standard and for which membership is mandatory;
  - c. certification associated with non-food safety standards (e.g. standards that establish requirements on labelling, quality, environment and trade);
  - d. private standards that are set under a buyer/seller contractual arrangement; and
  - e. certification that does not involve food safety audits by a third party accreditation body (e.g. audits carried out by the business, clients or customers, so called 1<sup>st</sup> and 2<sup>nd</sup> party).

### Third Party Food Safety Certification Schemes- Overview

9. Third party certification<sup>4</sup> schemes are formal documented systems developed and administered by industry to assure compliance with specified standards. Typical characteristics of a scheme include:

- a. voluntary membership;
- b. a governance structure that controls the scheme, accreditation<sup>5</sup> arrangements and agreed processes for dealing with non-conformity with scheme standards;
- c. technical experts that provide advice on standard setting; and
- d. independent verification that a scheme member is complying with the standard, sometimes referred to as accreditation by a third party which leads to certification status.

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<sup>1</sup> CAC/GL 82-2013, Para 36 i) & iii, Para 50, Para 56)

<sup>2</sup> Membership of the scheme is a business decision and is not a pre-requisite to trade

<sup>3</sup> *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995)

<sup>4</sup> Depending on the scheme, a physical certificate issued by the scheme is unlikely to accompany consignments.

<sup>5</sup> Accreditation is a system to formally recognise the competence of a person, or organisation, to carry out specific functions/tasks. It refers to the competence to audit a premises against the scheme standard.

10. There has been a proliferation of third party certification schemes used by industries in relation to food safety. These schemes have varying requirements and accreditation criteria reflecting a broad spectrum of business objectives, ranging from simple preventive control plans to complex food safety management systems based on international standards such as Codex and the International Organization for Standardization (ISO).

11. Third party certification schemes may be viewed by industry as an opportunity to maximize cost-effectiveness and resource-efficiency and to demonstrate to clients a product of consistent safety and quality. Some third party certification schemes are recognized by the Global Food Safety Initiative (GFSI), a non-governmental organization that establishes bench-marking criteria for food safety standards. The GFSI has emerged in response to concerns that many suppliers were facing requirements for multiple audits and certifications. Commonly accepted benchmarks enable suppliers to move towards a "once certified, accepted everywhere" situation, thereby reducing cost, facilitating trade and contributing to harmonization of standards<sup>6</sup>. Third party certification schemes also offer individual companies the opportunity to collaborate on technical matters.

12. Although Codex addresses both Hazard Analysis Critical Control Points (HACCP) and good practices through its *General Principles of Food Hygiene*<sup>7</sup>, an international food safety certification program does not exist.<sup>8</sup> Whilst there are Codex guidelines for the design and production of certificates describing arrangements for competent authority oversight of any third party issuing certificates on its behalf, there is no guidance on the criteria regulators could use to have confidence in third party certification schemes, or on the potential role that suitable schemes could play with regard to NFCSs.

### Opportunities

13. The traditional view of third party certification schemes is that they serve to enhance food safety and meet clients' demands, exclusively for the benefit of the business community. As part of regulatory modernisation programmes, some competent authorities have challenged this view and have begun to look more closely at ways to harness the opportunities such schemes offer to complement Official Controls and strengthen NFCSs. The approach, where used, relies on schemes which may have some or all of the following characteristics:

- a. robust governance systems;
- b. standards which align with, or incorporate, core elements of regulatory requirements; and/or
- c. competent authority oversight of the independent verification process.

14. The rapidly evolving landscape in the global food environment highlights the need for governments and industry to work together more closely to coordinate activities and work more collaboratively towards food safety as a common goal. Such an approach has the potential to enable the competent authorities and industry to improve food safety outcomes, while allowing each side to operate within its defined roles and responsibilities. Public/private collaboration not only has the potential to monitor and improve compliance levels, but to also drive innovation in food safety management systems and allow regulatory resources to focus more effectively on areas of highest risk<sup>9</sup>.

15. While the potential of public/private collaboration is already being explored and implemented in some countries, it is worth noting that a prominent feature is that competent authorities have retained regulatory authority to verify compliance with mandatory requirements while businesses remain responsible for determining if and which third party certification scheme meets their business needs.

### Considerations

16. The integrity of a third party certification scheme is largely determined by the governance of the scheme, the standard setting process, and robustness of third party audit arrangements. From a NFCS perspective, the standard must ideally replicate, or incorporate, the core mandatory requirements of the country. Other areas for consideration include:

- a. auditor competencies;
- b. approaches to auditing;

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<sup>6</sup> Use of Private Certification to Inform Regulatory Risk-Based Oversight: Discussion Document, Canadian Food Inspection Agency, May 2014

<sup>7</sup> CAC/RCP 1-1969, rev 2003

<sup>8</sup> Food Safety Certification, Food and Nutrition Division, Food Agriculture Organization (FAO) of the United Nations, 2006

<sup>9</sup> Pathway to Partnership? Private Food Standards in Canada, Center for Food in Canada, Conference Board of Canada, January 2013

- c. audit quality and consistency;
- d. the ability to share audit information with the competent authority;
- e. processes for dealing with non-conformity with scheme standards; and
- f. trade implications.

17. In developing a strategy to establish and maintain credibility and confidence in the certification body, competent authorities should consider, as one of several criteria, whether the accrediting body is subject to relevant ISO standards or national equivalent for conformity assessment (e.g. membership to the International Accreditation Forum).

### **Concerns and Challenges**

18. A reservation to third party certification schemes by many producers and some Governments, particularly those from developing countries, is that smaller companies lack the funds and resources to participate in such schemes and that scheme standards may not be entirely science-based and so viewed as being more trade restrictive than is necessary to protect human, animal and plant health. There are also concerns that larger companies may monopolise the standard setting process to effectively exclude smaller companies from accessing new markets and customers. In addition scheme members may have much quicker access to food safety information and support, which again puts smaller companies / producers at a commercial disadvantage.

19. Enhanced collaboration between governments and international organizations would enable a better understanding of the impacts and benefits of third party certification schemes for developing countries<sup>10</sup>, with a focus on the opportunities that may exist to strengthen NFCSs and otherwise leverage benefits from private certification schemes.

20. The impact of third party certification schemes on developing countries is also an area that merits careful consideration by governments and industry. The impacts of third party certification scheme standards on food exports from developing countries are uncertain and, for many small companies, implementation of certification standards may represent a significant departure from their traditional production practices. Membership of third party certification schemes can impose additional costs and burdens on small companies, notably through commercial audit requirements. As such, care must be taken to minimize the potential for trade barriers, particularly for small companies and developing countries trying to enter more industrialized markets by ensuring that scheme membership does not become a prerequisite to trade.

21. The subject of third party certification standards has been discussed extensively within the World Trade Organization (WTO), specifically in the Committee on Sanitary and Phytosanitary Measures, with a focus on the degree to which such standards are consistent with and subject to the disciplines of the WTO SPS Agreement. While some governments are seeking to leverage third party certification schemes as an effective and efficient way to pursue public food safety objectives, consideration should be given to uphold the boundary between voluntary buyer-seller industry standards and public mandatory requirements<sup>11</sup>.

### **Risk Management Approaches in Regulatory Modernisation Programmes**

22. Where third party certification schemes are aligned to regulatory standards and the competent authority has confidence in the integrity of both the scheme and audit process, there is the potential to recognise the scheme in the context of the NFCS, particularly those elements of a scheme designed to quantify risk and verify compliance with food safety requirements. A certain degree of alignment has been observed between approaches to date by competent authorities in the Netherlands, Canada, and the UK<sup>12</sup> to collaborate with third party certification schemes to further food safety objectives. In these cases, governments have developed policies on certification standards which influence the risk characterization at the establishment level and the subsequent frequency of official intervention by the regulatory authority, allowing regulatory resources to be better targeted at areas of higher risk. While governments benefit from better targeting of resources and increased access to food safety information, industry also benefits from reduced inspections/audits and more effective intervention by the competent authority.

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<sup>10</sup> Private Food Safety Standards: Their Role in Food Safety Regulation and Their Impact, Food and Nutrition Division, Food Agriculture Organization (FAO) of the United Nations, 2010

<sup>11</sup> The Impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Process, ALINORM 09/32/9D-Part II, Codex Alimentarius Commission, May 2009

<sup>12</sup> <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/mou-red-tractor.pdf>

23. In the UK, early research shows that there is an association between scheme membership and increased levels of compliance<sup>13</sup>. Consumer research indicated that consumers appreciated the value that such collaboration could bring to improving consumer safety outcomes, providing that the competent authority retains oversight and remains in ultimate control of the system.

24. In the European Union (EU), member states have discretion to recognise the performance of third party certification schemes and 'Own Checks'<sup>14</sup> when considering how official controls are delivered. This discretion has led to variations across the EU in how third party certification schemes are considered and used in evaluating risk and determining regulatory approach as part of national control arrangements. An EU Heads of Agency Working Group has been established to exchange best practices and provide guidance on the role of assurance schemes to EU member states<sup>15</sup>. Current EU rules are also being modernised and a new EU Official Control Regulation will come into force in 2017. The principle of "own controls" and "earned recognition" is enshrined and includes:

- a. an appreciation that operators' systems of own controls need to be complemented by a dedicated system of official controls to ensure effective market surveillance along the agri-food chain;
- b. rules that national food control systems shall take into account the reliability and results of own controls performed by the operators when establishing the risk of non-compliance and thus the required frequency of official controls;
- c. inclusion of controls performed by third parties and under private quality assurance schemes;
- d. powers for authorities to instruct operators to increase the frequency of their own controls in cases of non-compliance; and
- e. allows for relevant facts and data obtained from an operators' own-control system to be considered for official certification purposes. The prerequisite for this is that own-check data is complemented and confirmed by results of official controls, and the certifying officer is satisfied that the general conditions for the issuing of official certification has been met.

25. In support of China's new food safety law that came into effect in October 2015, a number of public-private partnership commitments were made between the GFSI and the Chinese Food and Drug Administration with respect to information sharing, capacity building, and pioneering a new assessment approach that aims to strengthen China's NFCS. Specifically, the China HACCP scheme has been determined to be equivalent to the relevant technical requirements of the GFSI Guidance Document.<sup>16</sup>

26. Under the *Food Safety Modernization Act*, the government of the United States (U.S.) can use certifications from auditors that it has accredited in determining whether to admit certain imported food into the U.S. It may also use certifications from accredited auditors in determining whether an importer is eligible to participate in the Foreign Supplier Verification Program. Furthermore, the U.S. has expressed an interest in using accredited third party certification as an overlay to the work conducted by the competent authority in providing further food safety assurances that consumers seek<sup>17</sup>. While the use of U.S. Food and Drug Administration accredited auditors may simplify the importation of food, membership of qualifying schemes is not a prerequisite to trade with the U.S.

## Principles

27. In developing regulatory approaches to third party certification schemes in food safety, the following principles should be considered:

- a. Effective third party certification schemes offer an opportunity to strengthen NFCS by supporting the delivery of Official Controls to more effectively target regulatory resources.
- b. Competent authorities should retain responsibility for regulatory oversight, regardless of individual members of a third party certification scheme.
- c. Standards within a third party certification scheme should be consistent with core regulatory requirements applicable to the area under consideration and regulator approaches must be consistent with international rights and obligations.

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<sup>13</sup> <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/earnedrecog.pdf>

<sup>14</sup> Regulation (EC) 882/2004, Chapter 1 Article 3, 1 (c)

<sup>15</sup> Personal communication – To be published

<sup>16</sup> <http://www.mygfsi.com/news-resources/news/press-releases/438-gfsi-embarks-on-public-private-partnership-with-china-s-cnca-to-accelerate-food-safety-development.html>

<sup>17</sup> Use of Private Certification to Inform Regulatory Risk-Based Oversight: Discussion Document, Canadian Food Inspection Agency, May 2014

- d. Third party certification audits must be carried out by an independent accredited body, using competent auditors working to a specified standard.
- e. The third party scheme owner should always be in a position to demonstrate to the competent authority its governance arrangements, the certification process and status of an individual member.
- f. The third party certification scheme should have an effective and transparent process for dealing with non-compliance with scheme standards.
- g. The third party certification scheme should always have a process to alert the competent authority of significant public health risks.

### **Recommendations**

28. As a key driver of global food safety standards, Codex has a role in responding to the challenges and opportunities presented by the emerging use of third party certification schemes in some countries to strengthen official controls. The Committee is invited to support the new work proposal appended to this discussion paper and agree to the establishment of an electronic working group that would:

- develop draft Codex guidance and/or principles, for discussion at the 24<sup>th</sup> Session of the CCFICS, on the use of third party certification schemes as part of national food safety control systems.

29. The proposed work would take into account the need to promote a consistent approach to the assessment of third party certification schemes, including: scheme ownership; governance; data sharing; standards development; and audit arrangements where schemes are integrated into NFCS.

## PROJECT DOCUMENT

### NEW WORK TO DEVELOP GUIDANCE ON REGULATORY APPROACHES TO THIRD PARTY CERTIFICATION IN FOOD SAFETY

#### 1. Purpose

The purpose of the new work is to provide Codex members with guidance on the assessment and use of third party certification schemes by competent authorities. The objective is to promote a harmonised and robust approach in countries' consideration of third party certification schemes to strengthen their regulatory arrangements and delivery of official controls, in order to improve food safety outcomes for consumers.

#### 2. Scope

The guidance is intended to cover the use of voluntary<sup>18</sup> third party certification schemes as they relate to food safety within National Food Control Systems (NFCSs).

This paper excludes:

- Official inspection systems and official certification systems administered by a government agency having jurisdiction to perform a regulatory or enforcement function or both; and,
- Official recognised schemes that certify to a regulatory standard and for which membership is mandatory.

#### 3. Its relevance and timeliness

Competent authorities are starting to consider how to make use of information derived from third party certification schemes to inform their regulatory activities. This emerging trend is set to continue as a feature of regulatory modernisation activities around the world as countries seek to strengthen their NFCSs. While current Codex guidelines include references to the use of third party certification schemes there is no guidance that would assist a competent authority in assessing the robustness of a scheme, e.g. whether it meets criteria that would allow elements of the scheme to be leveraged for regulatory purposes. Codex is best placed to fill this gap given its status as the pre-eminent food standards setting body in the world, and the recognition afforded to its standards and guidelines by the World Trade Organisation.

#### 4. The main aspects to be covered

The guidance will cover the following aspects:

- Definitions
- Roles and responsibilities: competent authorities, businesses, and scheme owners
- The core characteristics of voluntary third party certification schemes
- Criteria used to assess the robustness of a scheme including e.g.:
  - Governance arrangements
  - Standard setting and alignment with national and international standards
  - Audit/inspection, information exchange and reporting<sup>19</sup>
  - Accreditation arrangements
  - Sanctions
- Regulatory approaches to integrate schemes into a country's NFCS, e.g. risk profiling and risk management decisions

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<sup>18</sup> Scheme membership is a business decision.

<sup>19</sup> As discussed in the Draft Codex *Principles and Guidelines for Monitoring Performance of National Food Control Systems*.

## 5. An assessment against the *Criteria for the establishment of work priorities*

### **General Criterion**

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work responds to an emerging trend in some countries where efforts to improve regulatory activities include taking account of third party certification schemes in the planning and delivery of official controls to assure compliance with food laws, and improve food safety outcomes for consumers. Initiatives that aim to strengthen a country's NFCS are designed to enhance food safety outcomes for consumers and provide a trusted platform for the sale of food on national and international markets.

For developing countries, third party certification schemes may offer opportunities to help strengthen a country's NFCS.

Furthermore, public private partnerships may facilitate fair trade practices between countries with different regulatory systems through benchmarking common to many third party certification schemes.

Hence, robust third party certification schemes are a source of information and data that can be used by competent authorities to monitor aspects of their NFCSs in line with the Draft Codex Principles and Guidelines for Monitoring Performance of National Food Control Systems.

### **Criteria applicable to general subjects**

Diversification of national legislation and apparent resultant or potential impediments to international trade:

Some governments (e.g. The Netherlands, Canada) have developed policies on the use of third party certification schemes, which can influence the risk characterization at the establishment level and the subsequent frequency of official intervention by the regulatory authority, allowing regulatory resources to better target areas of higher risk. Development of Codex guidance will provide a framework for a harmonised approach on how competent authorities can take into consideration voluntary third party certification schemes to strengthen their NFCSs

Scope of work and establishment of priorities between the various sections of the work

Refer to scope above.

Work already undertaken by other international organizations in this field:

The project will take into consideration work undertaken by:

- The International Organization for Standardization (ISO), which has developed standards that support the integrity of third party certification schemes. An effective third party accredited certification program should contain the following elements:
  - International Accreditation Forum (IAF) oversight (ISO/IEC 17011)
  - Accreditation Body subject to ISO standards (ISO/IEC 17021 and 17065, and ISO/TS 22003)
  - Certification Body subject to ISO standards (ISO/TS 22003)
- The Global Food Safety Initiative (GFSI), a non-governmental organization that establishes bench-marking criteria for food safety standards.<sup>20</sup>

Amenability of the subject of the proposal to standardization

There are many similarities in approaches in those countries that have started to take account of third party certification schemes in their NFCSs suggesting that development of Codex guidance would be timely.

Consideration of the global magnitude of the problem or issue

As competent authorities seek to modernize their regulatory regimes, some have begun to look more closely at ways to harness the opportunities that third party certification schemes offer to complement, support and improve their regulatory oversight. These countries include: The Netherlands, Canada, China, Belgium, and the United Kingdom. There is a growing interest by other countries to leverage these opportunities. Guidance is necessary to promote a harmonized approach, assist those countries considering it, and to avoid future barriers to trade.

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<sup>20</sup> Global Food Safety Initiative website: <http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html>

## 6. Relevance to the Codex strategic objectives and goals

The proposed new work is consistent with Codex's Strategic Vision Statement:

- *To be the preeminent international food standards-setting body to protect the health of consumers and ensure fair practices in the food trade*

The development of the guidelines also supports particular objectives and activities contained in the **Codex Strategic Plan 2014–2019**<sup>21</sup>, in particular:

Objective 1.2, Activity 1.2.2

- *Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade. Proactively identify emerging issues and Member needs and, where appropriate, develop relevant food standards.*

Objective 1.3, Activity 1.3.2

- *Promote cooperation with other international governmental and non-governmental standard setting organizations to support development of relevant Codex standards and to enhance awareness, understanding and use of Codex standards.*

## 7. Information on the relationship between the proposal and other existing Codex documents

The work will take into consideration existing Codex texts, such as the: *Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)* and the *Guidelines for Design, Production, Issuance And Use Of Generic Official Certificates (CAC/GL 38-2001)*; *Guidelines for Design, Production, Issuance and use of Generic Official Certificates, CAC/GL 38-2001*; *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)*; *General Principles of Food Hygiene (CAC/RCP 1-1969)*; *the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013)* and, any other applicable guidelines. **8. Identification of any requirement for any availability of expert scientific advice**

Nil

## 9. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Technical input is expected from the International Organization for Standardization, the Global Food Safety Initiative and the International Accreditation Forum.

## 10. The proposed time line for completion of the new work

Step	Date
CCFICS23 – recommendation for undertaking new work	May 2017
CAC40 – approval of new work	July 2017
CCFICS24 - Consideration at Step 3	2018
CAC41 – adoption at Step 5	2019
CCFICS25 - Consideration at Step 6	2020
CAC42 - Adoption at Step 8	2021

<sup>21</sup> [http://ftp.fao.org/codex/Publications/StrategicFrame/Strategic\\_plan\\_2014\\_2019\\_EN.pdf](http://ftp.fao.org/codex/Publications/StrategicFrame/Strategic_plan_2014_2019_EN.pdf)