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**Facts on the Horizon:
Future German Ink and Mineral Oil
Ordinance. A National Approach and its
European Spill Over: Risk Management,
Compliance and Avoidance of Liability**

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Dr. Gregory T. Papanikos
President
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**Facts on the Horizon:
Future German Ink and Mineral Oil Ordinance.
A National Approach and its European Spill Over:
Risk Management, Compliance and Avoidance of Liability**

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Abstract

Almost 40 years ago, Igor Ansoff described the important role that detecting and analysing weak signals plays in strategic planning. Weak signals are those weird, ambiguous nutshells of information about the environment that are habitually hidden among the "noise" of the prevailing sense-making criterions that merge to form a pattern of intelligence. Solid board and corrugated board converters that print and process food packaging operate their businesses within a complex and strict set of regulations and guidelines, set in force by both government agencies and industry associations. These rules ensure that packaging does not negatively impact the products contained within. This paper aims to give an overview of the current status of the German Ink and Mineral Oil Ordinance still to come in relation to recent and future risk management according to the liability risk of the regulation's future content. The theoretical goal of this paper is to narrow the gap between existing knowledge about present product liability due to migration from the paper based packaging and give recommendations for action towards adjusted and suitable behaviour due to the national regulation still to come. The paper generates basic insights and aim to weigh the pros and cons of future regulation. The possible European spill over will be highlighted.

Key Words: Weak signals, Liability, Packaging, German Ink Ordinance, Boiling Frog Syndrome

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Introduction

Nowadays, food retailers and grocers offer consumers a wide-open choice. In this respect, the packaging is the principal means of communication, distinguishing the product from its competitors and provoking the decision to buy. The packaging therefore, serves as protection during transport and storage, prohibits spoilage and ensures hygiene. It is carrier for information for usage, serves as sales promotion and an advertising factor at the place of sale. More than 95% of all groceries packaging that are put on the market in Western Europe are packaged (Rappold et al., 2005).

For ecological and economical purposes, paper-based packaging-material is largely produced using recycled paper (Wenzel, 2012, p.42). Swiss studies have shown that cardboard boxes made from recycled material can contain significant portions of mineral oil (Biedermann et al., 2010, p.785). The mineral oils stem from printing ink which is commonly used in newspaper printing. Frequent intake of such contaminated foodstuffs can thus lead to excess in the toxicological limit values. Animal studies¹ have shown that mineral oil mixtures with low viscosity are stored in the body and can lead to accumulations and damage in the liver, heart valves and lymph nodes (Hellwig et al., 2010, p.18). Currently there are no studies on the effects of MOSH and MOAH on humans, but it cannot be ruled out that this fraction contains carcinogenic compounds.

The increase in the number of food-packaging migration alerts in recent times² has been highlighted by consumer protection organisation and the media and the German legislator has decided to act.

The remainder of the paper is structured as follows: Section 2 makes known all about paper-based packaging in brief details on the subject. Section 3 shows the complex mechanisms of migration and the pollution of substances undesirable in any type of food. Section 4 attempts to outline the dilemma between environmental sustainability subjected to circle economy and preventative measures for the health of the public. Section 5 points out the recent statutory framework conditions and the German national approach. Section 6 is a brief discussion of the situation. Section 7 provides recommendations and Section 8 conclusions.

Paper-based packaging

Paper-based packaging has many faces. According to Soroka (2010, p.3), packaging is best described as a coordinated system of preparing goods for transport, distribution, storage, retailing, and use. Packaging is an entity of components with the obligation to serve predictably and to cover a certain product. Packaging must ensure its ability to transport and store materials as

¹See BfR 008/2010; Doak et al., (1983); Lavoie et al., (1985); Rice et al. (1987), cited in Hellwig et al., (2010).

²See food safety scares: ITX (2006), Benzophenon (2009) and mineral oil traces (2010)

well as transmitting information. As far as packaging is concerned to food and feed it is primarily related at protecting the content by maintaining its properties.

For ecological and economical purposes, paper-based packaging material is largely produced using recycled fibres for paper and board manufacturing. The proportion of recovered paper was the most important fibrous material needed in the German papermaking industry in 2009 at 14,8 m tons or 73% of the entire cycle of fibres (*Kersten et al., 2011, p.14*). According to CEPI Key Statistics 2008, packaging papers utilize about 60.9% of the total volume of recovered paper, i.e. nearly two thirds of the total recovered paper consumption are used in packaging production.

Migration of Mosh and Moath

As to food, feed and human health safety, packaging paper and board in general has to meet specific, characteristic requirements, to be characterised as suitable for its direct contact with foods. Recycled paper and board may contain many potential contaminants, which may migrate from packaging materials into foodstuffs. Migrants are substances which are able to be transferred through a material layer. This is based on to their chemical, mobile characteristics and molecular size; they diffuse across the packaging material (*Muncke, 2009, p.4549*). Recent research by Biedermann and Grob (2010) has shown that cardboard boxes made from recycled material can contain unexpected, significant high portions of mineral oil. Mineral oils include a wide range of hydrocarbon substances and are generally divided into mineral oil saturated hydrocarbon (MOSH) and mineral oil aromatic hydrocarbon (MOAH). As a rule, mineral oil enters the recycling process via stem from printing ink (mineral oil-based) generally used to print newspapers.

The Scientific Committee on Food (SCF) of the European Food Safety Authority (EFSA) consider the entire range of molecular weight of less than 1000 Daltons (Da) to be toxicologically relevant because it can be absorbed through the human gastrointestinal tract. The hydrocarbons under cover duration for MOSH and MOAH fulfil this criterion. The statements or scientific opinions from official national or European authorities vary between “ ... identified potential concern...”, “ ... The MOAH fraction may be both mutagenic and carcinogenic...”, “...because of its potential carcinogenic risk, the CONTAM Panel considers the exposure to MOAH through food to be of potential concern...” (EFSA, 2013, p.6-7) and „... Today’s opinion does not identify any specific food safety concerns. “ (FSA, 2012, p.1). In summary, uncertainty remains.

Mineraloil is Ubiquitous, a Dilemma

This knowledge is an ecological and economic dilemma, because government institutions and the Environment Agency at European level are very much in favour of promoting the use of renewable waste paper. As well as exposure to MOSH and MOAH by recycled fibres there are other sources of contamination. According to Matissek and Rathers (2012, p.2) the origin of an environmental "body burden" of raw food materials with mineral oil hydrocarbon substances can be related to the exhaust from gasoline engines, emissions from electric utilities and industrial facilities as well as fine dirt of asphalted roads. Another source of particulate pollutant inputs are lubricants from machinery for soil tilling and harvesting, from filling and packaging systems for the beverages industry and the food and non-food industry (EFSA, 2013). In conclusion we have established uncertainty based on origin, detection, method of proof and consequently due to compliance, regulations or guidelines too. One is faced with a perfect catch 22 situation.

The Regulatory Framework

In the EU there is still no harmonized regulatory framework on food contact paper, board and corrugated board applications. Especially for applications and on the use of recycled paper fibres in contact with food and feed, there is no specific directive about paper and board coming into contact with foods. The main underlying rules for paper and board food contact applications come from the EU Regulation (EC) No 1935/2004 and the Regulation on Good Manufacturing Practice (EC) No 2023/2006. The Framework Regulation applies to all materials or articles which, "in their finished state:

- (1) are intended to be brought into contact with food;
- (2) or are already in contact with food and were intended for that purpose;
- (3) or can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use."

The essential safety requirement of the Framework Regulation is found in Article 3, which requires and demands that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice (GMP) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (1) endanger human health or

- (2)bring about an unacceptable change in the composition of the food
- (3)or bring about a deterioration in the organoleptic characteristics thereof.

The legislation known as REACH EC No. 1907/2006 came into force on 1st June 2007. The key objective of the legislation is to improve protection of human health and the environment. The reason why REACH was mentioned here is the fact that the lion's share of the entry of mineral oil in the recycling loop process is uniquely identified as inks from newspapers. It may be asserted, however, that, not least for this reason, changes will be made to legislation with general validity for consumer goods and not only for food packaging.

The Council Regulation (EEC) No 315/93 of 8th February 1993 laid down procedures for contaminants in food. The overall goal of consumer health protection is to minimise contaminants in food as far as possible. The EU Contaminants Regulation requires Member States, for example, to prevent circulation of food containing a contaminant in quantities which cannot be tolerated for health or in particular toxicological reasons.

The German Inks Ordinance is structured along similar lines to the Swiss Ordinance SR 817.023.21, with a list of substances allowed to be used in the manufacture of food packaging inks, and migration limits for substances migrating from the printed packaging. Another focus will be put on so-called NIAS, non-intentionally added substances, that any kind of cross-contamination with other raw materials, consumables and supplies products is avoided under all circumstances. The compliance with legal requirements passes on to an upstream member of the packaging chain to the packaging company, co-packer and marketer.

The notification process for EC legislation (law standards acceptable across the EU), a must when a national regulation has come in force, shall take place 2015-2017, and the 2 years represent the transitional period for largely completed sale of foodstuffs and commodities that do not comply with the German Ink Ordinance still to come.

For nearly 4 and a half years, both ordinances have been under construction and evaluated in the consultation phase of a law yet to come. Key issues of the 2nd law bill of the Mineral Oil Ordinance (information and consultation December 2013) are: (1) No migration of aromatic hydrocarbons with carbon numbers range from C₁₀ to C₂₅ into food and feed (2) Evidence of migration potential in use of recycling, secondary packaging (3) No evidence when migrations can be excluded (barrier principle) (4) New safeguards on margin of exposure (5) A general barrier requirement for recycled cardboard, exceptions only if an absolute barrier can be demonstrated (6) Conformity confirmation for recycling packaging, no measurement of the food required (and not taking into account other sources).

On 23. October 2013 the 4th draft of the Ink Ordinance appeared and key issues were: (1) Declaration of Conformity (2) Principle of positive and

negative list of substances to use (3) two years transmission period by a reduction in stock levels.

Critical Review

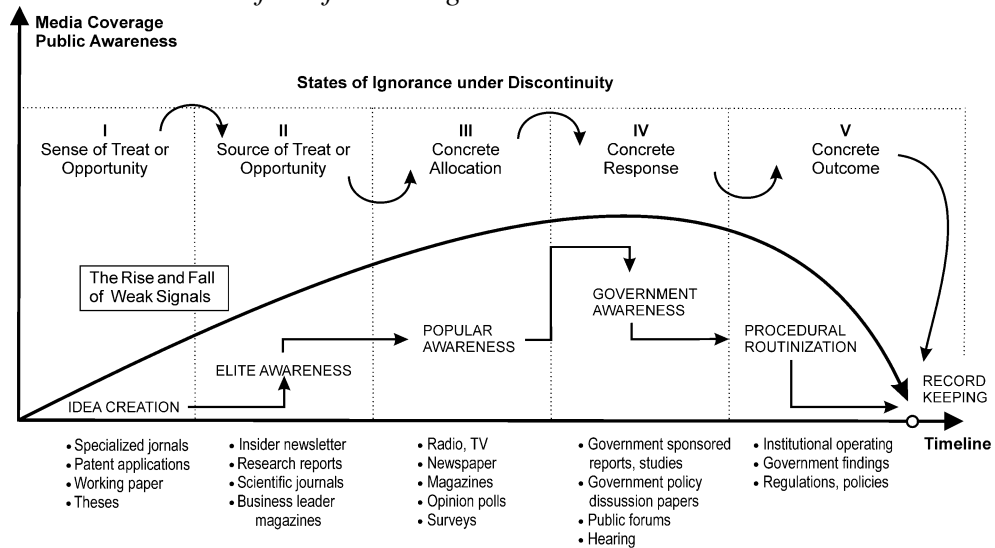
This is very strange in an internal market if a law bill creates compositions that assume a peculiar state of suspension. From early findings to fixed margins of exposure for public health protection both regulations have been sitting idle for nearly four years. This brings us to the question of whether the regulations will ever come into effect.

The Rise and fall of Weak Signals

This question shall be examined based on Ansoff (1975, p.24) "Theory of weak Signals" which classified the occurrence of the signals and the related strength into 5 levels, the so-called "states of ignorance under discontinuity". In view of the conditions of uncertainty concerning the proper functioning of the paper-based packaging supply chain, liability and limitation of liability of the marketer and supplier, the behaviour of supervisory authorities, the stakeholders attitude towards the facing of the situation may be described as an "wait-and-see" attitude (Kam, 2004, p.190) or a "paralysis by analysis" situation (Harremoës et al. 2001, p.181). "Political and economic fog of uncertainty"¹ makes it necessary to prepare and to arm a company and to reduce the response time to weak signals. Weak signals are based on the assumption that every event or disaster caused by man is at times to be foreseen and unsurprising. Under the auspices of discrete discontinuities in economic, political, technical and social affairs, they should take notice before they come into existence as a whole.

¹Leslie Smith (Chairman of the BOC Limited, London), personal communication (cited in Ansoff 1975, p.24)

Figure 1. The Rise and fall of Weak Signals



Source: authors' own graph as an extension of Hiltunen (2008, p.24) and Choo (n.d.)

Inside direct professional-to-professional discussions and among industry insiders, the so-called “Mount of Olives”¹ or in recent research “The Forest of Peaks” were well known. Sources of weak signals may have been specialized journals, patent applications, doctoral dissertations and early expert’s discussions. Elite awareness took place. Hearings at the BMEL(V) and BfR took place; first internal findings were published in December 2009. The scientific community has been informed by Biedermann and Grob in 2010. The characteristics, nature and the timing of impact are understood by the stakeholder, they recognise the existence, but a determined response is still ineffective or unworkable. These are solely perception of issue in the media and public. Political debate came into existence and statements of industrial associations are well known at this stage.

The weak signal expanded to its final state: A driving force which affects the whole of society. The weak signal is by now quantized and coded, the impact and consequences of response are computable by now. Hiltunen (2008, p.2) pointed out that at this stage government-sponsored reports, studies of government policy discussion papers, draft legislation and law bills are on the horizon.

In support of the above mentioned Ansoff’s “states of ignorance under discontinuity”, however it may be asserted, that both national German regulations will come into existence. The courses of events have already reached a concrete outcome. Ansoff predicted that a gap of some years is likely between the stakeholder first pick up of new, weak signals and crafting, executing and implementing of a new strategy.

¹A so-called chromatographic "hump", colloquial named “Mount of Olives”

A European Response or Spillover?

Since the first disputes in 2010, all stakeholders and involved parties would prefer a European-wide approach. In the light of these considerations, DG SANCO¹ concludes that, from a legal point of view, there is no reason to give priority towards the German national approach, and no need or interest for regulation (Matissek, 2014, p.11):

- (1)The very most fundamental, underlying law relating the safety of food contact materials in the European Union is the Regulation EC 1935/2004. The overall spirit of Article 3 is deliberate because it deals with the issue of the transfer of substances (migration) from food packaging materials into food. It also requires proof that the concentration of the substances in the food is at a level which will not pose a risk to the health of the consumer from the vantage point of the present knowledge.
- (2)The EC 2023/2006 on good manufacturing practice (GMP) sets out general demands for materials and articles intended to come into contact with food, and apply to all the categories of materials identified in Annex I of the Framework Regulation. It also applies to combinations of those materials and articles and to recycled materials and articles used in those materials and articles. It therefore clearly applies to paper and cardboard and to multilayer structures containing paper and cardboard.

One of the most significant elements in the GMP Regulation is the requirement that starting materials must be selected to comply with pre-established specifications. These specifications must ensure compliance of the material or article with the rules applicable to it.

- (3)In order to limit the negative impact of contaminants in food and to prevent the risks to human health, the European Union (EU) is taking measures to reduce the level of contaminants in food. Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food. Article 2 states "... food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market...", and furthermore, "... contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages referred to in Article 1.
- (4)Regulation (EC) No [178/2002](#) ensures the quality of foodstuffs intended for human consumption and animal feed. Food shall not be placed on the market if it is unsafe and shall be condemned if it is considered to be injurious to health unfit for human consumption. In allocation whether any food is unfit for human

¹Acronym for the Directorate General for Health and Consumer Affairs

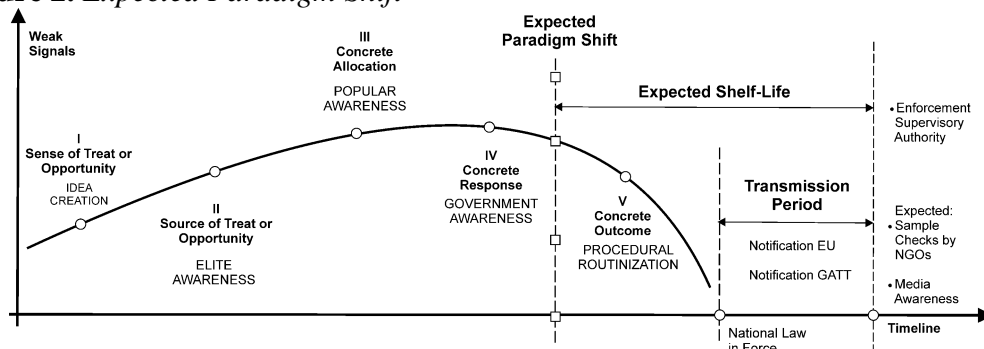
consumption, regard shall be had to whether the food is unacceptable for human consumption according to "...reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay."

The above mentioned regulations demonstrate the legally important aspect that national authorities are enforced on European level. They can act in conformity with existing laws or collective agreements or other jointly agreed arrangements: consequently, there is no need to act.

The EU has only to consider whether there is opposition to EU law or follow-up at EU level. Member States may at any time set more stringent limit values or set limit values for other substances and parameters.

Only Austria has a recommendation published for the use of barriers and no other Member State has developed activities. For that matter the German BMELV fully acknowledges the need for a separate national approach.

Figure 2. Expected Paradigm Shift



Source: authors' own graph

The EU Directorate SANCO has refused to start regulatory process. This decision may be for financial reasons or due to insufficient time and resource scarcity, respectively. It can also be assumed that they know what it means to regulate a ubiquitous substance with multiple use characteristics like MOSH and MOAH.

Both the German and the European regulator may have one thing in common: that is a "sit and wait" attitude. The interesting question is, however, why they agree on this issue? Why does the industrial branch behave like a boiling frog?¹

From a German perspective, the proposal on mineral oil in food packaging is a national approach - though a common approach is more effective. In the

¹The boiling frog is a scientific, urban legend or myth. The parable states that a frog thrown into a pot of boiling water will quickly jump out. But a frog thrown into a pot of temperate water may stay even if the temperature is slowly raised to boiling, leading to the untimely demise of the frog. Allegedly, the frog is not able to determine the gradual increase in temperature until it's too late for him. The boiling frog syndrome is a cautionary warning against complacency: An excellent metaphor for the human tendency to ignore the consequences of negative change if that change happens gradually.

international context, Swiss authorities for example just regulate the characteristics of inks, the ingredients of manufacturing, methods and the utilisation of selected substances used for food packaging. Austria, contrarily, has just given a non-legally binding recommendation.

The date of the expected German paradigm change may be subjected to the bargaining power of buyers or bargaining power of customers; on the other hand by threats of substitutes, specially-sealed flow wrapping packaging versus paper based packaging.

Is the fixed date of minimum durability of foodstuffs before the beginning of the transmission period, the expected scenario will take place earlier, inventory and market clearances must take place before the end of the transmission period. It may be assumed that at this turning point the late majority will have been committed towards new regulations. If laggards are still in the field, they may focus on leaving the market or may bear high costs to overcome market entry barriers in short time. The late majority and the laggards benefit from the extension of the transmission period. Everyone else will be the losers like the innovators, early adapters and early majority, they do not gain a first mover advantage. For that reason the "sit and wait" behaviour may be succeed.

The first weak signals of the yet to come paradigm shift might be located upstream within the packaging supply chain; specific reference may be made here towards the suppliers of raw materials. Many paper and board producers currently tend to optimize existing machines and improve their runability in combination with suitable surface coatings.

They offer a functional barrier, inline coated on recycled fibres. Ink manufactures, for example offer low migration inks before they are forced by law. In a nutshell upstream suppliers enhance and secure their inverter delivery capacities before the shift of paradigm. Research recently carried out by Simat (2013) shows firstly that from 2010 to 2013 there has been a steady growth of fresh fibres instead of recycled fibres.

Moreover, it is discovered that substitution occurs from paper based packaging towards sealed bags and stand-up pouches. Like facts, weak signals are on the horizon!

At the European level, there is no need to regulate. Proper implementations of framework regulations are done and with respect to the existing legislation, every member state can act in behave of public health.

For Europeans means that they must find answers and think through properly, when an "island solution" may arise due to the possible German market yet to come. Market entry barriers subjected to the barrier principle and conformity assessment (declaration of compliance). For companies, the EU internal market without national frontiers is a source of reliable and competitively priced supplies, but by now one is forced to craft and execute a three-road strategy. At first one can split the market into two segments - i.e. an EU-wide internal market with or without the inclusion of the German market - because there are no exit barriers except revenue and economy of scales in production. It can be assumed that the German market for paper based packed

food is too big to fail, and that the loss of economies of scales effects and thus, unnecessarily increases the associated costs as well as sales risks.

On the other hand food manufacturers/operators can be early adapter and broaden the range of German paper-based packaging all over Europe. In this case two kinds of packaging quality are in the market; and on top all that, this hallmark of quality is may not known to the customer and is not meaningful due to sale, no properties of search and experience. The outcome of the proceedings is for sure, a lemon problem¹, the good quality will not succeed. At last we can assume that by analogy as regards to sectorial crises (BSE crisis, Foot-and-Mouth Disease) linked to economic restructuring, German regulations may push EU jurisprudence, which needs to be founded by a mutual European solution.

The key assumptions postulated above concerning the future and other key sources of paper-based food packaging in the EU may lead to the question when it is time to move? Is there a change of paradigm at a European level too?

In view of the assumption of the postulated lemon problem, early adaptors and the early majority will not succeed. Yet, all actors that perform a second mover strategy will do. As a hypothesis, the optimum for a European turning point is the end of the transmission period, the gross time less the time required for adjustments to production and compliance. As always, the devil is in the detail, and it should therefore be expected that much work remains to be undertaken in the EU and Germany for a substance-based risk management due to paper-based packaging. Yet, both postulated hypothesis differ only with regard to the assigned time of likelihood of their occurrence and to their quantitative impact.

Recommendations for Actions

From a strategic supplier standpoint the packaging supply chain is by now subjected to the final state of ignorance; the concrete outcome and the procedural routinization are close at hand. Owing to this fact, a shift of paradigm may be expected and a trend towards packaging that meets statutory requirements yet to come. The point in time can be calculated when the enforcement of the supervising authority and additional expanded inspection referred to NGOs will take place: it's the end of the transmission period, including or excluding the expected minimum shelf life date or consumption date of packed food or feed within the modular packaging on the whole. According to recent national and EC regulations, it is the manufacturer of the food packaging and the marketer of food who are responsible for compliance with the law, but the Framework Regulation does not cover paper and board yet, not a single specific regulation. Paper and board are not synthetics based on cellulose.

¹This form of market failure is also described as the "Lemon Problem" according to Akerlof (1970): The Market for Lemons - Quality Uncertainty and the Market Mechanism. The Quarterly Journal of Economics, (84, 3) p.488–500

From the perspective of Fiedler et al. (2013, p.5), Kersten et al. (2011, p.15) possible recommendations for action, approaches and a variety of options have been discussed:¹

- V Low migration inks
- VI Prohibition of waste paper for food packaging
- VII Encourage substitution by virgin fibres
- VIII Improvement of the recycling process
- IX Use of an inner bag (functional barrier)
- X Use of a product-side coating

All approaches can not be effectively and promptly implemented and they are neither economically nor ecologically meaningful in the present state of affairs. Due to the absence of guidelines and safeguards at present time, the overarching principle behind these requirements is the avoidance of liability risks, internally and externally.

- 1 Comprehensive consultation in the packaging supply chain,
- 2 Overall assessment of raw materials, packaging and finished products
- 3 Own due diligence faced realistically and compliance with laws or regulations
- 4 Necessary diligence (migration test)
- 5 Review of the contracts governing: Limitations of liability of the suppliers, given warranties, rules of evidence and adjusting the insurance cover²

Closing and Outlook

The pollution of waste papers with MOH is incorporated in our current recycling system and will remain for several years to come. The uptake of substances from the environment, mainly through accumulation in the food and packaging supply chain, can hardly be avoided. Instead of using paper-based boxes with functional inner pouches for food and animal feed, one can conclude that it may be suitable to print directly on the non-contact surface of an absolute barrier, such as flow-wrappings of multi-layered plastic materials which are stored in a common tray. This opportunity has the potential to redefine whole branches of current industry related to papermaking and paper-based packaging.

Henry Kissinger once famously remarked: An issue ignored is a crisis invited (Ruff et al., 2003, p.xii). Weak signals have been spread and highlighted and investigated by the media. German national authorities take a

¹See also BfR Opinion No. 008/2010, FAQ of BfR from 10th of March 2010.

²Third party liability insurance and extended product liability insurance to cover compensation claims.

position on the content of mineral oil migration into food. Highlighted by the media, this issue was resonated and recommended for discussion in politics. The pollution of mineral oil is ubiquitous. It is omnipresent in food and feed, food contact materials and the political wish is that Europe must aim for a closed circle economy. The issue cannot be solved just by modifying packaging.

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