

From Chaos to Separation – An Update of the Hungarian Food Safety Regulation System

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In 2006 the Hungarian system of food safety regulation was described as “chaotic”¹, fragmented and lacking accountability.² Now, five years later and almost seven years after Hungary’s accession to the European Union (EU) it is time to take stock again. Food safety regulation has undergone a “threefold change” and follows a separated model. Competences for risk assessment, risk management and risk communication are well distributed and the Hungarian Food Safety Office (HFSO)/Magyar Élelmiszer-biztonsági Hivatal (MÉBiH) fits into the overall structure now. But there are still problems concerning its legal position, weak status and especially insufficient independence.

This report shows the evolution of the Hungarian system and highlights the brand new developments and the current situation, challenges and organisation of the HFSO.³

I. The threefold change

The food safety regime in Hungary has a long tradition. Directives concerning hygienic standards and prevention of mass infections date back to the year 1878. Accordingly the first steps towards a food regulation system can be retraced to the Austrian-Hungarian Monarchy and the introduction of the “Codex Alimentarius Austriacus”.⁴

During communism both the food regulation and the state as a whole were run “in a paternalistic fashion”⁵ – hierarchical organisation and “command-and-control” became the catchwords of this period. Information about risks was concealed from the public and from civil society organisations. Decisions were taken behind closed doors. The system essentially involved very strict inspections of food production and treatment as well as the authorisation of imported goods.⁶ In contrast to other socialist countries Hungary’s “Gulasch-Communism”⁷ was more liberal and soon the small country became the major food supplier within the COMECON and beyond. Hungary adapted Western quality and production standards much earlier than its neighbours.⁸

1. Post-socialism

The democratic transition that started in 1989 became a big turning point in Hungary’s public administration. It also implicated the compilation from planned to market economy and the liberalisation of the Hungarian market. With the deepening of the European integration process the traditionally important role of food quality became more and more important through the incremental adaptation to EU standards. Legally the central Food Act (Law XC/1995) adapted Hungarian food safety regulation to the new economic situation, recent research advances and the conditions given by the Europe Agreement of 1993.⁹

Organisationally, the regulation of Hungarian food safety was shared among eleven government institutions, mainly working independently. Of these eleven, three key actors were the Ministry of Agriculture and Regional Development (MARD), the Ministry of Health (MH) and the Ministry of Economics (ME).

The first steps to harmonise Hungarian regulation with European standards were taken much earlier, but the goals became concrete in the accession phase. The Commission’s progress reports strictly controlled

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1 Gabriele Abels and Alexander Kobusch, “Regulation of food safety in the EU: Changing patterns of multilevel governance”, Paper presented at the Conference of the ECPR Standing Group on Regulatory Governance, June 17–19, 2010, University College, Dublin, p. 23.

2 See Zoltán Ferencz, Mariann Hajdu and Anna Vári, “Food Safety Regulation in Hungary”, in Ellen Vos and Frank Wendler (eds), *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Antwerpen, Oxford: Intersentia, 2006), pp. 383 *et seq.*, at p. 447.

3 Most of the results I’m going to present in this report are based on field studies. Between 26 April and 5 May 2010 I interviewed a number of experts in Budapest, Hungary.

4 Ferencz *et al.*, “Food Safety Regulation in Hungary”, *supra* note 2, at pp. 383–385.

5 *Ibid.*, at p. 434.

6 *Ibid.*, at pp. 383, 384; 415.

7 Jürgen Dieringer, *Das politische System der Republik Ungarn: Entstehung – Entwicklung – Europäisierung* (Opladen, Farmington Hills: Barbara Budrich Publishers, 2009), at p. 39 (translated).

8 See István Fehér and R. Fejös, “The main elements of food policy in Hungary – Hlavní prvky maďarské potravinové politiky”, *Agricultural Economics* (2006), pp. 461 *et seq.*, at p. 463.

9 See Heinrich Ferenc Glatz, “Lebensmittelrecht in Ungarn”, *Begegnungen. Schriftenreihe des Europa Institutes Budapest* (2000), pp. 211 *et seq.*, at p. 212.

Hungary's efforts to adopt the Union's *acquis* and the first ideas to create an agency. After some difficulties HFSSO became operational on 15 May 2003. The Office's foundation was closely linked to the EU accession process: Although there was no direct judicial regulation, the Hungarian government interpreted the plans for a European food safety agency and the order to name some kind of focal point as an invitation to establish a national counterpart for the European Food Safety Authority (EFSA).¹⁰

HFSSO was also envisioned as an institution for internal and external coordination activities in the fragmented and multi-actor system. Reacting to critics from the European Commission, an institute "which is baring in his name Food or even Food Safety"¹¹ meant an improvement in consumer transparency. Though the EU was not only the indirect initiator for reform processes in Hungary, it also influenced the establishment of HFSSO in a conducive way, as it instigated a PHARE twinning project. With the help of Germany as twinning partner Hungary wanted to restructure its system and implement European regulations effectively by establishing a food safety agency.¹²

Law LXXXII/2003 served as the legal basis and upgraded the central Food Act from 1995.

2. Reshuffle after the aflatoxin crisis

But with these manifold modifications the major reforms related to EU-accession had not been completed and at the same time there had been conflicts between MARD and MH. During the aflatoxin crisis this conflict hit its peak. The crisis had been scandalous, because on the one hand Hungarian red paprika powder internationally ranks among the most popular brands, and on the other hand it has an al-

most "iconic"¹³ status in Hungary. Through mixing cheaper imported paprika from Morocco to the quality product it was partially contaminated with aflatoxin. The scandal led to a strong decline in consumers' trust in food and the responsible institutions; it revealed a lack in accountability and transparency.¹⁴ The scandal had institutional repercussions – control over HFSSO was transferred from MARD to MH.

Judicially the foundation decree 66/2003 was amended by government decree 333/2004. By this modification HFSSO gained more authority regarding coordination and crisis management. Since then every inspection authority has to cooperate with the agency. Additionally the acting general director at that time was replaced by a health professional, the contemporary general director Dr. Mária Szeitzné Szabó.

3. Overview-"tangle-tangle"

Although HFSSO was founded in 2006 for the purpose of coordination, experts still observed a high level of fragmentation.¹⁵ Competences were not well allocated leading to unclear responsibilities in case of crises.

The avian flu in 2006/2007 once again revealed the authorities' deficient responsiveness: MH was heavily criticised in public. As a consequence the competences to control HFSSO were given back to MARD.

In general, this development is perceived in a very positive way: All the competences in the area of risk management now lie in the hands of one ministry. But this inter-institutional "tangle-tangle"¹⁶ also had negative implications. Hence there has been a great fluctuation within HFSSO's operational structure and, besides, personnel and financial cuts. In addition, the incidents during the avian flu crisis showed that the agency's coordination functions had not been sufficient to implement the comprehensive approach of food safety regulation required by the EU – leading to further restructuring processes: all relevant legal acts are now subsumed under Law XLVI/2008.¹⁷ Furthermore *one* major authority, the Central Agricultural Office (CAO), under the aegis of MARD is responsible for inspections of the whole food chain "from farm to table".

In 2006/07 Hungary underwent an extensive – crisis-induced – change of its administrative structure. In this period a significant increase in govern-

10 Peter Akos Biacs, Interview, 2010.

11 *Ibid.*

12 See Arpad Somogyi and Miklós Süth, "European Union Twinning Project: Food Safety Office" (Final Report, HU 2002/IB/AG/05, 2005).

13 Gyula Kasza, Interview, 2010.

14 Ferencz *et al.*, "Food Safety Regulation in Hungary", *supra* note 2, at p. 423.

15 *Ibid.*, at p. 417.

16 Peter Akos Biacs, Interview, *supra* note 10.

17 HFSSO, "Outline from the draft version of the FVO Country Profile" (Budapest, 2010).

mental activities took place, linked to the attempts of the second Gyurcsány cabinet to regain the control lost during the financial crisis.¹⁸ The reform was embedded in far-reaching administrative developments causing tremendous changes within many governmental agencies.

In sum, the intensity primarily of the last reform processes was high, as this change brought a shift in the balance of power and also a change in paradigms towards an integrative regulation approach. Moreover, the reform represents the end of the fragmented system.

II. The bi-institutional separated model¹⁹

Recently the Hungarian institutional food safety structure underwent enormous changes. Since 2007 a bi-institutional separated model with clearly distributed competences displaced a system of chaos and fragmentation. The contemporary regulatory structure is consolidated now.²⁰ Before the major reforms took place the subject areas of food safety – but not the steps of risk analysis – were sharply divided from each other.²¹ Today risk assessment and management are separated institutionally; now competences are distributed more clearly and HFSO can focus on its duties more accurately. By allocating the several steps of risk analysis, Hungarian food safety regulation is functionally and inter-institutionally separated at present (see Figure 1). Among the 2004 accession countries Hungary is considered a “good example”²² because of the completed consolidation of a modern system with a food safety agency.

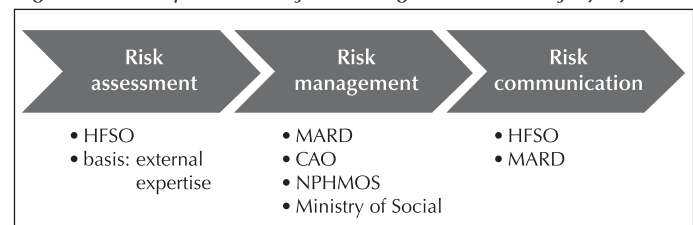
The assessment of risks is first and foremost the duty of HFSO. Representatives of HFSO emphasise that the agency is not allowed to give concrete advice, but only to evaluate risks as a basis for management decisions.²³ The Office also serves as a “clearing house”²⁴. It gathers information, processes and transmits it to the respective control point. Due to the fact that HFSO does not have intra-mural laboratories, a number of institutes like the National Institute for Food and Nutrition Science (OÉTI) and the Central Food Research Institute (KÉKI) supply the research needed.

Risk management can be divided into two phases – decision making/legislation and control/inspection. Sources of law consist, on the one hand, of acts of parliament and on the other hand of governmental or ministerial decrees. Especially the Department of

Food Chain Control in the Ministry of Agriculture is in charge of preparing the relevant legal texts. 95 % of all food chain control belongs to MARD, mainly its control institution, CAO. Regional administrative bodies, so called County Agricultural Offices in the 19 counties (komitate) are responsible for implementing food law.²⁵

The risk communication tasks are covered mostly and officially by HFSO. It informs the public through information material, its own homepage, a food journal and e-mail-newsletters, but also communicates with experts, national and international partners. In a situation of crisis the public relations department of MARD is solely responsible for matters of risk communication.

Figure 1: Principle Actors of the Hungarian Food Safety System



(Source: Compiled by the author (highly simplified); NPHMOS = National Public Health and Medical Officer's Service)

III. Fit-in HFSO

How does the Hungarian food safety agency “fit[...] into the overall structure of governing”²⁶?

18 See György Hajnal, “Patterns of administrative policy pre- and post-NPM: An analysis of the institutional dynamics of Hungarian central government agencies”, Paper presented at the ECPR Standing Group on Regulatory Governance, June 17–19, 2010, University College, Dublin, p. 16.

19 Names of institutions are based on the time before the elections in 2010.

20 See BfR, “EU-Almanach Lebensmittelsicherheit”, 2009, p. 83, available on the Internet at <http://www.bfr.bund.de/cm/238/eu_almanach_lebensmittelsicherheit.pdf> (last accessed on 27 October 2011).

21 Ferencz *et al.*, “Food Safety Regulation in Hungary”, *supra* note 2, at p. 447.

22 Peter Akos Biacs, Interview, *supra* note 10.

23 Anonymous, Interview, 2010.

24 Mária Szeitzné Szabó, Interview, 2010.

25 Gyula Kasza, Interview, *supra* note 13; HFSO 2010, p. 1.

26 Lise Hellebø Rykkja, “Independent Food Agencies – Restoring Confidence”, Policy and Society (2004), pp. 125 *et seq.*, at p. 129.

1. Allocation of rights and duties

Today Hungary's food safety regulation system is much more transparent than it used to be. HFSO faced difficulties in fulfilling its co-ordinating role, as it could not create an accountable and efficient structure. It took about four years until the Office found its place in the system. Now competences are well-allocated and separated (in the way mentioned above). Whereas MARD and its control institution are in charge of most of the management tasks, HFSO does not have any regulatory competences. It was primarily founded to coordinate the fragmented system and to be a partner of European and international actors. Since CAO entered into force, HFSO reduced its coordination activities and its focus on risk assessment and communication is prominent today.

However, the agency is not only an EFSA focal point, but it also functions as a RASFF contact point,²⁷ it is indirectly involved in management tasks.

2. Legal status as a "non-authority"

Although HFSO is officially and legally an "independent legal entity"²⁸, it calls itself a "non-authority"²⁹ in order to distinguish itself from institutions, which have their own control or sanctioning power. Subordination to HFSO's controlling body limits its autonomy.

After the joint supervision in the beginning and the ministerial "tangle-tangle" later, the responsibility to oversee the agency lays in the hands of MARD. But what degree of control does it have? The Hun-

garian administrative system classifies three types of control: a very strict form of control (command – service); indirect control, on this basis work complexes are delegated to agencies or other institutions (tasks – service); and finally professional control. This means that the controlling body could only give general directions that leave much room for discretion.³⁰

Accordingly HFSO is under the direct professional control of MARD. As a "legal controlling system"³¹ it can only act on the legal aspects of the agency's work. Beyond that the ministry appoints HFSO's general director and sends delegates to its Scientific Advisory Body. Regarding personnel and financial issues some rights exist vis-à-vis the Office. Furthermore HFSO is obligated to deliver annual reports.

All in all it seems that despite its independent position HFSO is subordinate to MARD's intensive control. The next paragraphs show how this control influences the agency's independence.

3. Small resources

As a "central budgetary entity"³² HFSO receives a ring-fenced amount of money from the ministry. A central governmental authority conducts the strict budget control. This partial financial independence is, however, limited by the fact that about 90 % of the guaranteed sum is designated for salaries, rent for the building and fees for international organisations. Only 10 % remain to be allocated autonomously. Moreover HFSO's budget has declined continuously over the last years. After the 2007 reform it was cut from 204 to 148 million forints (about 520.000 €).³³

There have also been personnel cut-backs from 25 staff members in 2004 to only 18 today. But as most of the experts underline, the employees' high motivation compensates this lack of staff. The employment relationships mirror HFSO's weak legal status: Contrary to the civil servants in the ministries all of the agency's members of staff are public employees, leading to lower payment, lower legal status and less access to information. Simultaneously, they do not have the same duties as civil servants and are free in their statements.³⁴

Altogether HFSO is not a strong player within the Hungarian regulatory system. Given its subordination under MARD and its serious lack of resources HFSO's possibilities always depend on the cooperation with others.

27 The Rapid Alert System for Food and Feed (RASFF) is an information system of the European Commission, which spreads important news on food safety to all the affected institutions to permit a coordinated reaction in case of crisis immediately.

28 HFSO, "Executive Summary of the activities of Hungarian Food Safety Office in 2007" (2007), p. 2, available on the Internet at <http://www.mebih.gov.hu/attachments/289_HFSO_Summary_EN.pdf> (last accessed on 27 October 2011).

29 Anonymous, Interview, *supra* note 23.

30 Gyula Kasza, Interview, *supra* note 13.

31 *Ibid.*

32 HFSO, "Executive Summary of the activities of Hungarian Food Safety Office in 2009" (Budapest, 2009), p. 3.

33 HFSO, "Executive Summary" (2007), *supra* note 28, p. 2.

34 See Anna Vári, Interview, 2010.

IV. HFSO's internal organisation

1. Primary aim: Being a "clearing house"³⁵

Although HFSO is certainly considered to be among the small European food safety agencies, it fulfils almost the same tasks as its equivalents in other states. HFSO describes its central duty as follows: "The mission of the Hungarian Food Safety Office is to maintain national and international relations. Coordination, communication and risk assessment are the primary tasks for the Office."³⁶ Thus the agency's goal is to strengthen consumer trust in food through international expertise and national institutes' knowledge. Public health should be protected against food-borne risks and food safety crises should be reduced, not only to save Hungary's reputation, but also to change the public awareness. In order to achieve this ambitious goal HFSO tries to inform the Hungarian government, all of the affected authorities, producers and the public comprehensively. Therefore the agency acts as a "clearing house", as information channels – national, European and international – are interlinked.

Contrary to the big food safety agencies in France or Germany HFSO's focus is on food (and feed – but only in terms of food safety). Veterinarian, nutritional or chemical questions are excluded.

2. Classification of HFSO's central missions

Three cornerstones frame HFSO's work: risk assessment, risk communication and (especially before 2007) coordination. First and foremost it has to provide risk-based scientific opinions and advice in the fields of food and feed safety, which serve as the basis for management decisions and guide the control activities of the authorities concerned. HFSO does not conduct intra-mural research, thus it has to rely on external scientific knowledge.

Other primary tasks involve diverse communication activities: HFSO informs not only experts (by a weekly newsletter, professional publications, seminars and conferences), but also the general public (by its website, leaflets etc.).

As a leftover from the old structure HFSO administers the internal communication among the Hungarian food safety system. Today not all of the information is channelled through HFSO, but it is still in charge of presenting the country report to the European Commission.

In addition HFSO acts as contact point for international organisations and represents Hungary in several committees.

As a "non-authority" public enquiries officially do not belong to the agency's tasks. Notwithstanding, HFSO receives many such requests and it sometimes responds to them. But in most cases it transmits them to the authorities in charge.³⁷

In contrast to the British food safety agency the Hungarian office is only involved in risk assessment and communication and therefore has no regulatory powers.

Table 1 classifies the organisation's central missions on the basis of a system used by Lise Hellebø Rykkja.³⁸

Table 1: Classification of HFSO's Central Missions

| | regulatory competence | assessment/advice | communication | expertise | public enquiry | representation |
|------|-----------------------|-------------------|---------------|-----------|----------------|----------------|
| HFSO | | X | X | | (X) | X |

(Source: Compiled by the author on the basis of Hellebø Rykkja 2004: 140)

3. Internal structure à la EFSA

HFSO's activities are organisationally separated – the departments for risk assessment, for laboratories and project coordination, for administrative coordination, for internal administration and public relations (and before 2007 also a department for the coordination of risk management).³⁹ Because of the personnel situation of the Office this segmentation is neither strict nor definite.

The operational leadership (including financial and personnel questions) is taken over by the general director (for an overview see Figure 2), supported by a secretariat and deputy. MARD nominated her for a four-year term. 2009 the appointment of the con-

35 Mária Szeitzné Szabó, Interview, *supra* note 24.

36 HFSO, "Executive Summary" (2009), *supra* note 32, p. 2.

37 Anonymous, Interview, *supra* note 23.

38 Hellebø Rykkja, "Independent Food Agencies", *supra* note 26, at p. 140.

39 HFSO 2010, "Outline from the draft version of the FVO Country Profile", *supra* note 17, p. 8.

temporary general director, Dr. Mária Szeitzné Szabó, was renewed.

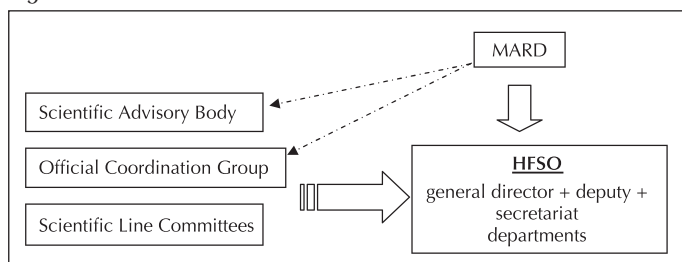
Compared to other food safety agencies – for example EFSA or the *German Bundesinstitut für Risikobewertung* – there is no additional management board.

A Scientific Advisory Body supports the agency. Although HFSO has the right to give opinions on its own, the Advisory Board can define guidelines and suggest topics. The committee consists of 17 members most of them delegated by several ministries.⁴⁰ There are also six seats assigned to stakeholders: the Hungarian consumer assembly, representatives of the industry and other experts.

Due to the small number of staff, external experts in nine Scientific Line Committees foster the Office's work. With these committees EFSA's panel structure is copied.⁴¹ On behalf of the general director the panels work on specific issues requiring specialised scientific knowledge.

Another institution within HFSO is the Official Coordination Group – composed of ministry representatives. In cases of emergency (lastly the melamine scandal), where a coordinated action is necessary, it takes over tasks of the national crisis strategy.

Figure 2: Internal Structure HFSO



(Source: Compiled by the author on the basis of the statements of HFSO experts)

40 Four persons are delegated by MARD; MH, ME and the Ministry of Social respectively are delegating two persons and one person is delegated by the Ministry of Environment; see Mária Szeitzné Szabó, Interview, *supra* note 24.

41 The panels are also named Scientific Standing Committees. They cover the following topics: Microbiological/chemical food safety; GMO; animal health; feed safety; plant health/residues; novel food; nutrition; drinking water safety.

42 Mária Szeitzné Szabó, Interview, *supra* note 24.

43 Anonymous, Interview, *supra* note 23.

44 Ferencz *et al.*, "Food Safety Regulation in Hungary", *supra* note 2, at p. 409.

45 See Mária Szeitzné Szabó, Interview, *supra* note 24.

46 *Ibid.*

V. Conformance with the principles of good governance

EFSA was not only the model for HFSO's internal structure, but also inspired its operational principles: excellence, openness and integrity. Furthermore independence plays a significant role in the Office's work.⁴² Other relevant key words are credibility and reliability.⁴³ But does it meet its standards and conform to the principles of good governance?

1. Transparency and openness

Transparent and open procedures are closely linked to the agency's risk communication tasks. By spreading up-to-date information through diverse channels it meets the requirements. In contrast to the lack of medial presence identified by Ferencz *et al.*⁴⁴, in 2009 HFSO appeared 2.700 times in the media.

Yet, the fact that most of the provided information is only available in Hungarian restricts transparency and openness. This focus on a Hungarian audience is surely due to the Office's lack of resources.

2. Marginal possibilities of stakeholder participation

Openness also implies the possibility to include stakeholders. There is only one legally binding form of stakeholder participation – HFSO's Scientific Advisory Body, which includes six representatives of NGO's and the industry. But MARD defines who is chosen for this committee.

Compared to eleven seats for government delegates the number of stakeholders within the board is relatively small. HFSO also seeks to include stakeholders via regular open-access conferences and seminars.⁴⁵

Since civil society organisations are underrepresented within HFSO's Scientific Advisory Body and participation is not provided on institutionalised grounds, the possibilities to include stakeholders are generally marginal.

3. Independence?

To evaluate if an agency constitutes an independent voice, one has to take into account many different factors: As "independent legal body"⁴⁶ HFSO has its

own budget and the main control over personnel and financial questions. The ministerial control is only professional. This and the procedures to nominate and denominate the institute's general director constitute its independent status.

Although its opinions are not binding in character and only consultative for governmental institutions, this fact does not touch the agency's independence in general. Furthermore, HFSO is not subject to extensive external lobbying, as it is not in the position to decide on sanctions and other risk management tasks.

In contrast to other European food safety institutes HFSO's independence is weakened by the absence of a management board and by an Advisory Board dominated by government representatives and experts, whose independence from economic or other interests remains still unclear. Because HFSO lacks laboratory capacities it relies on external expertise. Moreover the lack of resources and the fact that MARD decides on the budget limits the agencies possibilities to act. "All this underlined the Office's lack of political independence."⁴⁷

According to Fabrizio Gilardi's⁴⁸ index of formal independence the value of 0.3234 confirms these weaknesses.

VI. Quo Vadis HFSO?

Compared with other European countries the reshuffle of the food safety system and the establishment of a new agency in Hungary were not influenced by the BSE crisis, since "BSE didn't really shake Hungary"⁴⁹. By creating HFSO a central point for risk assessment and coordination in a fragmented system was set up. And in conjunction with Hungary's EU accession a partner for EFSA was built. After the national scandal in 2004 and the crisis-induced broad reform processes in 2006/07 the system changed fundamentally – from fragmentation and chaos to a bi-institutional and clearly separated structure. After the last change HFSO's coordination role is marginal, but its focus is much clearer now.

47 Ferencz *et al.*, "Food Safety Regulation in Hungary", *supra* note 2, at p. 386.

48 Fabrizio Gilardi, *Delegation in the regulatory state: Independent regulatory agencies in Western Europe* (Cheltenham: Edward Elgar, 2008), at p. 140.

49 Anna Vári, Interview, *supra* note 34.

Taking into account its small size and the lack of resources HFSO cannot be compared with other national institutes (e.g., France or Germany). But despite being a small institution, which neither counts as a powerful player within the Hungarian system nor fulfils the principles of good governance perfectly, it takes over almost the same tasks as its huger equivalents; it cooperates smoothly with the EU and its sister organisations. So the foundation of HFSO can be seen as an important improvement in a post-communist state.

Its future is uncertain, especially after the 2010 elections. The current government under premier Viktor Orbán and its conservative party Fidesz pursues new priorities. And HFSO's role after its dismissal as chief coordinator is still unforeseeable. Whether the small Office can survive is still an open question.

Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis

*Meir Perez Pugatch**

This article examines the issue of risk in research and development (R&D) pertaining to new pharmaceuticals, especially those aimed at neglected diseases and/or relevant primarily to the developing world. In partic-

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